BIOMARIN PHARMACEUTICAL INC
Form 10-Q
November 03, 2006
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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, 2006

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	**(I.R.S. Employer**
Incorporation or organization)	**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: 91,351,953 shares common stock, par value $0.001, outstanding as of October 30, 2006.

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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, 2005 (1)	September 30, 2006 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,092	$ 191,782
Short-term investments	9,700	102,118
Accounts receivable, net	5,860	13,000
Advances to BioMarin/Genzyme LLC	1,071	1,561
Inventory	10,898	25,762
Other current assets	3,320	5,143
Total current assets	68,941	339,366
Cash balances related to long-term debt	17,049	
Investment in BioMarin/Genzyme LLC	31,983	33,587
Property, plant and equipment, net	37,321	52,469
Acquired intangible assets, net	15,306	12,748
Goodwill	21,262	21,262
Other assets	3,441	7,640
Total assets	$ 195,303	$ 467,072
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 20,934	$ 29,200
Current portion of acquisition obligation, net of discount	7,477	6,787
Current portion of deferred revenue	8,096	7,242
Current portion of equipment and facility loans	3,860	
Total current liabilities	40,367	43,229
Convertible debt	125,000	223,940
Long-term portion of acquisition obligation, net of discount	70,873	69,144
Deferred revenue, net of current portion	11,825	6,796
Equipment and facility loan, net of current portion	17,049	
Other long-term liabilities	7,651	1,846
Total liabilities	272,765	344,955
Stockholders equity (deficit):		
Common stock, $0.001 par value: 150,000,000 shares authorized; 74,301,610 and 91,291,305 shares issued and outstanding at December 31, 2005 and September 30, 2006, respectively	75	91
Additional paid-in capital	485,570	703,283

Accumulated other comprehensive loss	(16)	(24)
Accumulated deficit	(563,091)	(581,233)
Total stockholders equity (deficit)	(77,462)	122,117
Total liabilities and stockholders equity (deficit)	$ 195,303	$ 467,072

(1) December 31, 2005 balances were derived from the audited consolidated financial statements.

See accompanying notes to 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, 2005 and 2006

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Revenues:				
Net product sales	$ 2,456	$ 14,660	$ 8,881	$ 33,297
Collaborative agreement revenues	5,123	4,908	7,313	13,857
Royalty and license revenues		5,359		15,036
Total revenues	7,579	24,927	16,194	62,190
Operating expenses:				
Cost of sales (excludes amortization of developed product technology)	164	2,612	1,301	5,124
Research and development	13,894	18,105	43,708	46,163
Selling, general and administrative	9,797	12,292	30,480	35,059
Amortization of acquired intangible assets	286	1,093	858	2,558
Total operating expenses	24,141	34,102	76,347	88,904
Equity in the income of BioMarin/Genzyme LLC	3,388	5,059	8,766	13,604
Loss from operations	(13,174)	(4,116)	(51,387)	(13,110)
Interest income	561	4,003	1,177	8,738
Interest expense	(2,863)	(3,608)	(9,064)	(10,455)
Debt conversion expense		(3,315)		(3,315)
Net loss	$ (15,476)	$ (7,036)	$ (59,274)	$ (18,142)
Net loss per share, basic and diluted	$ (0.21)	$ (0.08)	$ (0.88)	$ (0.22)
Weighted average common shares outstanding, basic and diluted	71,996	86,269	67,047	82,232

See accompanying notes to consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2005 and 2006

(In thousands, unaudited)

	Nine Months Ended September 30,	
	2005	2006
Cash flows from operating activities		
Net loss	$ (59,274)	$ (18,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,300	9,397
Imputed interest on acquisition obligation	4,240	3,530
Equity in the income of BioMarin/Genzyme LLC	(8,766)	(13,604)
Stock-based compensation		7,366
Loss on disposals of property, plant and equipment	430	
Changes in operating assets and liabilities:		
Accounts receivable	(1,281)	(7,140)
Advances to BioMarin/Genzyme LLC	1,308	(490)
Inventory	(5,404)	(14,864)
Other current assets	266	(1,823)
Other assets	53	(1,074)
Accounts payable and accrued liabilities	(5,172)	8,398
Other liabilities	198	(5,029)
Deferred revenue	22,092	(5,883)
Net cash used in operating activities	(44,010)	(39,358)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,547)	(21,366)
Decrease in restricted cash	25,180	
Sales of short-term investments	26,380	24,906
Purchases of short-term investments		(117,324)
Distributions from BioMarin/Genzyme LLC	1,500	12,000
Settlement of dispute with Medicis	6,000	
Net cash provided by (used in) investing activities	57,513	(101,784)
Cash flows from financing activities		
Proceeds from equipment and facility loans	17,543	
Proceeds from ESPP and exercise of stock options	5,181	10,240
Reclassification of amounts (to) from cash balances related to long-term debt	(1,608)	17,049
Repayment of equipment and facility loans	(15,734)	(20,909)
Repayment of acquisition obligation	(32,100)	(5,950)
Proceeds from public offering of common stock, net	56,346	127,431
Proceeds from convertible debt offering, net		166,979
Net cash provided by financing activities	29,628	294,840
Effect of foreign currency translation on cash	1	(8)

Net increase in cash and cash equivalents	43,132	153,690
Cash and cash equivalents:		
Beginning of period	13,081	38,092
End of period	$ 56,213	$ 191,782

See accompanying notes to consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2006

(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. The Company and its joint venture partner, Genzyme Corporation (Genzyme), received marketing approval for Aldurazyme® (laronidase) in the United States (U.S.) in April 2003 and in the European Union (E.U.) in June 2003. BioMarin received marketing approval for Naglazyme® (galsulfase) in the U.S. in May 2005, and in the E.U. in January 2006. In May 2004, BioMarin completed the transaction to acquire the Ascent Pediatrics business, for which the North American rights were sublicensed to a third party by BioMarin in March 2006. 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 acquisition transaction in 2004 and Note 5 for further discussion of the sublicense in 2006. The Company is incorporated in the state of Delaware.

Through September 30, 2006, the Company had accumulated losses of approximately $581.2 million. Management believes that the Company s cash, cash equivalents and short-term investments at September 30, 2006 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, 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 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.

The Company is subject to a number of risks, including the financial performance of Naglazyme, the Aldurazyme joint venture and the Orapred sublicense; 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 nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. These consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2005, 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.

(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,

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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September 30, 2006

(Unaudited)

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. See Note 8 for further information on inventory balances.

Regulatory approval for Naglazyme was received 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 May 2005, the Company began capitalizing Naglazyme inventory at the lower of cost or fair market value. As of September 30, 2006, 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, 2006. Stock-based compensation of $0.2 million and $0.9 million were capitalized into Naglazyme inventory for the three and nine months ended September 30, 2006, respectively.

(d) Cash Balances Related to Long-Term Debt

Cash balances related to long-term debt represent an amount that the Company was required to keep on deposit with Comerica Bank pursuant to the terms of the equipment and facility loan that the Company executed in May 2004. In April 2006, the outstanding balance on this loan was repaid in full and this balance was reclassified to cash and cash equivalents.

(e) 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 6 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, 2006, the Company has only one reporting unit. The sublicense of North American rights of Orapred in March 2006 eliminated the previous Orapred 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. The sublicense of North American rights of Orapred was deemed to be a triggering event and an impairment analysis of goodwill was performed in March 2006, for which no impairment was determined. 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 leasehold improvements for the Company s facilities will depend on the successful execution of the Company s business initiatives 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.

(f) Revenue Recognition

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

The Company s revenues consist of Naglazyme product sales and Orapred product sales through March 2006, revenues from its collaborative agreement with Serono and revenues from its sublicense agreement with a third party for North American Orapred rights (see Note 5). All Aldurazyme sales are reported by BioMarin/Genzyme LLC and are included in the results of the joint venture (see Note 7).

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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 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 income statement, in that taxes billed to customers are not included as a component of net product sales, as per Emerging Issues Task Force (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 the Company s authorized European distributor or directly to hospitals, which act as the end users. 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. 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 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 its 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. The Company first recorded sales of Naglazyme during the second quarter of 2005 and as of September 30, 2006, the Company had 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 following sublicensing the North American rights to the product to a third party 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. In the first quarter of 2006, the Company s liability for certain rebates was reduced due to the sublicense of North American rights for Orapred to a third party. The decrease in estimated future rebates resulted in reserve reversals and an increase in net revenue of approximately $1.3 million for the nine months ended September 30, 2006.

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 its estimates of return liabilities primarily due to retail product demand realized in excess of previous estimates and the early settlement

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of product returns with a customer for an amount less than previous estimates. 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.

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of December 31, 2005 and September 30, 2006, the Company s allowance for doubtful accounts was insignificant.

Collaborative agreement revenues Collaborative agreement revenues from 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. 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 Serono s share of Phenoptin (sapropterin dihydrochloride) development costs under the agreement, which are recorded as research and development expenses. Collaborative agreement revenues include $1.8 million and $5.6 million of the up-front license fee received from Serono recognized as revenue during the three and nine months ended September 30, 2006, respectively, and $3.1 million and $8.3 million of reimbursable Phenoptin development costs incurred during the three and nine months ended September 30, 2006, respectively.

The up-front license fee received from Serono was being amortized as revenue on a straight-line basis over approximately 3.25 years, which represented the best estimate of the time from inception of the agreement until European regulatory approval of Phenoptin for the treatment of phenylketonuria (PKU), at which point the Company s performance obligations for developing Phenoptin for the treatment of PKU will end. The estimate was revised in July 2006 when the estimated timing of European regulatory approval changed from approximately 3.25 years to approximately 3.4 years. The change in estimate reduced revenues during the first nine months of 2006 by approximately $0.1 million, and the change in estimate is expected to reduce license revenues in future periods by approximately $0.1 million per quarter, or approximately $0.6 million annually. There is no cost of sales associated with the amortization of the up-front license fee received from Serono.

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 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 the third party 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 revenue includes $0.6 million and $2.5 million of the up-front license fee received from the third party recognized as revenue during the three and nine months ended September 30, 2006, 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 $7.5 million in milestone revenue during the second quarter of 2006 as a result of the FDA approval for the marketing application for Orapred ODT, received in June 2006. The Company also 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.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2006

(Unaudited)

(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 and contingent issuances of common stock related to convertible debt and acquisition payable. 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,	
	2005	2006
Options to purchase common stock	7,258	8,354
Common stock issuable under convertible debt	8,920	14,075
Portion of acquisition payable in common stock	985	604
Total	17,163	23,033

(h) Stock Option Plans

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.

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.

At September 30, 2006, the Company had net outstanding foreign exchange forward contracts to buy $9.7 million, comprised of buy contracts of $8.3 million of equivalent Euros and $4.7 million of equivalent British Pounds and sell contracts of $1.4 million of equivalent Euros and $1.9 million of equivalent British Pounds, all 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

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changes of all contracts are reported in earnings as foreign exchange gain or loss. For the three and nine months ended September 30, 2006, approximately $41,000 of income has been included in the Company s statement of consolidated earnings with respect to these forward exchange contracts.

(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 or discounted cash flows. The fair value of trade accounts receivables, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

(k) Accumulated Other Comprehensive Loss

Accumulated Other Comprehensive Loss as of September 30, 2006 includes foreign currency translation adjustments of approximately $24,000. There were no tax effects allocated to any components of other comprehensive income during 2006.

(l) 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, 2005.

(m) Recent Accounting Pronouncements

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108. SAB No. 108 provides guidance on the consideration of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. The Company does not currently anticipate any adjustments resulting from the application of SAB 108.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* . This Standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating the provisions of SFAS No. 157; however, the Company does not expect the adoption of SFAS No. 157 to have a material effect on its consolidated financial position, results of operations or cash flows.

(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 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, BioMarin records expense over the offering period, in connection with shares issued under its employee stock purchase plan.

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. As a result of the adoption of SFAS No. 123R, BioMarin s loss from operations and net loss for the three and nine month period ended September 30, 2006, was $2.7 million and $6.5 million higher than under BioMarin s previous accounting method for stock-based compensation, respectively. Basic and diluted net earnings per common share for the quarter ended September 30, 2006, were not impacted by the change in accounting method. Prior to adoption of

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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 quarter ended September 30, 2006, no net excess tax benefits were generated from option exercises. The Company evaluated the need to record a cumulative effect adjustment for estimated forfeitures upon the adoption of SFAS No. 123R and determined the amount to be immaterial. 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 compensation costs for the three months ended September 30, 2006 totaled $2.9 million, of which $0.2 million was capitalized into inventory, $0 was included in cost of sales, $1.6 million was included in selling, general and administrative expense and $1.1 million was included in research and development expense. Stock compensation costs for the nine months ended September 30, 2006 totaled $7.4 million, of which $0.9 million was capitalized into inventory, $0 was included in cost of sales, $3.6 million was included in selling, general and administrative expense and $2.9 million was included in research and development expense. No stock compensation costs were recognized for the three and nine months ended September 30, 2005, which was prior to the Company s adoption of SFAS No. 123R.

For stock options granted prior to the adoption of SFAS No. 123R, if compensation expense for the Company s various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123, the Company s pro forma net loss, and basic and diluted loss per share would have been as follows:

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss as reported	$ (15,476)	$ (59,274)
Deduct: Total stock-based compensation expense determined under fair value based method for all awards, net of tax	(2,331)	(7,846)
Pro forma net loss	$ (17,807)	$ (67,120)
Net loss per share as reported, basic and diluted	$ (0.21)	$ (0.88)
Pro forma net loss per share, basic and diluted	$ (0.25)	$ (1.00)

Stock Options

BioMarin s 2006 Share Incentive Plan, which was approved on June 21, 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, 2006, the only awards issued under the 2006 Share Incentive Plan were stock options. The options generally vest on a cliff basis six months after the grant date and then monthly over a four-year period 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.

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, 2006. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of BioMarin stock and, for fiscal periods in which there is sufficient trading volume in options on the Company s stock, the implied volatility of traded 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		Nine months Ended	
	September 30,		September 30,	
Stock Option Valuation Assumptions	**2005**	**2006**	**2005**	**2006**
Expected volatility	53.9%	52.2%	53.8-54.8%	52.2-57.87%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	6.4 years	4.9 years	6.0-6.4 years	4.9-5.0 years
Risk-free interest rate	4.1%	4.6%	4.1%	4.4-5.1%

The Company has 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, respectively, recognized in accordance with SFAS No. 123R. As of September 30, 2006,

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there was $21.7 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 3.6 years.

A summary of stock option activity under the plans for the nine months ended September 30, 2006 is presented as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance, January 1, 2006	6,968,569	$ 8.60		
Granted	2,916,571	$ 12.48		
Exercised	(1,243,289)	$ 7.74		$ 7,622
Cancelled	(287,512)	$ 9.61		
Balance, September 30, 2006	8,354,339	$ 10.05	7.5	$ 34,939
Exercisable, September 30, 2006	4,065,106	$ 9.69	5.9	$ 18,474

The weighted-average fair value of stock options granted during the three months ended September 30, 2005 and 2006, was $4.49 and $7.44, respectively. The weighted-average fair value of stock options granted during the nine months ended September 30, 2005 and 2006, was $3.65 and $6.39, respectively. The aggregate intrinsic value for outstanding options as of September 30, 2006 is calculated as the difference between the exercise price of the underlying awards and the quoted price of our common stock for the 7.6 million options that were in-the-money at September 30, 2006. During the three months ended September 30, 2006, the aggregate intrinsic value of options exercised under our stock option plans was $4.2 million. During the three and nine months ended September 30, 2005, the aggregate intrinsic value of options exercised under our stock option plans was $1.0 million and $1.1 million, respectively. The aggregate intrinsic value of options exercised was determined as of the date of option exercise.

At September 30, 2006, an aggregate of 17.0 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 plans. Awards that expire or are cancelled under the Company s suspended 1997 Stock Plan or 1998 Director Option Plan may not be reissued.

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. On each anniversary date of becoming a director, each outside member is granted an additional option to purchase 30,000 shares of common stock at the fair market value on such date. These options vest over one year and have a term of ten years.

Employee Stock Purchase Plan

Under BioMarin s Employee Stock Purchase Plan, which was approved on June 21, 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 Purchase Plan permits eligible employees to purchase common stock through payroll deductions for up to 10% of qualified compensation. The Employee Stock Purchase Plan has been treated as a compensatory plan. The Company has recorded compensation expense related to the Purchase Plan in the three and nine month periods ended September 30, 2006 of $0.3 million and $0.5 million, respectively. No stock compensation costs were recognized for the three and nine months ended September 30, 2005, which was prior to the Company s adoption of SFAS No. 123R. For the nine month periods ended September 30, 2005 and 2006, 125,339 shares and 147,377 shares were purchased under the Purchase Plan, respectively.

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.

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	Three and Nine Months Ended September 30,	
Employee Stock Purchase Plan Valuation Assumptions	**2005**	**2006**
Expected volatility	54-57%	44-54%
Dividend yield	0.0%	0.0%
Expected life	6-24 months	6-24 months
Risk-free interest rate	2.6-3.9%	2.7-4.9%

(4) ASCENT PEDIATRICS TRANSACTION

On May 18, 2004, the Company acquired the Orapred product line from Ascent Pediatrics, a wholly owned subsidiary of Medicis Pharmaceutical Corporation (Medicis). The transaction provided the Company with financial and strategic benefits, primarily the addition of a commercial product and a commercial infrastructure. In January 2005, the agreements related to the transaction were amended due to a settlement of a dispute with Medicis and the acquisition obligation was reduced. The effect of these amendments totaled $21.0 million and was recorded in the first quarter of 2005 as a reduction of the acquisition obligation and goodwill. Medicis also agreed to pay the Company $6.0 million for Orapred returns, all of which was received in 2005.

Medicis agreed to make available to the Company a convertible note of up to $25.0 million beginning July 1, 2005, based on certain terms and conditions, including a change of control provision. Advances under the convertible note are convertible into shares of the Company s common stock at a conversion price equal to the average closing price of the stock for the 20 trading days prior to such advance. The convertible note, if drawn upon, matures in August 2009, but may be repaid by the Company, at the Company s option, at any time prior to the maturity date. At the time of repayment, Medicis may elect to receive cash or convert the amount due into shares of the Company s common stock. As of September 30, 2006, the Company has not made any draws on the note.

The amended transaction agreements provided for total acquisition payments of $169.0 million payable to Medicis in specified amounts through 2009, of which $88.9 million remains payable as of September 30, 2006. The remaining payments to Medicis include a payment due in 2009 of $70.6 million, of which $8.6 million can be paid in cash or the Company s common stock, at the Company s option. The number of shares issuable in 2009, if the Company elects to pay in common stock, will be based on the per share stock price at that time. The total acquisition cost, as amended, including transaction costs totaling approximately $3.5 million, acquired tangible assets and operating liabilities, and the $6.0 million reimbursement for product returns discussed above, was $168.0 million. The remaining payments to Medicis are payable as follows (in thousands):

		As of September 30, 2006
2006		1,750
2007		7,000
2008		6,500
2009		73,600
Total	$	88,850

Pursuant to the acquisition, the Company was required to deposit $25.0 million of BioMarin common stock and $25.0 million of cash in escrow until the last of the first four quarterly payments to Medicis were made. The $25.0 million of BioMarin common stock was released in 2004 and the $25.0 million of cash was released in the first nine months of 2005.

The acquisition has been accounted for as a purchase business combination. Under the purchase method of accounting, the assets acquired and liabilities assumed are recorded at the date of acquisition, at their respective fair values. The Company s consolidated financial statements for the period subsequent to the acquisition date reflect these values and the results of operations of the Ascent Pediatrics business. The total consideration has been allocated based on an estimate of the fair value of assets acquired and liabilities assumed. A summary of the material revisions to the purchase price allocation is as follows (in thousands):

The fair value of the transaction was allocated as follows (in thousands):

Product technology	$ 88,689
In-process research and development	31,453
Imputed discount on purchase price	27,054
Inventory	2,301
Equipment	131
Goodwill	21,262
Liabilities assumed	(2,901)
Total	$ 167,989

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The product technology is the only intangible asset subject to amortization and represents the rights to the proprietary knowledge associated with Orapred. These rights include the right to develop, use, and market Orapred. The product technology is being amortized over Orapred s estimated economic life of 3.5 years using the straight-line method of amortization and includes no estimated residual value. See Note 6 for further discussion of the Company s acquired intangible assets.

In-process research and development represents the fair value of the two additional proprietary formulations of Orapred that were under development at the time of the transaction but which had not yet been completed.

The imputed discount on the purchase obligation represents the gross value of the future cash payments to Medicis, discounted to their present value at a rate of 6.1%. The discount is being amortized and recorded as interest expense over the life of the obligation using the effective interest rate method.

The allocation to inventory at the purchase date included an adjustment of $0.9 million in addition to the cost basis of the finished inventory to reflect the fair value of the finished inventory, less the cost of disposal and a reasonable profit for the selling effort.

The transaction resulted in a purchase price allocation of $21.3 million to goodwill, representing the financial, strategic and operational value of the transaction to BioMarin. Goodwill is attributed to the premium that the Company was willing to pay to obtain the value of the Orapred business and the synergies created with the integration of key components of a commercial infrastructure. The entire amount of goodwill is expected to be deductible for tax purposes. The purchase price allocation also included $2.9 million of estimated liabilities assumed for product returns and unclaimed rebates.

(5) SUBLICENSE OF NORTH AMERICAN ORAPRED RIGHTS

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

Pursuant to the agreement, the third party paid BioMarin $2.5 million as consideration for executing the agreement, and agreed to make additional milestone payments of up to $15.5 million based on the approval and successful commercial launch of Orapred ODT. As a result of receiving FDA approval for the marketing application for Orapred ODT in June 2006, the Company received a milestone payment of $7.5 million, which was recorded as royalty and license revenues during the quarter ended June 30, 2006. The Company also recognized $4.0 million in milestone revenue during the quarter ended September 30, 2006 as a result of the commercial launch of Orapred ODT. During the three and nine months ended September 30, 2006, the Company also recognized $0.8 million and $0.9 million, respectively, in royalty revenues from Orapred product sold by the sublicensee.

Royalty and license revenues totaling $0.6 million and $2.5 million were recognized for the three and nine months ended September 30, 2006, respectively, related to amortization of the up-front license fee.

(6) ACQUIRED INTANGIBLE ASSETS AND GOODWILL

(a) Acquired Intangible Assets

Acquired intangible assets relate to the Ascent Pediatrics transaction completed during May 2004 (Note 4) and consist of the

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Orapred product technology as of September 30, 2006. The gross and net carrying value of the Orapred product technology as of September 30, 2006 were as follows (in thousands):

Gross value	$ 20,437
Accumulated amortization	(7,689)
Net carrying value	$ 12,748

The Company completed its 2005 annual impairment test during the fourth quarter of 2005 and determined that no impairment of the acquired intangible assets existed as of December 31, 2005. 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 other triggering events have occurred during 2006 that would require an updated impairment test.

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 five years is as follows (in thousands):

	As of September 30, 2006
2006	$ 1,092
2007	4,371
2008	4,371
2009	2,914
Total	$ 12,748

As a result of the change in estimate, annual amortization expense through 2009 will increase by approximately $3.3 million, to $4.4 million from $1.1 million prior to the sublicense. Amortization expense for the three and nine months ended September 30, 2006 increased by $0.8 million ($0.01 per share) and $1.7 million ($0.02 per share), respectively, to $1.1 million and $2.6 million respectively, as compared to amortization expense for the three and nine months ended September 30, 2005 of $0.3 million and $0.9 million, respectively.

(b) Goodwill

Goodwill as of September 30, 2006 relates to the Ascent Pediatrics transaction completed during May 2004 (Note 4). The aggregate amount of goodwill acquired in the transaction was approximately $21.3 million, which reflects the reduction for the settlement of the dispute with Medicis during the first quarter of 2005. 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. The

Company also completed its annual impairment analysis using the same methodology and determined that no impairment existed as of December 31, 2005. 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 other triggering events have occurred during 2006 that would require an updated impairment test.

(7) JOINT VENTURE

(a) Joint Venture Financial Data

The results of the joint venture s operations for the three and nine months ended September 30, 2005 and 2006, 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

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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, 2006.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Revenue	$ 20,122	$ 25,029	$ 55,201	$ 69,891
Cost of goods sold	4,686	6,037	10,134	17,044
Gross profit	15,436	18,992	45,067	52,847
Operating expenses	8,743	9,063	27,749	26,129
Income from operations	6,693	9,929	17,318	26,718
Other income	82	188	214	489
Net income	$ 6,775	$ 10,117	$ 17,532	$ 27,207
Equity in the income of BioMarin/Genzyme LLC	$ 3,388	$ 5,059	$ 8,766	$ 13,604

At December 31, 2005 and September 30, 2006, 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, 2005	September 30, 2006
Assets	$ 70,436	$ 73,415
Liabilities	(6,470)	(6,242)
Net equity	$ 63,966	$ 67,173
Investment in BioMarin/Genzyme LLC (50% share of net equity)	$ 31,983	$ 33,587

(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

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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 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 7(a) above for discussion of the difference in inventory cost basis between the Company and BioMarin/Genzyme LLC.

(8) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2005 and September 30, 2006, accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2005	September 30, 2006
Accounts payable	$ 484	$ 1,498
Accrued accounts payable	10,018	10,915
Accrued vacation	1,581	1,804
Accrued compensation	4,219	5,075
Accrued interest and taxes	372	661
Accrued other	335	1,628
Accrued rebates	3,297	1,587
Short-term returns reserves	430	5,925
Current portion of deferred rent	198	107
	$ 20,934	$ 29,200

As of December 31, 2005 and September 30, 2006, other long-term liabilities consisted of the following (in thousands):

	December 31, 2005	September 30, 2006
Long-term portion of returns reserve	$ 5,684	$
Long-term portion of deferred rent	1,967	1,166
Deferred compensation liability		680
Total other long-term liabilities	$ 7,651	$ 1,846

As of December 31, 2005 and September 30, 2006, inventory consisted of the following (in thousands):

	December 31, 2005	September 30, 2006
Orapred raw materials	$ 821	$
Naglazyme raw materials	1,717	1,779
Naglazyme work in process	8,032	11,959
Naglazyme finished goods	328	12,024
Total inventory	$ 10,898	$ 25,762

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(9) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2005 and September 30, 2006, consisted of (in thousands):

	Property & Equipment		
Category	**December 31, 2005**	**September 30, 2006**	**Estimated Useful Lives**
Leasehold improvements	$ 57,809	$ 24,475	Shorter of life of asset or lease term
Building and improvements		22,597	20 years
Manufacturing and laboratory equipment	13,938	14,985	5 years
Computer hardware and software	5,055	5,958	3 years
Office furniture and equipment	3,269	3,548	5 years
Land		4,259	
Construction-in-progress	759	2,033	
Total property, plant and equipment, gross	80,830	77,855	
Less: Accumulated depreciation	(43,509)	(25,386)	
Total property, plant and equipment, net	$ 37,321	$ 52,469	

In April 2006, the Company purchased its previously leased manufacturing facility on Galli Drive in Novato, California, and retains ownership of all leasehold improvements made to the property. The purchase price of the facility was approximately $17.0 million, which was paid in cash in April 2006. The purchase price of $17.0 million was allocated to building and land based on estimates of fair value. Certain leasehold improvements to the building, which were capitalized in prior periods with a gross value of approximately $33.9 million and a net value of $10.7 million as of the building purchase date, were reallocated as building costs using the net basis. Due to the reallocation of leasehold improvements on a net basis, gross leasehold improvements of $33.9 million and related accumulated depreciation of approximately $23.2 million were eliminated. As a result of a longer expected life of the previous leasehold improvements reclassified to building costs, depreciation expense in future periods will decrease by approximately $0.4 million per quarter, or $1.6 million annually. Also as a result of the purchase, the Company reversed deferred rent liabilities of approximately $0.9 million, which offset the cost basis of the building.

Depreciation expense for the three and nine months ended September 30, 2006 was $1.6 million and $5.1 million, respectively, and depreciation expense for the three and nine months ended September 30, 2005 was $1.9 million and $5.8 million, respectively.

(10) CONVERTIBLE DEBT

In March 2006, the Company sold $172.5 million of senior subordinated convertible debt 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 Company common stock at a conversion price of approximately $16.58 per share, subject to adjustment in certain circumstances. There is no call provision included and the Company is unable to unilaterally redeem the notes 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 its 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 $0.4 million of amortization expense during the three and nine months ended September 30, 2006, respectively.

In June 2003, the Company sold $125 million of convertible debt due on June 15, 2008. The debt was issued at face value and bears interest at the rate of 3.5% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately $14.01 per share, subject to adjustment in certain circumstances. On or after June 20, 2006, the Company may, at its option, redeem the notes, in whole or in part, at predetermined prices, plus any accrued and unpaid interest to the redemption date. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the 2003 debt, the Company paid approximately $4.1 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, 2005 and 2006, respectively.

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 the Company s common

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2006

(Unaudited)

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.

(11) COMMON STOCK OFFERING

In March 2006, the Company completed a public offering of its common stock concurrent with its public offering of senior subordinated convertible debt (see Note 10). In the common stock offering, the Company sold 10,350,000 shares at a price to the public of $13.00 per share, or a total offering price of $134.6 million. The net proceeds were approximately $127.4 million.

(12) EQUIPMENT AND FACILITY LOANS

In May 2004, the Company executed a $25 million credit facility to finance the Company s equipment purchases and facility improvements. The outstanding balance on this loan was repaid in full in April 2006. The lender required that the Company maintain a total unrestricted cash balance, including short-term investments, of at least $25 million and that the Company maintain a deposit with the lender equal to the outstanding balance, or $10.0 million, whichever was greater. The facility also contained additional customary non-financial covenants.

(13) SUPPLEMENTAL CASH FLOW INFORMATION

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

	Nine Months Ended September 30,	
	2005	2006
Settlement of dispute with Medicis, net of discount	$ 22,648	$
Conversion of 3.5% convertible notes due 2008		73,560
Deferred offering costs reclassified to additional paid in capital as a result of the conversion of a portion of notes due in 2008		868

(14) 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. Accounts receivable as of September 30, 2006 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 two largest customers accounted for 48% and 8% of net revenues, respectively, or 56% of the Company s total net product sales of Naglazyme in aggregate for the nine months ended September 30, 2006. In 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, 2006.

(15) DEFERRED COMPENSATION PLAN

On December 1, 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 and annual cash bonus. 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. Investments are held on a trading basis and the recorded cost approximates fair value. Investments and the related deferred compensation liability were $0.7 million as of September 30, 2006. Changes in market value of the investments are recorded as a component of non-operating income. The change in market value was insignificant for the three and nine months ended September 30, 2006, respectively.

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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 *Risk Factors*, 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 this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2005, 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. In addition to the other information in this Form 10-Q, investors should carefully consider the following discussion and the information under *Risk Factors* when evaluating us and our business.

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 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 Aldurazyme ® (laronidase) and Naglazyme® (galsulfase). 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.

We are developing several investigational product candidates for the treatment of genetic diseases including: Phenoptin (sapropterin dihydrochloride), a proprietary oral form of tetrahydrobiopterin (6R-BH4 or BH4), for the treatment of Phenylketonuria (PKU); and Phenylase (phenylalanine ammonia lyase), an enzyme substitution therapy for the treatment of phenylketonurics who are not 6R-BH4 responsive. We are also developing BH4 for the treatment of multiple cardiovascular indications, beginning with a Phase 2 clinical trial in individuals with poorly controlled hypertension. We initiated this trial in July 2006.

We are evaluating preclinical development of several other enzyme product candidates for genetic and other diseases as well as an immune tolerance platform technology to overcome limitations associated with the delivery of existing pharmaceuticals.

Commercial Products

Aldurazyme has been approved for marketing in the United States (U.S.) by the U.S. Food and Drug Administration (FDA), in the European Union (E.U.) by the European Commission (E.C.) and in other countries for the treatment of mucopolysaccharidosis I (MPS I), for which no other drug treatment currently exists. MPS I is a progressive and debilitating life-threatening genetic disease that frequently results in death during childhood or early adulthood. It is caused by the deficiency of alpha-L-iduronidase, an enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). Aldurazyme has been granted orphan drug status in the U.S. and the E.U., which gives Aldurazyme seven years of market exclusivity in the U.S. and 10 years of market exclusivity in the E.U. for the treatment of MPS I, expiring in 2010 and 2013, respectively. We have developed Aldurazyme through a 50/50 joint venture with Genzyme. Aldurazyme net revenue recorded by our joint venture for the third quarter and first nine months of 2006 totaled $25.0 million and $69.9 million, respectively, compared to $20.1 million and $55.2 million for the third quarter and first nine months of 2005, respectively.

In May 2005, the FDA granted marketing approval for Naglazyme for the treatment of mucopolysaccharidosis VI (MPS VI), a debilitating life-threatening genetic disease for which no other drug treatment currently exists. MPS VI is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), an enzyme normally required for the breakdown of GAGs. Naglazyme net product sales for the third quarter and first nine months of 2006 totaled $12.9 million and $30.2 million, respectively, as compared to $2.3 million and $2.4 million during the third quarter and first nine months of 2005, respectively. In January 2006, the E.C. granted

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marketing approval for Naglazyme in the E.U. Naglazyme has been granted orphan drug status in the U.S. and the E.U., which confers seven years of market exclusivity in the U.S. and 10 years of market exclusivity in the E.U. for the treatment of MPS VI, expiring in 2012 and 2016, respectively. Product launch in the E.U. is underway on a country-by-country basis. Additionally, we are receiving some revenue from named patient sales of Naglazyme in other countries.

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 a third party for the continued sale and commercialization of the Orapred product line. Through the sublicense agreement, the third party acquired exclusive rights to market these products in North America, and we retained exclusive rights to market these products outside of North America. The third party and we are individually responsible for the costs of commercializing the products within our respective territories. 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.

Revenues related to Orapred include net product sales of $1.8 million and $3.1 million for the three and nine months ended September 30, 2006, respectively, as compared to $0.2 million and $6.5 million for the three and nine months ended September 30, 2005, respectively. Additionally, we recorded $0.8 million and $0.9 million of royalty and license revenues during the three and nine months ended September 30, 2006, respectively, pursuant to our sublicense of the Orapred product line. We will also receive additional milestone payments and royalties on net sales of the entire Orapred product line, which includes Orapred ODT and Orapred liquid formulations.

Products in Development

In May 2005, we entered into an agreement with Serono for the further development and commercialization of Phenoptin and Phenylase for PKU and 6R-BH4, the active ingredient in Phenoptin, for other diseases such as cardiovascular indications, including those associated with endothelial dysfunction. Through the agreement, 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. We and Serono will generally share equally all development costs following successful completion of Phase 2 clinical trials for each product candidate in each indication. We and Serono are individually responsible for the costs of commercializing the products within our respective territories. 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 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 Phenoptin, if approved. PKU is caused by a deficiency of an enzyme, phenylalanine hydroxylase (PAH), which is required for the metabolism of Phenylalanine (Phe). Phe is an amino acid found in most 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. Phenoptin, 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, Phenoptin could become the first drug for the treatment of PKU.

In December 2004, we announced that we initiated our Phase 2 clinical trial of Phenoptin for PKU. Patients enrolled in the Phase 2 clinical trial who met certain criteria were eligible to enroll in the Phase 3 clinical trial, which began in April 2005. The Phase 3 clinical trial of Phenoptin was a six-week, multi-center, international, double-blind, placebo-controlled study. On March 15, 2006, we announced positive results from the Phase 3 clinical trial. We also have initiated a supplemental diet study in children between 4 to 12 years of age. We have received orphan drug designation for Phenoptin for the treatment of PKU in both the U.S. and E.U. If Phenoptin 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 Phenoptin as a fast track product for the treatment of PKU. We expect to file the New Drug Application (NDA) for Phenoptin with the FDA in the first half of 2007.

Endothelial dysfunction is a condition characterized by the inability of the endothelium (the single cell layer lining that forms the barrier between blood vessel walls and the blood) 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. In July 2006, we announced that we initiated our Phase 2 clinical trial of 6R-BH4 for poorly controlled hypertension, which is an 8-week, multi-center, double-blind, placebo-controlled study. We expect results from the Phase 2 clinical trial in early 2007. We plan to initiate several preclinical and clinical studies of BH4 for indications related to endothelial dysfunction in the fourth quarter of 2006.

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 are not 6R-BH4 responsive, and do not respond to Phenoptin.

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Key components of our results of operations for the three and nine months ended September 30, 2005 and 2006, include the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Total net product sales	$ 2,456	$ 14,660	$ 8,881	$ 33,297
Research and development expense	13,894	18,105	43,708	46,163
Net loss	(15,476)	(7,036)	(59,274)	(18,142)
Orapred acquisition-related expenses	1,504	2,257	5,212	6,089
Stock-based compensation expense		2,653		6,489

Our cash, cash equivalents and short-term investments and cash balances related to long-term debt totaled $293.9 million as of September 30, 2006 compared to $64.8 million as of December 31, 2005.

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 include our investment in BioMarin/Genzyme LLC, property, plant and equipment, and the acquired Orapred intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of long-lived assets, other than goodwill, 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, 2005 and the nine months ended September 30, 2006.

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 Orapred business was eliminated following the sublicense of North American rights for Orapred, which was previously our only separate reporting unit. Immediately prior to the sublicense, which was considered a triggering event, we performed an impairment test at the Orapred reporting unit level and determined that there was no impairment at March 2006. We 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. No other triggering events have occurred during 2006 that would require an impairment test.

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 discounted 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 $10.1 million and $27.2 million

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during the third quarter and first nine months of 2006, respectively. We and our joint venture partner maintain the ability and intent to fund the joint venture s operations, as necessary.

The recoverability of the carrying value of 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 No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* . Our revenues consist of Naglazyme product sales and Orapred product sales through March 2006, revenues from our collaborative agreement with Serono and revenues from our Orapred sublicense agreement.

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.

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 hospitals, which act as end users. 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 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 just over 1 year 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. The nature and amount of our current estimates of the applicable revenue dilution item that are applied to gross sales of Naglazyme to derive net sales are described in the table below.

Revenue Dilution Item	Percentage of Gross Sales	Description
Rebates	3-6%	Rebates payable to state Medicaid and other government programs
Cash Discounts	1-2%	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. We first recorded sales of Naglazyme during the second quarter of 2005 and as of September 30, 2006, 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.

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Orapred product sales As a result of our sublicense of North American rights to a third party 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 revenue for the up-front and milestone payments as well as royalty revenue for future sales of Orapred products by the third party. 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 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 are 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 a third party. The decrease in estimated future rebates resulted in reserve reversals and an increase in net revenue of approximately $1.3 million for the nine months ended September 30, 2006.

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.

The amount of Orapred returns in the normal course of business compared to sales has been reasonably consistent historically. Our experience is that the length of time between the period of original sale and the product return is between one and two years. Because the product has been on the market for approximately four years and the product expiration dating is two to three years, we are continuing to obtain and analyze the returns history. Additionally, in the Ascent Pediatrics transaction we acquired liabilities for certain Orapred product returns and unclaimed rebates for the period prior to our acquisition of the product.

As discussed above, our estimates of revenue dilution items are based primarily on the historical experience for the product, as adjusted to reflect known and forecasted changes in the factors that impact the revenue dilutions. The nature and amount of our current estimates of the applicable effective rates for revenue dilution items that are applied to gross sales of Orapred to derive net sales are described in the table below. There are no additional material revenue dilution items other than those disclosed below and there have been no material revisions to our estimates of our revenue dilution items to date, except as discussed above.

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Revenue Dilution Item	Estimated 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%	

Collaborative agreement revenues Collaborative agreement revenues from 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 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 Serono and recognized it as revenue on a straight-line basis over approximately 3.25 years, which represented our initial estimate of the time from inception of the agreement until European regulatory approval of Phenoptin for the treatment of PKU, at which point our performance obligations for developing Phenoptin for the treatment of PKU will end. The estimate was revised in July 2006 from approximately 3.25 years to approximately 3.4 years, based on updated information regarding the estimated timing of European regulatory approval. The change in estimate reduced revenues during the first nine months of 2006 by approximately $0.1 million, and the change in estimate is expected to reduce license revenues in future periods by approximately $0.1 million per quarter, or approximately $0.6 million annually. Our estimate of the Phenoptin 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 Phenoptin. As Phenoptin advances through the clinical development and regulatory process, our estimates of our performance obligation period may change. Further 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 are no cost of sales associated with the amortization of the up-front license fee received from 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 Serono s share of Phenoptin development costs under the agreement, which are recorded as research and development expenses.

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 communication with 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 from sales in subsequent periods.

We deferred the up-front license fee of $2.5 million received from a third party for the North American Orapred rights, 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. Our estimate of the Orapred ODT commercial launch period was based on several underlying assumptions about uncertain events, including actions by U.S. regulatory authorities and successful commercialization efforts by the third party. 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, we received a milestone payment of $7.5 million, which has been recorded as revenue during the period. As a result of the commercial launch of Orapred ODT, we also recognized $4.0 million in milestone revenue during the third quarter of 2006. 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

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compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and additional inventory write-offs may be required.

Regulatory approval for Naglazyme was received 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 May 2005, we began capitalizing inventory at the lower of cost or fair value. As of September 30, 2006, 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, 2006. Stock-based compensation of $0.2 million and $0.9 million was capitalized into Naglazyme inventory 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. 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, inventory 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 (CROs), 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 CROs 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. 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 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 compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

Recent Accounting Pronouncements

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

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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 operations compared to our total 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.

Three and Nine Months Ended September 30, 2006

BioMarin Results of Operations

Net Loss

Our net loss for the three and nine months ended September 30, 2006 was $7.0 million and $18.1 million, respectively, as compared to $15.5 million and $59.3 million for the three and nine months ended September 30, 2005, respectively. Net loss for the three and nine months ended September 30, 2006 decreased 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 2005	$ (15.5)	$ (59.3)
Increased Naglazyme gross profit	8.9	24.4
Increased (Decreased) collaborative agreement revenues	(0.4)	6.3
Milestone revenue related to sublicense of Orapred franchise	4.0	14.0
Decreased Orapred net operating expenses	3.3	4.3
Decreased Naglazyme development expenses	1.1	9.4
Increased Naglazyme sales and marketing expenses	(2.3)	(6.8)
Increased Phenoptin manufacturing and clinical trial costs	(1.6)	(5.1)
Increased Phenoptin commercial preparation costs	(0.5)	(1.8)
Increased 6R-BH4 development costs for endothelial dysfunction	(3.1)	(2.3)
Increased Phenylase development costs	(0.4)	(1.6)
Increased profits from BioMarin/Genzyme LLC	1.7	4.8
Stock-based compensation expense	(2.7)	(6.5)
Increased interest expense	(0.8)	(1.4)
Increased interest income	3.4	7.5
Increase in corporate overhead and other	(2.1)	(4.0)
Net loss for the period ended 2006	$ (7.0)	$ (18.1)

See below for additional information related to the primary net loss fluctuations presented above.

Net Product Sales and Gross Profit

Net product sales increased $12.2 million to $14.7 million in the third quarter of 2006 from $2.5 million in the third quarter of 2005. Net product sales in the third quarter of 2006 included $12.9 million of net product sales of Naglazyme, and net product sales of Orapred of $1.8 million. The net product sales of Orapred of $1.8 million during the period is primarily attributable to sales of raw materials to the sublicensee of $1.0 million and $0.7 million due to reversal of returns reserves. Net product sales in the third quarter of 2005 of $2.5 million included $0.2 million of net product sales of Orapred and $2.3 million of net product sales of Naglazyme. The increase in Naglazyme net product sales of $10.6 million from the third quarter of 2005 to the third quarter of 2006, is primarily attributable to an increase in the number of patients receiving therapy.

Net product sales increased $24.4 million to $33.3 million in the first nine months of 2006 from $8.9 million in the first nine months of 2005. Net product sales in the first nine months of 2006 included $30.2 million of net product sales of Naglazyme and $3.1 million of net product sales of Orapred. Included in the $3.1 million of net product sales of Orapred are $2.9 million of net product sales and $0.2 million of net rebate and return reserve reversals. Net product sales in the first nine months of 2005 of $8.9 million included $6.5 million of net product sales of Orapred

and $2.4 million of net product sales of Naglazyme. The increase in Naglazyme net product sales of $27.8 million for the nine months ended September 30, 2005 to the nine months ended September 30, 2006, is primarily attributable to an increase in the number of patients receiving therapy.

In May 2005, we received marketing approval for Naglazyme in the U.S. and began shipping product in late June 2005. 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

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exchange rates on Naglazyme sales from customers based outside of the U.S. was insignificant for the three and nine months ended September 30, 2006. Gross profit 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. Excluding the inventory write-offs, gross margins would have been approximately 90%. 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 and first nine months of 2006 had an insignificant cost basis. We expect to report lower cost of goods sold for Naglazyme until all of the inventory manufactured prior to marketing approval is sold or used in clinical trials. The majority of inventory with an insignificant cost basis has been sold or used in clinical trials as of September 30, 2006.

Commencing with our acquisition of the Ascent Pediatrics business on May 18, 2004 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.

In March 2006, we sublicensed rights to sell and distribute Orapred in North America for up-front and milestone payments of up to $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. Current and future revenue streams related to the Orapred product will include license and 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 Serono, which was executed in May 2005. 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 Phenoptin development costs incurred during the period, respectively. The related costs are included in research and development expenses.

Royalty and License Revenues

Royalty and license revenues, totaling $5.4 million and $15.0 million for the third quarter and first nine months of 2006, respectively, include a $7.5 million milestone payment related to FDA approval of the marketing application for Orapred ODT, 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 for the third quarter and first nine months of 2006 also include $0.6 million and $2.5 million related to the current period amortization of the $2.5 million up-front license fee received from the third party, respectively. During the third quarter and first nine months of 2006, we recognized $0.8 million and $0.9 million, respectively, in royalty revenues from Orapred product sold by the sublicensee.

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 $18.1 million and $46.2 million for the three and nine months ended September 30, 2006, respectively, from $13.9 million and $43.7 million for the three months ended September 30, 2005, respectively. Research and development expenses changed for the three and nine months ended September 30, 2005 and 2006 primarily as a result of the following (in millions):

	Three Months Ended September 30	Nine Months Ended September 30
Research and development expense for the period ended 2005	$ 13.9	$ 43.7
Decreased Naglazyme development expenses	(1.1)	(9.4)
Increased Phenoptin clinical trial and manufacturing costs	1.6	5.1
Increased 6R-BH4 development costs for endothelial dysfunction	3.1	2.3

Increased Phenylase development costs	0.4	1.6
Stock-based compensation expense	1.1	2.9
Decreased research and development on other programs	(0.9)	
Research and development expense for the period ended 2006	$ 18.1	$ 46.2

The increase in Phenoptin clinical trial and manufacturing costs is primarily due to increased clinical trial expenses due to the

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continuation of the Phase 3 clinical trials. The increase in 6R-BH4 development costs is related to increases for pre-clinical studies of 6R-BH4 in endothelial dysfunction and costs related to a Phase 2 clinical trial of 6R-BH4 for poorly controlled hypertension. 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 incur significant Naglazyme research and development costs in the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments.

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; sales operations in support of Naglazyme and Orapred 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 $12.3 million and $35.1 million for the three and nine months ended September 30, 2006, respectively, from $9.8 million and $30.5 million for the three and nine months ended September 30, 2005, respectively. The components of the increase between the three and nine months ended September 30, 2005 and 2006 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 2005	$ 9.8	$ 30.5
Decreased Orapred sales and marketing expenses	(1.9)	(8.8)
Increased Naglazyme sales and marketing expenses	2.3	6.8
Stock-based compensation expense	1.6	3.6
Increased Phenoptin commercial preparation costs	0.5	1.8
Net increase in corporate overhead and other administrative costs		1.2
Selling, general and administrative expense for the period ended 2006	$ 12.3	$ 35.1

We have initiated commercial operations in Brazil and expect additional costs to be incurred in future periods as a result.

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 2006 were $1.1 million and $2.6 million, respectively, compared to $0.3 million and $0.9 million for the third quarter and first nine months of 2005, respectively, when the expected useful life was 15 years. The amortization period was revised following the sublicense of North American rights to Orapred in March 2006, as the underlying intellectual property will be transferred to the third party in August 2009, following our purchase of the common stock of Ascent Pediatrics from Medicis. 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 $5.1 million and $13.6 million in the third quarter and first nine months of 2006, respectively, compared to $3.4 million and $8.8 million in the third quarter and first nine months of 2005, respectively. The increase in profit from BioMarin/Genzyme LLC in the third quarter and first nine months of 2006 was principally due to increases in Aldurazyme net revenue, which totaled $25.0 million and $69.9 million in the third quarter and first nine months of 2006, respectively, compared to $20.1 million and $55.2 million in the third quarter and first nine months of 2005, respectively.

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 $4.0 million and $8.7 million in the third quarter and first nine months of 2006, respectively, from $0.6 million and $1.2 million in the third quarter and first nine months of 2005, respectively. The increase is primarily due to higher interest rates and increased levels of cash and investments during the third quarter and first nine months of 2006 compared to the third quarter and first nine months of 2005.

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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 $3.6 million and $10.5 million in the third quarter and first nine months of 2006, respectively, as compared to $2.9 million and $9.1 million in the third quarter and first nine months of 2005, respectively, representing an increase of $0.7 million and $1.4 million, respectively. The increase in the third quarter and first nine months of 2006 is primarily due to the convertible debt issuance in March 2006, partially offset by lower imputed interest expense related to the Ascent Pediatrics transaction. The decline in imputed interest expense was due to a lower outstanding balance of the acquisition obligation in 2006. Imputed interest expense totaled $1.2 million and $3.5 million for the three and nine months ended September 30, 2006, respectively, as compared to $1.2 million and $4.2 million for the three and nine months ended September 30, 2005, respectively.

Debt Conversion Expense

In September 2006, certain holders of our 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 our common stock. As a result of the conversion, we agreed to pay an inducement to the holders of approximately $3.3 million, which was recognized as additional expense during the three and nine-months ended September 30, 2006.

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 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, 2006. See Note 7(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 $25.0 million and $69.9 million of net revenue in the third quarter and first nine months of 2006, respectively, and $20.1 million and $55.2 million in the third quarter and first nine months of 2005, respectively. The increase in net revenue of $4.9 million and $14.7 million from the third quarter and first nine months of 2005 to the third quarter and first nine months of 2006, respectively, is primarily attributable to an increase in the number of patients receiving therapy.

Gross profit was $19.0 million and $52.8 million for the third quarter and first nine months of 2006, as compared to $15.4 million and $45.1 million in the third quarter and first nine months of 2005, respectively, representing an increase of $3.6 million and $7.7 million, respectively. Gross margins for the third quarter and first nine months of 2006 were approximately 76%, as compared to gross margins for the third quarter and first nine months of 2005 of 77% and 82%, respectively. The decreases in gross margin during the third quarter and first nine months of 2006 compared to the third quarter of 2005 is attributable to the recognition of higher cost of sales in the third quarter of 2006 as the joint venture sells more of the inventory that was produced after obtaining regulatory approval, which has a higher cost basis. Excluding the effect of the difference in inventory cost basis between us and the joint venture, gross profit was $18.9 million and $51.7 million, representing gross margins of 76% and 74%, for the third quarter and first nine months of 2006, respectively, as compared to gross profits of $13.8 million and $37.2 million, representing gross margins of 69% and 67%, for the third quarter and first nine months of 2005, respectively.

Operating Expenses

Operating expenses of the joint venture include the costs associated with the development and commercial support of Aldurazyme and totaled $9.1 million and $26.1 million for the third quarter and first nine months of 2006, respectively, as compared to $8.7 million and $27.7 million for the third quarter and first nine months of 2005, 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 support of Aldurazyme, respectively, and $3.1 million and $10.1 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

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of 2005 included $5.2 million and $16.5 million of selling, general and administrative expenses associated with the commercial launch of Aldurazyme, respectively, and $3.5 million and $11.2 million of research and development expenses, primarily clinical trial costs, respectively. Selling, general and administrative expenses decreased in the third quarter and first nine months of 2006 due to normalization of sales and marketing efforts for the product following post-launch commercialization.

Liquidity and Capital Resources

Cash and Cash Flow

We have financed our operations by the issuance of common stock, convertible debt, equipment and other commercial financing and the related interest income earned on cash, cash equivalents and short-term investments. During the first nine months of 2006, we received $127.4 million of net proceeds from a public offering of common stock, $167.0 million of net proceeds from a public offering of convertible senior subordinated notes and $14.0 million of proceeds related to our sublicense of North American rights for Orapred. During the first nine months of 2005, we financed our operations primarily through net proceeds of $56.3 million from the public offering of our common stock in July 2005, $25.0 million received from Serono as consideration for execution of the Development, License and Commercialization Agreement, $1.1 million received from Serono for expense reimbursement related to the development of Phenoptin for PKU, $1.8 million of net proceeds from our equipment and facility loan and $5.2 million from stock option exercises and our employee stock purchase plan.

As of September 30, 2006, our combined cash, cash equivalents, short-term investments and cash balances related to long-term debt totaled $293.9 million, an increase of $229.1 million from $64.8 million at December 31, 2005. Cash balances related to long-term debt represented an amount totaling $17.0 million as of December 31, 2005 that was a portion of the amount that we were required to keep on deposit with Comerica Bank pursuant to the terms of the equipment and facility loan. This amount was equal to the long-term portion of the outstanding balance under this facility. In April 2006, the outstanding balance on these loans was repaid in full.

The $229.1 million increase in cash, cash equivalents, short-term investments, restricted cash and cash balances related to long-term debt during the first nine months of 2006 includes net proceeds from the public offering of common stock of $127.4 million and from the concurrent public offering of convertible debt of $167.0 million. Excluding the net offering proceeds, the decrease in cash, cash equivalents, short-term investments, restricted cash and cash balances related to long-term debt during the first nine months of 2006 was $65.3 million, which was $2.5 million more than the net decrease in cash, cash equivalents, short-term investments and restricted cash during the first nine months of 2005 of $62.8 million. The primary items contributing to the increase in net cash outflow, excluding the net offering proceeds, in 2006 were as follows (in millions):

Decreased cash payments for the acquisition of the Ascent Pediatrics business	$ 26.2
Increased cash flows from BioMarin/Genzyme LLC	8.7
Net repayments of equipment and facility loans	(22.7)
Increased capital asset purchases	(19.8)
Absence of Serono license payment	(25.0)
License payments from third party related to sublicense of North American Orapred rights	14.0
Decreased operating spend, net, partially offset by working capital increases	17.9
Other	(1.7)
Total increase in net cash outflow excluding net offering proceeds	$ (2.5)

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. Increases in net payments for working capital primarily include Naglazyme inventory and accounts receivable. As a result of increased Naglazyme sales, our net accounts receivable increased by $7.1 million during the first nine months of 2006. We expect that our net accounts receivable will continue to increase in the near future. Our inventory increased by $14.9 million during the first nine months of 2006, as a result of the capitalization of manufacturing costs following regulatory approval and continued production of Naglazyme to meet increasing demand.

The primary uses of cash during the first nine months of 2005 were to finance operations, which primarily included the manufacturing and clinical trials of Naglazyme and the related supporting functions, the Ascent Pediatrics transaction, the manufacturing and clinical development of Phenoptin and 6R-BH4 for endothelial dysfunction and the manufacturing of Orapred. Uses of cash during the first nine months of 2005 include payments related to the Ascent Pediatrics transaction totaling $32.1 million, a $3.3 million license payment to Daiichi Suntory Pharma

and net cash outflows for working capital requirements. These uses of cash were partially offset by equipment and facility loan net proceeds of $17.5 million, distributions from the joint venture of $1.5 million and $6.0 million of the reimbursement from Medicis for Orapred returns received during the first nine months of 2005.

Pursuant to our settlement of a dispute with Medicis in January 2005, Medicis made available to us a convertible note of up to

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$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, 2006, we have not made any draws on the note. We anticipate that we will only draw funds from this note to the extent necessary to fund operations or to maintain financial covenants.

If we elect to increase our spending above current long-term plans or are unable to achieve our long-term goals, we may not be able to generate net positive cash flows. We expect to continue to incur substantial operational expenses and continue our research and development activities, including:

- preclinical studies and clinical trials;
- process development, including quality systems for product manufacture;
- regulatory processes in the U.S. and international jurisdictions;
- clinical and commercial scale manufacturing capabilities and contract manufacturing; and
- expansion of sales and marketing activities, including commercial launch activities for Naglazyme.

As a result of the Ascent Pediatrics transaction and the January 2005 amendments to the transaction agreements, we expect to pay Medicis $80.3 million in specified cash payments through 2009, of which $1.8 million is payable in the remainder of 2006.

Funding Commitments

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

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, 2005 and 2006 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
	2005	2006	2005	2006	
Naglazyme	$ 3.4	$ 2.3	$ 17.3	$ 7.9	$ 102.4
Phenoptin	6.0	7.5	12.9	18.0	49.7
6R-BH4 for endothelial dysfunction		3.2	3.4	5.7	9.2
Phenylase	0.7	1.1	1.7	3.3	5.8
Orapred	2.4	1.8	3.6	4.3	10.1
Not allocated to specific major current projects	1.4	2.2	4.8	7.0	119.9
Total	$ 13.9	$ 18.1	$ 43.7	$ 46.2	$ 297.1

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 this Form 10-Q and in our Form 10-K for the year ended December 31, 2005, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in our Form 10-K

If we fail to maintain regulatory approval to commercially market or sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating 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.*

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We expect that available cash, cash equivalents and short term investments, and to the extent necessary, proceeds from equity or debt financing, loans or collaborative agreements will be used to fund future operating costs, capital expenditures and working capital requirements, which may include: costs associated with the commercialization of our products; additional clinical trials and the manufacturing of Aldurazyme, Naglazyme and Phenoptin; 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 in the U.S. and E.U.;
- our joint venture partner s ability to successfully commercialize Aldurazyme;
- the progress, timing, scope and results of our preclinical studies and clinical trials;
- the amount of royalties we receive from our license of Orapred;
- our ability to maintain compliance with our debt covenants;
- the time and cost necessary to obtain regulatory approvals;
- 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

Our $51.4 million of 3.5% convertible notes will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayment of the notes in 2008. Should we redeem the notes after June 2006, at our option according to the terms of the notes, we will be subject to premiums upon redemption ranging from 0.7% to 1.4%, depending on the time the notes are redeemed. We also must repay the debt if there is a qualifying change in control or termination of trading of our common stock.

Our $172.5 million of 2.5% convertible notes will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayment of the notes in 2013. There is no call provision included and we are unable to unilaterally redeem the notes prior to maturity in 2013. However, we must repay the debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock.

In May 2004, we entered into a $25.0 million credit facility with Comerica Bank executed to finance our equipment purchases and facility improvements. The loan balance was repaid in April 2006.

As a result of the Ascent Pediatrics transaction, we expect to pay Medicis $88.9 million through 2009, of which $1.8 million is payable in the remainder of 2006. 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, 2006 is presented below (in thousands).

	Payments Due by Period					
	Total	Remainder of 2006	2007	2008-2009	2010-2011	2012 and Thereafter
Medicis obligations	$ 88,850	$ 1,750	$ 7,000	$ 80,100	$	$
Convertible debt and related interest	255,572	900	6,113	60,965	8,625	178,969
Operating leases	17,215	605	2,446	5,016	4,970	4,178
Research and development and purchase commitments	17,433	8,782	6,292	2,359		
Total	$ 379,070	$ 12,037	$ 21,851	$ 148,440	$ 13,595	183,147

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Equipment and facility loans have been removed from the schedule above to reflect the full payment in April 2006. We have also licensed technology from others, for which we are required to pay royalties upon future sales, subject to certain annual minimums totaling $0.5 million.

We are also subject to contingent payments related to various development activities totaling approximately $43.4 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future. Included in the total amount is $9.3 million of contingent payments related to Neutralase, for which we terminated development during 2003 and, accordingly, we do not expect they will ever be payable.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our market risks at September 30, 2006 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005, 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. There have been no material developments related to potential rescission claims of certain holders who may have been issued shares of our common stock in violation of certain sections of the Securities Act under our 1998 Employee Stock Purchase Plan, as first reported in our Form 10-Q for the quarter ended June 30, 2006.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described in Item 1A of our Form 10-K for the fiscal year ended December 31, 2005 and Form 10-Q for the quarter ended March 31, 2006 and June 30, 2006 are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed in the filings referenced actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our securities to decline, and you may lose all or part of your investment. The risk factors previously disclosed in Item 1A. of our Form 10-K for fiscal year ended December 31, 2005 and Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006 have remained unchanged, except for the risk factor set forth below.

If we are unable to manufacture Phenoptin in commercial scale quantities, we may be unable to meet demand for the product, lose potential revenue, experience delays in obtaining approval for the product or be forced to terminate the program.

Phenoptin is produced from a small molecule drug substance and compressed into tablets for oral delivery. The production of small molecule drug products and tablets involves complex processes and manufacturing challenges that are very different from the biological, injectable products that we have developed in the past. As a company we have very limited experience with these processes or addressing these challenges. Additionally, although we have produced a number of clinical lots, we have not yet produced Phenoptin at commercial scale using the expected commercial configuration.

We may experience difficulty in transferring the clinical scale and configuration to a reliable commercial scale and configuration. If this were to occur, we may experience delays in obtaining approval for the product or, if we are unable to resolve such issues, could force us to terminate the program. Additionally, if we experience manufacturing or capacity problems after approval, we may be unable to meet the commercial demand for the product, which would cause us to lose potential revenue. If we are unable to resolve any such issues, we may be forced to terminate the program.

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.

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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, 2006

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.