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