BIOMARIN PHARMACEUTICAL INC
Form 10-K
February 28, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 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 Incorporation or organization)	**(I.R.S. Employer Identification No.)**
105 Digital Drive,	
Novato, California	**94949**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number: (415) 506-6700

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

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $.001 par value

Preferred Share Purchase Rights

(Title of Class)

Securities registered under Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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 if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained in this form, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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: 95,542,996 shares common stock, par value $0.001, outstanding as of February 20, 2007. The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2006 was $1,228.2 million.

The documents incorporated by reference are as follows:

Portions of the Registrant s Proxy Statement for the Annual Meeting of Stockholders to be held June 27, 2007, are incorporated by reference into Part III.

Part I.

FORWARD LOOKING STATEMENTS

This Form 10-K 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*, *Description of Business*, and other sections of this Form 10-K. 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*, as well as those discussed elsewhere in this Form 10-K. 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-K 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 annual report. In addition to the other information in this Form 10-K, investors should carefully consider the following discussion and the information under *Risk Factors* when evaluating us and our business.

Item 1. Description of 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 unmet medical need, have well-understood biology and provide an opportunity to be first-to-market. Our product portfolio is comprised of two approved products and multiple investigational product candidates. Approved products include Naglazyme® (galsulfase) and Aldurazyme® (laronidase). Additionally, we have rights to receive payments and royalties related to Orapred® (prednisolone sodium phosphate) and Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets) subsequent to the sublicense of North American rights in March 2006.

We are developing several investigational product candidates for the treatment of genetic diseases including: Kuvan (sapropterin dihydrochloride), formerly referred to as Phenoptin, 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. Effective in February 2007, we changed the trade name of Phenoptin to Kuvan. In the future, we will refer to the product by this new name. We are also developing BH4 for the treatment of multiple cardiovascular indications.

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.

Our principal executive offices are located at 105 Digital Drive, Novato, California 94949 and our telephone number is (415) 506-6700. Kuvan, and Phenylase are our trademarks. BioMarin and Naglazyme are our registered trademarks. Aldurazyme is a registered trademark of BioMarin/Genzyme LLC. Orapred is a registered trademark and Orapred ODT is a trademark of Medicis Pediatrics, Inc., and is used under license.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act are available free of charge at www.bmrn.com as soon as reasonably practicable after electronically filing such reports with the SEC. Additionally, these reports are available at the SEC s website at http://www.sec.gov. Information contained in our website is not part of this report.

A summary of our various commercial products and development programs, including key metrics as of December 31, 2006, is provided below:

Program	Indication	Orphan Drug Designation	Stage	Next Key Milestone	2006 Total Product Revenue (in millions)	2006 Research & Development Expense (in millions)
Naglazyme	MPS VI	Yes	Approved	N/A	$ 46.5	$ 9.7
Aldurazyme	MPS I	Yes	Approved	N/A	$ 96.3 (1)	N/A
Kuvan	PKU	Yes	Clinical	File NDA in Q2 2007	$ 18.7	$ 27.4
6R-BH4	Cardiovascular Indications	Not yet determined	Clinical	Phase II results in 2008	N/A	$ 8.9
Phenylase	PKU	Not yet determined	Preclinical	File IND in 2008	N/A	$ 4.5

(1) We have developed Aldurazyme through a 50/50 joint venture with Genzyme, BioMarin/Genzyme LLC, and recognize our 50% share of the net income of BioMarin/Genzyme LLC as Equity in the Income of BioMarin/Genzyme LLC in our consolidated statements of operations.

Recent Developments

Results From Phase 2 Clinical Study of BH4 in Poorly Controlled Hypertension

On February 20, 2007, we announced results from the Phase 2 clinical study of 6R-BH4 in poorly controlled hypertension. Results demonstrated that there was no statistically significant or clinically meaningful effect of 6R-BH4 on any efficacy or safety parameter measured, relative to placebo.

Positive Results From Phase 3 Diet Study of Kuvan (formerly referred to as Phenoptin) for PKU

On January 16, 2007, we announced positive results from the Phase 3 diet study of Kuvan for PKU in 4 to 12 year-old patients. Results showed that all pre-specified safety and efficacy end-points were met. Kuvan treatment caused a significant increase in phenylalanine (Phe) tolerance as well as a reduction in blood phenylalanine levels. In the primary end-point, Kuvan enabled a mean increase of 20.9 mg/kg/day of Phe supplementation for those patients on Kuvan, representing a doubling of their baseline intake.

Initiation of Phase 2 Clinical Trial of BH4 in Peripheral Arterial Disease

On January 4, 2007, we announced that the first patient has initiated treatment in the Phase 2 clinical study of 6R-BH4 for the treatment of symptomatic peripheral arterial disease. We expect to announce data from this study in the first half of 2008.

Remaining $51.4 Million of 3.50% Convertible Notes Due 2008 Converted to Common Stock

On December 22, 2006, we gave notice that we were calling for redemption of the remainder of the outstanding 3.50% Convertible Senior Subordinated Notes due June 15, 2008. Prior to the January 26, 2007 call date, all of the remaining noteholders elected to convert the notes into our common stock, pursuant to the terms of the notes. As a result, we issued approximately 3.7 million shares of common stock.

Positive Results From Phase 3 Extension Study of Kuvan for PKU

On December 18, 2006, we announced positive results from the open label extension study of the pivotal Phase 3 study of Kuvan. Results confirm that all pre-specified safety and efficacy endpoints were met, and data demonstrated the long-term safety and tolerability of Kuvan as a treatment to control blood Phe levels across a range of doses in PKU patients.

Marketing Approval for Aldurazyme in Japan

On October 31, 2006, we announced that Japan s Ministry of Health, Labor and Welfare has granted marketing authorization for Aldurazyme in Japan.

Commercial Products

Naglazyme

Naglazyme is a recombinant form of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) indicated for patients with mucopolysaccharidosis VI (MPS VI). MPS VI is a debilitating life-threatening genetic disease for which no other drug treatment currently exists and is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), an enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). Patients with MPS VI typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body. These symptoms include: inhibited growth, spinal cord compression, enlarged liver and spleen, joint deformities and reduced range of motion, skeletal deformities, impaired cardiovascular function, upper airway obstruction, reduced pulmonary function, frequent ear and lung infections, impaired hearing and vision, sleep apnea, malaise and reduced endurance.

Naglazyme was granted marketing approval in the U.S. in May 2005 and in the E.U. in January 2006. 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. However, different drugs can be approved for the same condition if they are determined to have a better safety and efficacy profile than Naglazyme. We market Naglazyme in the U.S. and E.U. using our own sales force and commercial organization. We have launched the product in the major markets of the E.U. and are continuing launch efforts on a country-by-country basis in the other E.U. countries. Additionally, we are receiving some revenue from named patient sales of Naglazyme in other countries. We have initiated commercial operations in Brazil during 2006 and are currently evaluating the option of using local partners in other countries as an alternative to direct marketing of Naglazyme. Naglazyme net product sales for 2006 totaled $46.5 million, as compared to $6.1 million for 2005.

Aldurazyme

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

in the body. These symptoms include: inhibited growth, delayed and regressed mental development (in the severe form), enlarged liver and spleen, joint deformities and reduced range of motion, impaired cardiovascular function, upper airway obstruction, reduced pulmonary function, frequent ear and lung infections, impaired hearing and vision, sleep apnea, malaise and reduced endurance.

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. However, different drugs can be approved for the same condition if they

are determined to have a better safety and efficacy profile than Aldurazyme. We have developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation. We are responsible for product development, manufacturing and U.S. regulatory submissions. Genzyme is responsible for sales, marketing, distribution, obtaining reimbursement for Aldurazyme worldwide and international regulatory submissions. See *Management s Discussion and Analysis of Financial Condition and Results of Operations BioMarin/Genzyme LLC* for discussion of the financial results of Aldurazyme. Aldurazyme net revenue recorded by our joint venture for 2006 totaled $96.3 million, compared to $76.4 million for 2005.

Orapred

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 a sublicense agreement with a third party for the continued sale and commercialization of the Orapred product line. Through the sublicense, the third party acquired exclusive rights to market these products in North America. The third party is responsible for the costs of commercializing the products in North America. In June 2006, the FDA granted marketing approval for Orapred ODT, the first orally disintegrating tablet form of prednisolone available in the United States.

Revenues related to Orapred include net product sales of $3.1 million for 2006, which were earned prior to the sublicense, as compared to $6.9 million for 2005. Additionally, we recorded $15.6 million of royalty and license revenues during 2006, related 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 Merck Serono, for the further development and commercialization of Kuvan (formerly referred to as Phenoptin) and Phenylase for PKU and 6R-BH4, the active ingredient in Kuvan, for other diseases such as cardiovascular indications including those associated with endothelial dysfunction. Through the agreement, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S. and Japan, and we retained exclusive rights to market these products in the U.S. We and Merck 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 Merck Serono are individually responsible for the costs of commercializing the products within our respective territories. Merck Serono will also pay us royalties on its net sales of these products and milestone payments for the successful completion of certain development and approval milestones.

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

Currently there are no approved drug therapies for the treatment of PKU. In the U.S. and most developed countries, PKU is diagnosed at birth through a blood test. To manage the disease and maintain non-toxic blood Phe levels, people with PKU must adhere to a highly-restrictive diet comprised of foods that are low in Phe and supplemented with medical foods, which are unpalatable. Compliance with this diet is difficult for patients and usually only occurs through middle childhood, a critical period to ensure normal brain development. Recent data demonstrates that adolescent and adult PKU patients who no longer follow restricted diets suffer from a number

4

of psychological and neurological symptoms. In October 2000, a Consensus Panel convened by the National Institutes of Health recommended that all people with PKU should adhere to this special diet throughout their lives. Kuvan is intended to provide PKU patients with a more convenient and effective way to manage their disease and potentially enable them to eat a more normal diet.

In December 2004, we announced that we initiated our Phase 2 clinical trial of Kuvan 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. On March 15, 2006, we announced positive results from the Phase 3 clinical trial, which was a six-week, multi-center international, double-blind placebo-controlled study. On December 18, 2006, we announced positive results from the Phase 3 extension study, and on January 16, 2007, we announced positive results from the Phase 3 diet study. We have received orphan drug designation for Kuvan for the treatment of PKU in both the U.S. and E.U. If Kuvan is the first approved drug for PKU, it will have seven years of market exclusivity in the U.S. and 10 years of market exclusivity in the E.U. In January 2006, the FDA designated Kuvan as a fast track product for the treatment of PKU. We expect to file the New Drug Application (NDA) for Kuvan with the FDA in the second quarter of 2007.

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

We initiated our Phase 2 clinical trial of 6R-BH4 for poorly controlled hypertension in July 2006, which is an 8-week, multi-center, double-blind, placebo-controlled study. On February 20, 2007, we announced results from the Phase 2 clinical study of 6R-BH4 in poorly controlled hypertension. Results demonstrated that there was no statistically significant or clinically meaningful effect of 6R-BH4 on any efficacy or safety parameter measured, relative to placebo.

In January 2007, we announced the initiation of a Phase 2 clinical trial of 6R-BH4 for peripheral arterial disease, which is a 24-week, multi-center, double-blind, placebo-controlled study. We expect results from the Phase 2 clinical trial in the first half of 2008, depending on trial enrollment rates. We plan to initiate several additional preclinical and clinical studies of BH4 for indications related to endothelial dysfunction in 2007.

Phenylase is an investigational enzyme substitution therapy currently in preclinical development. It is being developed as a subcutaneous injection and is intended for those who suffer from classic PKU and for those who do not respond to Kuvan. In preclinical models, Phenylase produced a rapid, dose-dependent reduction in blood Phe levels. We plan to conduct additional preclinical studies of Phenylase in 2007.

Manufacturing

We are manufacturing Naglazyme and Aldurazyme, which are both recombinant enzymes, in our approved Good Manufacturing Practices (GMP) production facility located in Novato, California. Vialing and packaging of Aldurazyme are performed by either our joint venture partner or contract manufacturers, and vialing and packaging of Naglazyme are performed by contract manufacturers. We believe that we have ample operating capacity to support the commercial demand of both Naglazyme and Aldurazyme through at least the remainder of this decade.

Our facilities have been licensed by the FDA, EC and health agencies in other countries for the commercial production of Aldurazyme and by the FDA and the EC for the commercial production of Naglazyme. Our

facilities and those of any third-party manufacturers will be subject to periodic inspections confirming compliance with applicable law. Our facilities must be GMP certified before we can manufacture our drugs for commercial sales.

In general, we expect to contract with outside service providers for certain manufacturing services, including final product vialing and packaging operations for our recombinant enzymes and bulk production for clinical and early commercial production of our other product candidates. Kuvan, formerly referred to as Phenoptin, is manufactured on a contract basis.

Raw Materials

Raw materials and supplies required for the production of our products and product candidates are available, in some instances from one supplier, and in other instances, from multiple suppliers. In those cases where raw materials are only available through one supplier, such supplier may be either a sole source (the only recognized supply source available to us) or a single source (the only approved supply source for us among other sources). We have adopted policies to attempt, to the extent feasible, to minimize our raw material supply risks, including maintenance of greater levels of raw materials inventory and implementation of multiple raw materials sourcing strategies, especially for critical raw materials. Although to date we have not experienced any significant delays in obtaining any raw materials from our suppliers, we cannot provide assurance that we will not face shortages from one or more of them in the future.

Sales and Marketing

We have established a commercial organization to support our product lines directly in the U.S., Europe and Latin America. For other selected markets, we have signed agreements with other companies to act as partners or distributors of Naglazyme. Additional markets are being assessed at this time and additional agreements may be signed in the future. We maintain a relatively small sales force in the U.S. and E.U. We believe that the size of our sales force is appropriate to effectively reach our target audience in markets where Naglazyme is directly marketed. We utilize a third-party logistics company to store and distribute Naglazyme from its warehouse in the United Kingdom (U.K.) for customers in the E.U. and from a second warehouse in Tennessee for customers in the U.S. and other countries outside of the E.U.

Pursuant to our joint venture agreement, Genzyme is responsible for sales, marketing, distribution, obtaining reimbursement worldwide and international regulatory submissions of Aldurazyme.

Customers

Our Naglazyme customers include a limited number of specialty pharmacies and end-users, such as hospitals, which act as retailers. We also sell Naglazyme to our authorized European distributor and to certain larger pharmaceutical wholesalers, which act as intermediaries between us and end-users and generally do not stock quantities of Naglazyme. During 2006, sales to our two largest customers accounted for the following portions of our Naglazyme net product sales and no other customer individually accounted for more than 5% of total net sales:

Healthcare at Home	53%
AmerisourceBergen	7%

	60%

Despite the significant concentration of customers, the demand for Naglazyme is driven by patient therapy requirements and we are not dependent upon any individual distributor with respect to Naglazyme sales. Due to the pricing of Naglazyme and the limited number of patients, the specialty pharmacies and wholesalers carry a very limited inventory, resulting in sales of Naglazyme being closely tied to end-user demand. In the E.U., hospital customers are generally serviced by an authorized distributor, which is our primary customer in the E.U.

Competition

The biopharmaceutical industry is rapidly evolving and highly competitive. The following is a summary analysis of known competitive threats for each of our major product programs:

Naglazyme and Aldurazyme

We know of no active competitive program for enzyme replacement therapy for MPS VI or MPS I that has entered clinical trials.

Bone marrow transplantation has been used to treat severely affected patients, generally under the age of two, with some success. Bone marrow transplantation is associated with high morbidity and mortality rates as well as with problems inherent in the procedure itself, including graft vs. host disease, graft rejection and donor availability, which limits its utility and application. There are other developing technologies that are potential competitive threats to enzyme replacement therapies. However, we know of no such technology that has entered clinical trials related to MPS VI or MPS I.

Kuvan (formerly referred to as Phenoptin) and Phenylase

There are currently no approved drugs for the treatment of PKU. PKU is commonly treated with a medical food diet that is highly-restrictive and unpalatable. We perceive medical foods as a complement to Kuvan and Phenylase and not a significant competitive threat. Dietary supplements of large neutral amino acids (LNAA) have also been used in the treatment of PKU. This treatment may be a competitive threat to Kuvan and Phenylase. However, because LNAA is a dietary supplement, the FDA has not evaluated any claims of efficacy of LNAA.

With respect to Kuvan, we are aware of two other companies that produce forms of 6R-BH4 (or BH4), and that BH4 has been used in certain instances for the treatment of PKU. We do not believe, but cannot know for certain, that either of these companies are currently actively developing BH4 in sponsored trials as a drug product to treat PKU in the U.S. or E.U. Although a significant amount of specialized knowledge and resources would be required to develop and commercially produce BH4 as a drug product to treat PKU in the U.S. and E.U., these companies may build or acquire the capability to do so. Additionally, we are aware that another company is developing an oral enzyme therapy to treat PKU; however we understand that the therapy is in an early stage of preclinical development.

With respect to BH4 as a drug product to treat endothelial dysfunction, there is currently no comparable directly competing product on the market. However, there is a significant amount of competition for the treatment of hypertension, peripheral arterial disease and other conditions associated with endothelial dysfunction through other active ingredients, some of which are currently on the market or are in development. We believe that the BH4 mechanism of action is unique and has multiple levels of benefit, with a good safety profile. We are not currently aware of other companies that are actively developing or conducting clinical trials of BH4 for the treatment of hypertension, peripheral arterial disease and other conditions associated with endothelial dysfunction.

Patents and Proprietary Rights

Our success depends on an intellectual property portfolio that supports our future revenue streams and also erects barriers to our competitors. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications; licensing and acquiring new patents and patent applications; and enforcing our issued patents. Furthermore, we seek to protect our ownership of know-how, trade secrets and trademarks through an active program of legal mechanisms including assignments, confidentiality agreements, material transfer agreements, research collaborations and licenses.

The number of our issued patents now stands at approximately 285, including approximately 35 patents issued by the U.S. Patent and Trademark Office (USPTO). Furthermore, our portfolio of pending patent applications totals approximately 190 applications, including approximately 40 pending U.S. applications.

We have four core patents related to Aldurazyme. These patents cover our ultra-pure alpha-L-iduronidase composition of Aldurazyme, methods of treating deficiencies of alpha-L-iduronidase by administering pharmaceutical compositions comprising such ultra-pure alpha-L-iduronidase, a method of purifying such ultra-pure alpha-L-iduronidase and the use of compositions of ultra-pure biologically active fragments of alpha-L-iduronidase.

Transkaryotic Therapies Inc. (TKT), which was acquired by Shire PLC, has announced that three U.S. patents on alpha-L-iduronidase had been issued and that these patents had been exclusively licensed to TKT. We have examined such issued U.S. patents, the related U.S. and foreign applications and their file histories, the prior art and other information. Corresponding foreign applications were filed in Canada, Europe and Japan. The European application was rejected and abandoned and cannot be re-filed, but the Canadian and Japanese applications are still pending and are being prosecuted by the applicants. Claims in the related Canadian application have been recently found allowable. We believe that such patents and patent applications may not survive a challenge to patent validity. However, the processes of patent law are uncertain and any patent proceeding is subject to multiple unanticipated outcomes. We believe that it is in the best interest of our joint venture with Genzyme to market Aldurazyme with commercial diligence, in order to provide MPS I patients with the benefits of Aldurazyme.

In October 2003, Genzyme and TKT announced their collaboration to develop and commercialize an unrelated drug product. In connection with the collaboration agreement, Genzyme and TKT signed a global legal settlement involving an exchange of non-suits between the companies. As part of this exchange, TKT has agreed not to initiate any patent litigation against Genzyme or our joint venture relating to Aldurazyme.

We believe that these patents and patent applications do not affect our ability to market Aldurazyme in Europe. As described above, a European patent application with similar claims was rejected by the European Patent Office, abandoned by the applicants, and cannot be refiled.

With respect to Naglazyme, we have a patent that covers our ultrapure *N*-acetylgalactosamine-4-sulfatase compositions of Naglazyme, methods of treating deficiencies of *N*-acetylgalactosamine-4-sulfatase, including MPS VI, and methods of purifying such ultrapure *N*-acetylgalactosamine-4-sulfatase compositions. A second patent covers the use of any recombinant human *N*-acetylgalactosamine-4-sulfatase to treat MPS VI at approved doses.

With respect to Kuvan and BH4, we have or have licensed a number of patents and pending patent applications that relate generally to formulations and forms of our drug substance, and methods of use for various indications under development and the dose regimen. With respect to the pending patent applications, unless and until actually issued, the protective value of these applications is impossible to determine.

Government Regulation

We operate in a highly regulated industry, which is subject to significant Federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug and Cosmetic Act, the Medicaid rebate program, the Veterans Health Care Act of 1992, and the Occupational Safety and Health Act, among others. Additionally, the following are of particular focus for us:

Food and Drug Administration Modernization Act of 1997 (Modernization Act)

The Modernization Act was enacted, in part, to ensure the availability of safe and effective drugs and medical devices by expediting the FDA review process for new products. The Modernization Act establishes a

statutory program for the approval of fast-track products. The fast-track provisions essentially codify the FDA s accelerated approval regulations for drugs. A fast-track product is defined as a new drug intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for that condition. Under the fast-track program, the sponsor of a new drug may request that the FDA designate the drug as a fast-track-product at any time during the clinical development of the product. The Modernization Act specifies that the FDA must determine if the product qualifies for fast-track designation within 60 days of receipt of the sponsor s request.

Approval of a marketing application for a fast-track product can be based on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. Approval of a marketing application for a fast-track product may be subject to post-approval studies to validate or confirm the effect on the clinical endpoint, or, if based on a surrogate endpoint, to validate or confirm the surrogate endpoint, plus the FDA must review all promotional materials prior to drug approval. If a preliminary review of the clinical data suggests that the product is effective, the FDA may initiate review of sections of a marketing application for a fast-track product before the application is complete. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act (PDUFA), which governs the time period goals the FDA has committed to reviewing a marketing application, does not begin until the complete application is submitted.

Because fast-track products are intended to treat serious or life-threatening conditions and must demonstrate the potential to address unmet medical needs for such conditions, a marketing application for a product in a fast-track drug development program ordinarily will be eligible for priority review wherein the PDUFA timeframe for the review is 6 months instead of 10 months. However, we cannot predict the ultimate impact, if any, of the fast-track process on the timing or likelihood of FDA approval of any of our potential products, which may receive this designation.

The FDA has designated Kuvan as a fast-track product for the treatment of PKU. We cannot predict the ultimate impact, if any, of the fast-track process on the timing or likelihood of FDA approval of Kuvan or any of our other potential products.

Orphan Drug Designation

Naglazyme, Aldurazyme and Kuvan have received orphan drug designations from the FDA. Orphan drug designation is granted by the FDA to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of less than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. A similar system for orphan drug designation exists in the E.U. Naglazyme, Aldurazyme and Kuvan received orphan medicinal product designation by the European Committee for Orphan Medicinal Products.

Orphan drug designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the U.S. and 10 years in the E.U. Although obtaining approval to market a product with orphan drug exclusivity may be advantageous, we cannot be certain:

- that we will be the first to obtain approval for any drug for which we obtain orphan drug designation;
- that orphan drug designation will result in any commercial advantage or reduce competition; or

that the limited exceptions to this exclusivity will not be invoked by the relevant regulatory authority.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Employees

As of February 1, 2007, we had 410 full-time employees, 204 of whom are in operations, 93 of whom are in research and development, 53 of whom are in sales and marketing and 60 of whom are in administration.

We consider our employee relations to be good. Our employees are not covered by a collective bargaining agreement. We have not experienced employment related work stoppages.

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 below 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 below 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.

If we continue to incur operating losses for a period longer than anticipated, we may be unable to continue our operations at planned levels and be forced to reduce or discontinue operations.

Since we began operations in March 1997, we have been engaged primarily in research and development and have operated at a net loss for the entire time. Based on our current business plans, we expect to continue to operate at an annual net loss at least until 2008. Our future profitability depends on our marketing and selling of Naglazyme, the successful commercialization of Aldurazyme by our joint venture partner, Genzyme, the amount of royalties we receive from our license of Orapred, the receipt of regulatory approval of our product candidates, our ability to successfully manufacture and market any approved drugs, either by ourselves or jointly with others, and our spending on our development programs. The extent of our future losses and the timing of profitability are highly uncertain. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or discontinue operations.

If we fail to obtain the capital necessary to fund our operations, our financial results and financial condition will be adversely affected and we will have to delay or terminate some or all of our product development programs.

We may require additional financing to fund our future operations, including the commercialization of our approved drugs and drug product candidates currently under development, preclinical studies and clinical trials, and potential licenses and acquisitions. We may be unable to raise additional financing if needed due to a variety of factors, including our financial condition, the status of our product programs, and the general condition of the financial markets. If we fail to raise additional financing if we need such funds, we may have to delay or terminate some or all of our product development programs and our financial condition and operating results will be adversely affected.

We expect to continue to spend substantial amounts of capital for our operations for the foreseeable future. The amount of capital we will need depends on many factors, including:

our ability to successfully market and sell Naglazyme;

our joint venture partner s ability to successfully commercialize Aldurazyme;

the progress, timing and scope of our preclinical studies and clinical trials;

the amount of royalties we receive from our license of Orapred;

the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;

the time and cost necessary to develop commercial manufacturing processes, including quality systems, and to build or acquire manufacturing capabilities;

the time and cost necessary to respond to technological and market developments;

any changes made 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.

Moreover, our fixed expenses such as rent, license payments, interest expense and other contractual commitments are substantial and may increase in the future. These fixed expenses may increase because we may enter into:

additional licenses and collaborative agreements;

additional contracts for product manufacturing; and

additional financing facilities.

We believe that our cash, cash equivalents and short-term investment securities at December 31, 2006 will be sufficient to meet our operating and capital requirements for the foreseeable future based on our current long-term business plans. These estimates are based on assumptions and estimates, which may prove to be wrong. We may need to raise additional funds from equity or debt securities, loans, or collaborative agreements if we are unable to satisfy our liquidity requirements. The sale of additional securities may result in additional dilution to our stockholders. Furthermore, additional financing may not be available in amounts or on terms satisfactory to us or at all. This could result in the delay, reduction or termination of our research, which could harm our business.

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.

As part of the regulatory approval process, we must conduct, at our own expense, preclinical studies in the laboratory on animals and clinical trials on humans for each product candidate. We expect the number of preclinical studies and clinical trials that the regulatory authorities will

require will vary depending on the product candidate, the disease or condition the drug is being developed to address and regulations applicable to the particular drug. Generally, the number and size of clinical trials required for approval increases based on the expected patient population that may be treated with a drug. We may need to perform multiple preclinical studies using various doses and formulations before we can begin clinical trials, which could result in delays in our ability to market any of our product candidates. Furthermore, even if we obtain favorable results in preclinical studies on animals, the results in humans may be significantly different. After we have conducted preclinical studies in animals, we must demonstrate that our drug products are safe and efficacious for use in the targeted human patients in order to receive regulatory approval for commercial sale.

Adverse or inconclusive clinical results would stop us from filing for regulatory approval of our product candidates. Additional factors that can cause delay or termination of our clinical trials include:

slow or insufficient patient enrollment;

slow recruitment of, and completion of necessary institutional approvals at, clinical sites;

longer treatment time required to demonstrate efficacy;

lack of sufficient supplies of the product candidate;

adverse medical events or side effects in treated patients;

lack of effectiveness of the product candidate being tested; and

regulatory requests for additional clinical trials.

Typically, if a drug product is intended to treat a chronic disease, as is the case with some of our product candidates, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more.

The fast-track designation for our product candidates, if obtained, may not actually lead to a faster review process and a delay in the review process or in the approval of our products will delay revenue from the sale of the products and will increase the capital necessary to fund these programs.

Our product candidates may not receive fast-track designation or a six-month review timeframe. Even with fast-track designation, it is not guaranteed that the total review process will be faster or that approval will be obtained, if at all, earlier than would be the case if the product had not received fast-track designation.

If we fail to obtain or maintain orphan drug exclusivity for some of our products, our competitors may sell products to treat the same conditions and our revenues will be reduced.

As part of our business strategy, we intend to develop some drugs that may be eligible for FDA and E.U. orphan drug designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined as a patient population of less than 200,000 in the U.S. The company that first obtains FDA approval for a designated orphan drug for a given rare disease receives marketing exclusivity for use of that drug for the stated condition for a period of seven years. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Similar regulations are available in the E.U. with a 10-year period of market exclusivity.

Because the extent and scope of patent protection for some of our drug products is limited, orphan drug designation is especially important for our products that are eligible for orphan drug designation. For eligible drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition and our revenues will be reduced.

Even though we have obtained orphan drug designation for certain of our products and product candidates and even if we obtain orphan drug designation for our future product candidates, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any orphan indication. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

If we fail to maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.

We must obtain regulatory approval before marketing or selling our drug products in the U.S. and in foreign jurisdictions. In the U.S., we must obtain FDA approval for each drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation. Naglazyme and Aldurazyme have received regulatory approval to be commercially marketed and sold in the U.S., E.U. and other countries. If we fail to obtain regulatory approval for our other product candidates, we will be unable to market and sell those drug products. Because of the risks and uncertainties in pharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval.

From time to time during the regulatory approval process for our products and our product candidates, we engage in discussions with the FDA and foreign regulatory authorities regarding the regulatory requirements for our development programs. To the extent appropriate, we accommodate the requests of the regulatory authorities and, to date, we have generally been able to reach reasonable accommodations and resolutions regarding the underlying issues. However, we are often unable to determine the outcome of such deliberations until they are final. If we are unable to effectively and efficiently resolve and comply with the inquiries and requests of the FDA and foreign regulatory authorities, the approval of our product candidates may be delayed and their value may be reduced.

After any of our products receive regulatory approval, they remain subject to ongoing regulation, including, for example, changes to the product labeling, new or revised regulatory requirements for manufacturing practices and reporting adverse reactions and other information. If we do not comply with the applicable regulations, the range of possible sanctions includes issuance of adverse publicity, product recalls or seizures, fines, total or partial suspensions of production and/or distribution, suspension of marketing applications, enforcement actions, including injunctions and civil or criminal prosecution. The FDA and foreign regulatory agencies can withdraw a product s approval under some circumstances, such as the failure to comply with existing or future regulatory requirements or unexpected safety issues. Further, the government authorities may condition approval of our product candidates on the completion of additional post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to safety. If data we collect from post-marketing studies suggest that one of our approved products may present a risk to safety, the government authorities could withdraw our product approval, suspend production or place other marketing restrictions on our products. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our management s credibility, the value of our company and our operating results will be adversely affected. Additionally, 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.

If we fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before we can begin commercial manufacture of our products, we, or our contract manufacturer, must obtain regulatory approval of our manufacturing facilities, processes and quality systems. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA, the State of California and foreign regulatory authorities, before and after product approval. Our manufacturing facilies have been inspected and licensed by the State of California for pharmaceutical manufacture and have been approved by the FDA, the EC and health agencies in other countries for the manufacture of Aldurazyme and by the FDA and EC for the manufacture of Naglazyme.

Due to the complexity of the processes used to manufacture our products and product candidates, we may be unable to continue to pass or initially pass federal or international regulatory inspections in a cost effective

13

manner. For the same reason, any potential third-party manufacturer of Naglazyme, Aldurazyme or our product candidates may be unable to comply with GMP regulations in a cost effective manner.

If we, or our third-party manufacturers with whom we contract, are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

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.

Due to the complexity of manufacturing our products we may not be able to manufacture drug products successfully with a commercially viable process or at a scale large enough to support their respective commercial markets or at acceptable margins.

Improvements in manufacturing processes typically are very difficult to achieve and are often very expensive and may require extended periods of time to develop. If we contract for manufacturing services with an unproven process, our contractor is subject to the same uncertainties, high standards and regulatory controls, and may therefore experience difficulty if further process development is necessary. Even a developed manufacturing process can encounter difficulties due to changing regulatory requirements, human error, mechanical breakdowns, and other events that cannot always be prevented or anticipated. Further, the availability of suitable contract manufacturing capacity at scheduled or optimum times is not certain.

Although we have entered into contractual relationships with third-party manufacturers to produce the active ingredient in Kuvan, 6R-BH4, if those manufacturers are unwilling or unable to fulfill their contractual obligations, we may be unable to meet demand for that product or sell that product at all, regulatory approval for Kuvan could be significantly delayed and we may lose potential revenue.

In addition, our manufacturing processes subject us to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of hazardous materials and wastes resulting from their use. We may incur significant costs in complying with these laws and regulations.

If our manufacturing processes have a higher than expected failure rate, we may be unable to meet demand for our products and lose potential revenue, have reduced margins, or be forced to terminate a program.

The processes we use to manufacture our product and product candidates are extremely complex. Many of the processes include biological systems, which add significant complexity, as compared to chemical synthesis. We expect that, from time to time, consistent with biotechnology industry expectations, certain production lots will fail to produce product that meets our quality control release acceptance criteria. To date, our historical failure rates for all of our product programs, including Naglazyme and Aldurazyme, have been within our expectations, which are based on industry norms.

In order to produce product within our time and cost parameters, we must continue to produce product within expected failure parameters. Because of the complexity of our manufacturing processes, it may be difficult or impossible for us to determine the cause of any particular lot failure and we must effectively and timely take corrective action in response to any failure.

If we are unable to effectively address manufacturing issues, we may be unable to meet demand for our products and lose potential revenue, have reduced margins, or be forced to terminate a program.

Our sole manufacturing facility for Naglazyme and Aldurazyme is located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facility and equipment, or that of our third-party manufacturers or single-source suppliers, which could materially impair our ability to manufacture Naglazyme and Aldurazyme or our third-party manufacturer s ability to manufacture Kuvan, formerly referred to as Phenoptin.

Our Galli Drive facility is our only manufacturing facility for Naglazyme and Aldurazyme. It is located in the San Francisco Bay Area near known earthquake fault zones and is vulnerable to significant damage from earthquakes. We, and the third-party manufacturers with whom we contract and our single-source suppliers of raw materials, are also vulnerable to damage from other types of disasters, including fires, floods, power loss and similar events. If any disaster were to occur, or any terrorist or criminal activity caused significant damage to our facilities or the facilities of our third-party manufacturers and suppliers, our ability to manufacture Naglazyme and Aldurazyme, or to have Kuvan manufactured, could be seriously, or potentially completely impaired, and our Naglazyme and Aldurazyme commercialization efforts, revenue from the sale of Naglazyme and Aldurazyme and our development efforts with respect to Kuvan could be seriously impaired. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

If we are unable to manufacture Kuvan 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.

Kuvan 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 limited experience with these processes or addressing these challenges. Additionally, although we have produced a number of clinical lots, we have not yet produced Kuvan 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.

Supply interruptions may disrupt our inventory levels and the availability of our products and cause delays in obtaining regulatory approval for our product candidates, or cause a loss of our market share and reduce our revenues.

Numerous factors could cause interruptions in the supply of our finished products, including:

- timing, scheduling and prioritization of production by our contract manufacturers or a breach of our agreements by our contract manufacturers;
- labor interruptions;
- changes in our sources for manufacturing;

the timing and delivery of shipments;

our failure to locate and obtain replacement manufacturers as needed on a timely basis; and

conditions affecting the cost and availability of raw materials.

Any interruption in the supply of finished products could hinder our ability to timely distribute finished products.

With respect to our product candidates, production of product is necessary to perform clinical trials and successful registration batches are necessary to file for approval to commercially market and sell product candidates. Delays in obtaining clinical material or registration batches could delay regulatory approval for our product candidates.

Because the target patient populations for some of our products are small, we must achieve significant market share and obtain high per-patient prices for our products to achieve profitability.

Naglazyme, Aldurazyme and Kuvan all target diseases with small patient populations. As a result, our per-patient prices must be relatively high in order to recover our development and manufacturing costs and achieve profitability. For Naglazyme, we believe that we will need to market worldwide to achieve significant market penetration of the product. Due to the expected costs of treatment for our products for genetic diseases, we may be unable to maintain or obtain sufficient market share at a price high enough to justify our product development efforts.

If we fail to obtain an adequate level of reimbursement for our drug products by third-party payers, the sales of our drugs would be adversely affected or there may be no commercially viable markets for our products.

The course of treatment for patients using Naglazyme and Aldurazyme is expensive. We expect patients to need treatment throughout their lifetimes. We expect that most families of patients will not be capable of paying for this treatment themselves. There will be no commercially viable market for Naglazyme or Aldurazyme without reimbursement from third-party payers. Additionally, even if there is a commercially viable market, if the level of reimbursement is below our expectations, our revenue and gross margins will be adversely affected.

Third-party payers, such as government or private health care insurers, carefully review and increasingly challenge the prices charged for drugs. Reimbursement rates from private companies vary depending on the third-party payer, the insurance plan and other factors. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis.

Reimbursement in the E.U. must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The negotiation process in some countries can exceed 12 months.

For our future products, we will not know what the reimbursement rates will be until we are ready to market the product and we actually negotiate the rates. If we are unable to obtain sufficiently high reimbursement rates for our products, they may not be commercially viable or our future revenues and gross margins may be adversely affected.

Actions by wholesalers relating to the purchase of Orapred could affect the timing of royalty revenues and end-user demand could affect the amount of royalty revenues.

Orapred is sold to major wholesalers and retail pharmacy chains. Consistent with pharmaceutical industry patterns, most Orapred sales are to three major drug wholesale concerns. Distribution allocation is determined by wholesale and drug chain customers. There can be no assurance that these customers will adequately manage their local and regional inventories to avoid spot outages.

It is difficult to control or influence greatly the purchasing patterns of wholesale and retail drug chain customers. These are highly sophisticated customers that purchase our products in a manner consistent with their industry practices and, presumably based upon their projected demand levels. The buying practices of the wholesalers include occasional speculative purchases of product in excess of the current market demand, at their discretion, in anticipation of future price increases. Purchases by any given customer, during any given period,

may be above or below actual prescription volumes of Orapred during the same period, resulting in fluctuations in product inventory in the distribution channel. In addition, if wholesaler inventories substantially exceed retail demand, we could experience reduced royalty revenue from sales of Orapred by our sub-licensee in subsequent periods due to overstocking or low end-user demand.

The total amount of Orapred related royalties is highly dependent on our licensee s ability to market the products and the end-user demand. If our licensee is unsuccessful and if end-user demand is lower than expected, our total amount of royalties from the Orapred product line could be lower than expected.

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.

Our competitors may develop, manufacture and market products that are more effective or less expensive than ours. They may also obtain regulatory approvals for their products faster than we can obtain them (including those products with orphan drug designation) or commercialize their products before we do. If we do not compete successfully, 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.

In the future, government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

We expect that, in the future, reimbursement will be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Governmental and private third-party payers have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. In some foreign markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect reimbursement for medical treatment by third-party payers, which may render our products not commercially viable or may adversely affect our future revenues and gross margins.

In the U.S., we expect branded pharmaceutical products to be subject to increasing pricing pressures. Implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), providing an out-patient prescription drug benefit under the Medicare program, became effective on January 1, 2006. While it is difficult to predict the final business impact of this legislation, there is additional risk associated with increased pricing pressures. While the MMA prohibits the Secretary of Health and Human Services (HHS) from directly negotiating prescription drug prices with manufacturers, we expect continued challenges to that prohibition over the next several years. Also, the MMA retains the authority of the HHS to prohibit the importation of prescription drugs, but we expect Congress to consider several measures that could remove that authority and allow for importation of products into the U.S. regardless of their safety or cost. If adopted, such legislation would likely have a negative effect on our U.S. sales.

As a result of the passage of the MMA, aged and disabled patients jointly eligible for Medicare and Medicaid will receive certain prescription drug benefits through Medicare, instead of Medicaid, as of January 1, 2006. This may relieve some state budget pressures but is unlikely to result in reduced pricing pressures. Additionally, in the U.S., we are required to provide rebates to state governments on their purchases of certain of our products under state Medicaid programs. Many states have begun to implement supplemental rebates and restricted formularies in their Medicaid programs, and these programs are expected to continue in the post-MMA environment. Other cost containment measures have been adopted or proposed by federal, state, and local government entities that provide or pay for health care. In most international markets, we operate in an environment of government-mandated cost containment programs, which may include price controls, reference

17

pricing, discounts and rebates, restrictions on physician prescription levels, restrictions on reimbursement, compulsory licenses, health economic assessments, and generic substitution. Several states are also attempting to extend discounted Medicaid prices to non-Medicaid patients. Additionally, notwithstanding the federal law prohibiting pharmaceutical importation, several states have implemented importation schemes for their citizens, usually involving a website that links patients to selected Canadian pharmacies. At least one state has such a program for its state employees. In the absence of federal action to curtail state activities, we expect other states to launch importation efforts. As a result, we expect pressures on pharmaceutical pricing to continue.

International operations are also generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property portfolio.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

If we are found in violation of federal or state fraud and abuse laws, we may be required to pay a penalty or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operation.

We are subject to various federal and state health care fraud and abuse laws, including antikickback laws, false claims laws and laws related to ensuring compliance. The federal health care program antikickback statute makes it illegal for any person, including a pharmaceutical company, to knowingly and willfully offer, solicit, pay or receive any remuneration, directly or indirectly, in exchange for or to induce the referral of business, including the purchase, order or prescription of a particular drug, for which payment may be made under federal health care programs, such as Medicare and Medicaid. Under federal government regulations, certain arrangements (safe harbors) are deemed not to violate the federal antikickback statute. We seek to comply with these safe harbors. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third party payers (including government payers) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Other cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products has resulted in the submission of false claims to government health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we also are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid.

Many states have adopted laws similar to the federal antikickback statute, some of which apply to referral of patients for health care services reimbursed by any source, not just governmental payers. In addition, California passed a law that requires pharmaceutical companies to comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the July 2002 PhRMA Code on Interactions with Healthcare Professionals.

Neither the government nor the courts have provided definitive guidance on the application of these laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict

18

us of violating, these laws. If we are found in violation of one of these laws, we are required to pay a penalty or are suspended or excluded from participation in federal or state health care programs, our business, financial condition and results of operation may be adversely affected.

We conduct a significant amount of our sales and operations outside of the United States, which subjects us to additional business risks that could adversely affect our revenue and results of operations.

A significant portion of the sales of Aldurazyme and Naglazyme are generated from countries other than the United States. Additionally, we have operations in several European countries and Brazil. We expect that we will continue to expand our foreign operations in the future. International operations inherently subject us to a number of risks and uncertainties, including:

- changes in foreign regulatory requirements;
- fluctuations in foreign currency exchange rates;
- political and economic instability;
- diminished protection of intellectual property in some countries outside of the United States;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing foreign operations;
- differing labor regulations and business practices; and
- potentially negative consequences from changes in tax laws.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations.

As we expand our existing international operations, we may encounter new risks. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenue and profitability.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

Where appropriate, we seek patent protection for certain aspects of our technology. Patent protection may not be available for some of the products we are developing. If we must spend significant time and money protecting our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed.

The patent positions of biopharmaceutical products are complex and uncertain. The scope and extent of patent protection for some of our products and product candidates are particularly uncertain because key information on some of our product candidates has existed in the public domain for many years. The composition and genetic sequences of animal and/or human versions of Naglazyme, Aldurazyme and many of our product candidates have been published and are believed to be in the public domain. The chemical structure of BH4 has also been published. Publication of this information may prevent us from obtaining composition-of-matter patents, which are generally believed to offer the strongest patent protection.

For enzymes or compounds with no prospect of broad composition-of-matter patents, other forms of patent protection or orphan drug status may provide us with a competitive advantage. As a result of these uncertainties, investors should not rely solely on patents as a means of protecting our products or product candidates, including Naglazyme, Aldurazyme, Orapred or BH4.

We own or license patents and patent applications related to Naglazyme, Aldurazyme, Orapred, and certain of our product candidates. However, these patents and patent applications do not ensure the protection of our intellectual property for a number of reasons, including the following:

- We do not know whether our patent applications will result in issued patents. For example, we may not have developed a method for treating a disease before others developed similar methods.

- Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors may also claim that we are infringing on their patents and therefore cannot practice our technology as claimed under our patent. Competitors may also contest our patents by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If a court agrees, we would lose that patent. We have no meaningful experience with competitors interfering with our patents or patent applications.

- Enforcing patents is expensive and may absorb significant time of our management. Management would spend less time and resources on developing products, which could increase our operating expenses and delay product programs.

- Receipt of a patent may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent.

In addition, competitors also seek patent protection for their technology. Due to the number of patents in our field of technology, we cannot be certain that we do not infringe on those patents or that we will not infringe on patents granted in the future. If a patent holder believes our product infringes on their patent, the patent holder may sue us even if we have received patent protection for our technology. If someone else claims we infringe on their technology, we would face a number of issues, including the following:

- Defending a lawsuit takes significant time and can be very expensive.

- If the court decides that our product infringes on the competitor s patent, we may have to pay substantial damages for past infringement.

- The court may prohibit us from selling or licensing the product unless the patent holder licenses the patent to us. The patent holder is not required to grant us a license. If a license is available, we may have to pay substantial royalties or grant cross licenses to our patents.

- Redesigning our product so it does not infringe may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how.

We may also support and collaborate in research conducted by government organizations, hospitals, universities or other educational institutions. These research partners may be unwilling to grant us any exclusive rights to technology or products derived from these collaborations prior to entering into the relationship.

If we do not obtain required licenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

The U.S. Patent and Trademark Office (USPTO) has issued three patents to a third-party that relate to alpha-L-iduronidase. If we are not able to successfully challenge these patents or related patents in Canada or Japan, if they issue in these countries, we may be prevented from producing Aldurazyme in countries with issued patents unless and until we obtain a license.

The USPTO has issued three patents to a third-party that include composition-of-matter, isolated genomic nucleotide sequences, vectors including the sequences, host cells containing the vectors, and method of use claims for human, recombinant alpha-L-iduronidase. Aldurazyme is based on human, recombinant alpha-L-iduronidase. A corresponding patent application was filed by a third party in the European Patent Office claiming composition-of-matter for human, recombinant alpha-L-iduronidase, and it was rejected over prior art and withdrawn and cannot be re-filed. However, a corresponding application is still pending in Japan, and this application is being prosecuted by the applicants. We do not know whether the Japanese application will issue or the scope of the claims that would issue. Claims to a related Canadian application have recently been found allowable. We believe that these patents, and the Canadian and Japanese patent applications, if issued, are invalid or not infringed on a number of grounds. In addition, under U.S. law, issued patents are entitled to a presumption of validity, and a challenge to the U.S. patents may be unsuccessful. Even if we are successful, challenging the U.S. patents may be expensive, require our management to devote significant time to this effort and may adversely impact commercialization of Aldurazyme in the U.S. (or in Canada and Japan, should patents issue in these countries.)

The holder of the patents described above has granted an exclusive license for products relating to these patents to one of our competitors, Transkaryotic Therapies Inc. (TKT), which was acquired by Shire PLC in 2005. If we are sued and are unable to successfully challenge the patents, we may be forced to pay damages to the patent holder and we may be unable to produce Aldurazyme in the U.S. (or in Canada or Japan, should patents issue in these countries) unless we can reach an accommodation with the patent holder and licensee. Neither the current licensee nor the patent holder is required to grant us a license or other accommodation and even if a license or other accommodation is available, we may have to pay substantial license fees, which could adversely affect our business and operating results.

On October 8, 2003, Genzyme, our joint venture partner, and TKT announced their collaboration to develop and commercialize an unrelated drug product. In connection with the collaboration agreement, Genzyme and TKT signed a global legal settlement involving an exchange of non-suits between the companies. As part of this exchange, TKT has agreed not to initiate any patent litigation against Genzyme or our joint venture relating to Aldurazyme. The holder of the patents, who is not party to the TKT-Genzyme settlement discussed above may also have a right to enforce the patents.

If our joint venture with Genzyme were terminated, we could be barred from commercializing Aldurazyme or our ability to successfully commercialize Aldurazyme would be delayed or diminished.

Either Genzyme or we may terminate the joint venture for specified reasons, including if the other party is in material breach of the agreement, has experienced a change of control, or has declared bankruptcy and also is in breach of the agreement. Although we are not currently in breach of the joint venture agreement and we believe that Genzyme is not currently in breach of the joint venture agreement, there is a risk that either party could breach the agreement in the future. Either party may also terminate the agreement upon one year prior written notice for any reason.

If the joint venture is terminated for breach, the non-breaching party would be granted, exclusively, all of the rights to Aldurazyme and any related intellectual property and regulatory approvals and would be obligated to buy out the breaching party s interest in the joint venture. If we are the breaching party, we would lose our rights to Aldurazyme and the related intellectual property and regulatory approvals. If the joint venture is terminated without cause, the non-terminating party would have the option, exercisable for one year, to buy out the terminating party s interest in the joint venture and obtain all rights to Aldurazyme exclusively. In the event of termination of the buy out option without exercise by the non-terminating party as described above, all right and title to Aldurazyme is to be sold to the highest bidder, with the proceeds to be split equally between Genzyme and us.

21

If the joint venture is terminated by either party because the other declared bankruptcy and is also in breach of the agreement, the terminating party would be obligated to buy out the other and would obtain all rights to Aldurazyme exclusively. If the joint venture is terminated by a party because the other party experienced a change of control, the terminating party shall notify the other party, the offeree, of its intent to buy out the offeree s interest in the joint venture for a stated amount set by the terminating party at its discretion. The offeree must then either accept this offer or agree to buy the terminating party s interest in the joint venture on those same terms. The party who buys out the other would then have exclusive rights to Aldurazyme.

If we were obligated, or given the option, to buy out Genzyme s interest in the joint venture, and gain exclusive rights to Aldurazyme, we may not have sufficient funds to do so and we may not be able to obtain the financing to do so. If we fail to buy out Genzyme s interest we may be held in breach of the agreement and may lose any claim to the rights to Aldurazyme and the related intellectual property and regulatory approvals. We would then effectively be prohibited from developing and commercializing Aldurazyme.

Our strategic alliance with Merck Serono may be terminated at any time by Merck Serono, and if it is terminated, our expenses could increase and our operating performance could be adversely affected.

Merck Serono may terminate the agreement forming our strategic alliance with them at any time by giving 90 days prior written notice if such termination occurs prior to the commercialization of any of the products licensed under our agreement, or by giving 180 days prior written notice if such termination occurs after the commercialization of such a product. Either Merck Serono or we may terminate our strategic alliance under certain circumstances, including if the other party is in material breach of the agreement and does not remedy the breach within a specified period of time, or has suffered certain financial difficulties, including filing for bankruptcy or making an assignment for the benefit of creditors. Although we are not currently in breach of the agreement and we believe that Merck Serono is not currently in breach of the agreement, there is a risk that either party could breach the agreement in the future. Upon a termination of the agreement by Merck Serono by giving notice or by us for a material breach by Merck Serono, all rights licensed to us under the agreement become irrevocable and fully-paid except in those countries where restricted by applicable law or for all intellectual property that Merck Serono does not own.

Upon a termination of the agreement by Merck Serono for a material breach by us or based on our financial difficulty, or upon the expiration of the royalty term of the products licensed under the agreement, all rights licensed to Merck Serono under the agreement become irrevocable and fully-paid upon the payment of amounts due by Merck Serono to us which accrued prior to the expiration of the royalty term, except in those countries where restricted by applicable law or for all intellectual property that we do not own and for which we do not have a royalty-free license. Upon a termination of the agreement for a material breach by us or for our financial difficulty, all rights and licenses granted by Merck Serono to us under or pursuant to the agreement will automatically terminate. Under the terms of our agreement with Merck Serono, Merck Serono is responsible to pay for a portion of the development costs of products developed pursuant to such agreement. However, at any time upon 90 days notice, Merck Serono can opt out of this responsibility. If Merck Serono opts out, or if the agreement is terminated by either Merck Serono or us, and we continue the development of products related to that agreement, we would be responsible for 100% of future development costs, our expenses could increase and our operating performance could be adversely affected.

If our license agreement with Ascent Pediatrics is terminated or becomes non-exclusive, our royalty revenues from Orapred would be reduced or eliminated.

The license agreement with Ascent Pediatrics is terminable upon specified material breaches by Ascent Pediatrics or us. If the license agreement were terminated, we would no longer have the ability to manufacture or sublicense Orapred.

Ascent Pediatrics has the right under the license agreement to cause the license to become non-exclusive in the event of certain specified breaches by us. If the license becomes non-exclusive, Ascent Pediatrics would be

22

able to commercialize Orapred itself or license it to others, which would reduce our competitive advantage and which could reduce our royalty revenue significantly.

If we fail to compete successfully with respect to acquisitions, joint venture and other collaboration opportunities, we may be limited in our ability to develop new products and to continue to expand our product pipeline.

Our competitors compete with us to attract organizations for acquisitions, joint ventures, licensing arrangements or other collaborations. To date, several of our product programs have been acquired through acquisitions, such as Phenylase, and several of our product programs have been developed through licensing or collaborative arrangements, such as Naglazyme, Aldurazyme and Kuvan. These collaborations include licensing proprietary technology from, and other relationships with, academic research institutions. If our competitors successfully enter into partnering arrangements or license agreements with academic research institutions, we will then be precluded from pursuing those specific opportunities. Since each of these opportunities is unique, we may not be able to find a substitute. Several pharmaceutical and biotechnology companies have already established themselves in the field of enzyme therapeutics, including Genzyme, our joint venture partner. These companies have already begun many drug development programs, some of which may target diseases that we are also targeting, and have already entered into partnering and licensing arrangements with academic research institutions, reducing the pool of available opportunities.

Universities and public and private research institutions also compete with us. While these organizations primarily have educational or basic research objectives, they may develop proprietary technology and acquire patents that we may need for the development of our product candidates. We will attempt to license this proprietary technology, if available. These licenses may not be available to us on acceptable terms, if at all. If we are unable to compete successfully with respect to acquisitions, joint venture and other collaboration opportunities, we may be limited in our ability to develop new products and to continue to expand our product pipeline.

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.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in many cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

We depend upon our key personnel and our ability to attract, train and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of the services of any member of our senior management or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. While certain of our senior executive officers are parties to employment agreements with us, these agreements do not guarantee that they will remain employed with us in the future. In addition, in many cases,

23

these agreements do not restrict their ability to compete with us after their employment is terminated. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our success depends on our ability to manage our growth.

Our product candidates are intended for patient populations that are significantly larger than either MPS I or MPS VI. In order to continue development and market these products, if approved, we will need to significantly expand our operations. To manage expansion effectively, we need to continue to develop and improve our research and development capabilities, manufacturing and quality capacities, sales and marketing capabilities and financial and administrative systems. Our staff, financial resources, systems, procedures or controls may be inadequate to support our operations and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third parties.

Growth in our business may also contribute to fluctuations in our operating results, which may cause the price of our securities to decline. Our revenue may fluctuate due to many factors, including changes in:

wholesaler buying patterns;

reimbursement rates;

physician prescribing habits; and

the availability or pricing of competitive products.

Changes in methods of treatment of disease could reduce demand for our products and adversely affect revenues.

Even if our drug products are approved, doctors must prescribe treatments that require using those products. If doctors elect a course of treatment which does not include our drug products, this decision would reduce demand for our drug products and adversely affect revenues. For example, if gene therapy becomes widely used as a treatment of genetic diseases, the use of enzyme replacement therapy, such as Naglazyme and Aldurazyme in MPS diseases could be greatly reduced. Changes in treatment method can be caused by the introduction of other companies products or the development of new technologies or surgical procedures which may not directly compete with ours, but which have the effect of changing how doctors decide to treat a disease.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities.

We are exposed to the potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceuticals. BioMarin/Genzyme LLC and we maintain insurance against product liability lawsuits for commercial sale of our products and for the clinical trials of our product candidates. Pharmaceutical companies must balance the cost of insurance with the level of coverage based on estimates of potential liability. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been

unpredictable. Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with the commercial use of Orapred, our clinical trials and commercial use of Naglazyme and Aldurazyme, or our clinical trials for Kuvan or BH4, for which our insurance coverage may not be adequate.

The product liability insurance we will need to obtain in connection with the commercial sales of our product candidates if and when they receive regulatory approval may be unavailable in meaningful amounts or at a reasonable cost. In addition, while we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we may incur

substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercialization of our product programs.

Our stock price may be volatile, and an investment in our stock could suffer a decline in value.

Our valuation and stock price since the beginning of trading after our initial public offering have had no meaningful relationship to current or historical earnings, asset values, book value or many other criteria based on conventional measures of stock value. The market price of our common stock will fluctuate due to factors including:

- product sales and profitability of Naglazyme, Aldurazyme and Orapred;
- manufacture, supply or distribution of Naglazyme, Aldurazyme or Orapred;
- progress of our product candidates through the regulatory process, particularly Kuvan;
- results of clinical trials, announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our product candidates or our competitors drug products in both the U.S. and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions and fluctuations for the emerging growth and pharmaceutical market sectors;
- economic conditions in the U.S. or abroad;
- broad market fluctuations in the U.S. or in the E.U.;
- actual or anticipated fluctuations in our operating results; and
- changes in company assessments or financial estimates by securities analysts.

In addition, the value of our common stock may fluctuate because it is listed on both the Nasdaq National Market and the Swiss Main Board. Listing on both exchanges may increase stock price volatility due to:

- trading in different time zones;

different ability to buy or sell our stock;

different market conditions in different capital markets; and

different trading volume.

In the past, following periods of large price declines in the public market price of a company s securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management s attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Anti-takeover provisions in our charter documents, our stockholders rights plan and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to the stockholders. Our anti-takeover provisions include provisions in our certificate of incorporation providing that stockholders meetings may only be called by the board of directors and provisions in our bylaws providing that the stockholders may not take action by written consent and requiring that stockholders that desire to nominate any person for election to the board of directors or to make any proposal with respect to business to be conducted at a meeting of our stockholders be submitted in appropriate form to our Secretary within a specified period of time in advance of any such meeting. Additionally,

our board of directors has the authority to issue an additional 249,886 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

In 2002, our board of directors authorized a stockholder rights plan and related dividend of one preferred share purchase right for each share of our common stock outstanding at that time. In connection with an increase in our authorized common stock, our board approved an amendment to this plan in June 2003. As long as these rights are attached to our common stock, we will issue one right with each new share of common stock so that all shares of our common stock will have attached rights. When exercisable, each right will entitle the registered holder to purchase from us one two-hundredth of a share of our Series B Junior Participating Preferred Stock at a price of $35.00 per 1/200 of a Preferred Share, subject to adjustment.

The rights are designed to assure that all of our stockholders receive fair and equal treatment in the event of any proposed takeover of us and to guard against partial tender offers, open market accumulations and other abusive tactics to gain control of us without paying all stockholders a control premium. The rights will cause substantial dilution to a person or group that acquires 15% or more of our stock on terms not approved by our board of directors. However, the rights may have the effect of making an acquisition of us, which may be beneficial to our stockholders, more difficult, and the existence of such rights may prevent or reduce the likelihood of a third-party making an offer for an acquisition of us.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The following table contains information about our current owned and leased properties:

Location	Approximate Square Feet	Use	Lease expiration date
Several locations in Novato, California	230,000	Corporate headquarters, office and laboratory	2007-2014
Galli Drive facility, Novato, California	70,000	Clinical and commercial manufacturing and laboratory	N/A: owned property
London, England	2,600	Office	2011
Sao Paulo, Brazil	3,300	Office	2011

Our administrative office space and plans to develop additional space are expected to be adequate for the foreseeable future. We may need to supplement the capacity of our production facilities in order to meet future market demands. We believe that, to the extent required, we will be able to lease additional facilities at commercially reasonable rates. We plan to use contract manufacturing when appropriate to provide product

for both clinical and commercial requirements until such time as we believe it prudent to develop additional in-house clinical and/or commercial manufacturing capacity.

Item 3. Legal Proceedings

We have no material legal proceedings pending.

Item 4. Submission of Matters to a Vote of Security-Holders

No matters were submitted to a vote of our security holders during the quarter ended December 31, 2006.

Part II

Item 5. Market for Common Equity and Related Stockholder Matters

Our common stock is listed under the symbol BMRN on both the Nasdaq National Market and the Swiss SWX Main Board. The following table sets forth the high and low sales prices for our common stock for the periods noted, as reported by Nasdaq National Market.

		Prices	
Year	**Period**	**High**	**Low**
2005	First Quarter	$ 6.41	$ 4.40
2005	Second Quarter	$ 7.77	$ 4.75
2005	Third Quarter	$ 9.47	$ 7.02
2005	Fourth Quarter	$ 11.70	$ 6.94
2006	First Quarter	$ 15.29	$ 10.55
2006	Second Quarter	$ 14.73	$ 11.55
2006	Third Quarter	$ 16.90	$ 13.38
2006	Fourth Quarter	$ 18.40	$ 14.97

On February 20, 2007, the last reported sale price on the Nasdaq National Market for our common stock was $18.00. We have never paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

Holders

As of February 1, 2007, there were 83 holders of record of 95,509,224 outstanding shares of our common stock. Additionally, on such date, options to acquire 10,253,546 shares of our common stock were outstanding.

Item 6. Selected Consolidated Financial Data

The selected consolidated financial data set forth below contains only a portion of our financial statement information and should be read in conjunction with the consolidated financial statements and related notes and *Management s Discussion and Analysis of Financial Condition and Results of Operations* included in this annual report.

We derived the statement of operations data for the years ended December 31, 2002, 2003, 2004, 2005 and 2006 and balance sheet data as of December 31, 2002, 2003, 2004, 2005 and 2006 from audited financial statements. Historical results are not necessarily indicative of results that we may experience in the future.

	Year ended December 31, (in thousands, except for per share data)				
	2002	**2003**	**2004**	**2005**	**2006**
Consolidated statements of operations data:					
Revenues:					
Net product sales	$	$	$ 18,641	$ 13,039	$ 49,606
Collaborative agreement revenues		12,100		12,630	18,740
Royalty and license revenues					15,863
Total revenues		12,100	18,641	25,669	84,209
Operating expenses:					
Cost of sales (excludes amortization of developed product technology)			3,953	2,629	8,740
Research and development	26,811	53,932	49,784	56,391	66,735
Selling, general and administrative	17,347	15,278	37,606	41,556	49,030
Amortization of acquired intangible assets			3,987	1,144	3,651
Acquired in-process research and development	11,223		31,453		
Impairment of acquired intangible assets			68,251		
Total operating expenses	55,381	69,210	195,034	101,720	128,156
Equity in the (loss) income of BioMarin/Genzyme LLC	(23,466)	(18,693)	(2,972)	11,838	19,274
Loss from operations	(78,847)	(75,803)	(179,365)	(64,213)	(24,673)
Interest income	2,017	2,559	2,466	1,861	12,866
Interest expense	(542)	(3,131)	(10,544)	(11,918)	(16,726)
Net loss from continuing operations	(77,372)	(76,375)	(187,443)	(74,270)	(28,533)
Income (loss) from discontinued operations	135				
Gain (loss) on disposal of discontinued operations	(224)	577			
Net loss	$ (77,461)	$ (75,798)	$ (187,443)	$ (74,270)	$ (28,533)
Net loss per share, basic and diluted:					
Net loss from continuing operations	$ (1.45)	$ (1.23)	$ (2.91)	$ (1.08)	$ (0.34)
Loss from discontinued operations					

Gain (loss) on disposal of discontinued operations		0.01			
Net loss per share, basic and diluted	$ (1.45)	$ (1.22)	$ (2.91)	$ (1.08)	$ (0.34)
Weighted average common shares outstanding, basic and diluted	53,279	62,125	64,354	68,830	84,582

	December 31, (in thousands)				
	2002	**2003**	**2004**	**2005**	**2006**
Consolidated balance sheet data:					
Cash, cash equivalents and short-term investments	$ 73,978	$ 206,357	$ 48,815	$ 47,792	$ 288,847
Total current assets	78,254	213,262	85,159	68,941	334,224
Total assets	110,616	256,340	232,966	195,303	463,436
Long-term liabilities, net of current portion	5,226	125,672	230,890	232,398	299,589
Total stockholders equity (deficit)	98,543	117,853	(67,978)	(77,462)	117,802

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

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 annual report. In addition to the other information in this Form 10-K, 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 unmet medical need, have well-understood biology and provide an opportunity to be first-to-market. Our product portfolio is comprised of two approved products and multiple investigational product candidates. Approved products include Naglazyme and Aldurazyme. Additionally, we have rights to receive payments and royalties related to Orapred and Orapred ODT.

Naglazyme received marketing approval in the U.S. in May 2005 and in the E.U. in January 2006. Naglazyme net product sales for 2005 totaled $6.1 million and increased to $46.5 million in 2006.

Aldurazyme has been approved for marketing in the U.S., E.U., Japan and in other countries. We have developed Aldurazyme through a joint venture with Genzyme. Aldurazyme net revenue recorded by our joint venture for 2006 totaled $96.3 million, compared to $76.4 million for 2005.

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. The third party is responsible for the costs of commercializing the products in North America. In June 2006, the FDA granted marketing approval for Orapred ODT (prednisolone sodium phosphate orally disintegrating tablets), the first orally disintegrating tablet form of prednisolone available in the United States.

We are developing several product candidates for the treatment of genetic diseases including: Kuvan (formerly referred to as Phenoptin), a proprietary oral form of tetrahydrobiopterin (6R-BH4 or BH4), for the treatment of moderate to mild forms of PKU; and Phenylase, a preclinical enzyme substitution therapy for the treatment of the more severe form of PKU. We are developing Kuvan for the treatment of BH4-responsive phenylketonurics and Phenylase for phenylketonurics who are not BH4-responsive. We are also developing BH4 for the treatment of other indications, including cardiovascular indications, with trials initiated in poorly controlled hypertension and peripheral arterial disease.

Key components of our results of operations for the years ended December 31, 2004, 2005 and 2006, include the following:

	2004	2005	2006
Total net product sales	$ 18,641	$ 13,039	$ 49,606

Research and development expense	49,784	56,391	66,735
Selling, general and administrative expense	37,606	41,556	49,030
Net loss	(187,443)	(74,270)	(28,533)
Orapred acquisition-related expenses	109,610	6,703	8,336
Stock-based compensation		327	10,596

Our research and development expense during 2006, primarily related to the ongoing support of Naglazyme and development of Kuvan, BH4 for cardiovascular indications and Phenylase. Our cash, cash equivalents, short-

term investments and cash balances related to long-term debt totaled $288.8 million as of December 31, 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 years ended December 31, 2005 and 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 amount of our goodwill originated from the acquisition of the Orapred business in 2004. The Orapred business was eliminated as a reporting unit 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 occurred during 2006 that required 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 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 $23.7 million and $38.5 million during 2005 and 2006, respectively. We and our joint venture partner maintain the ability and intent to fund the joint venture s operations, if necessary.

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

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104: *Revenue Recognition* , and Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* . Our revenues consist of Naglazyme product sales during 2006 and Orapred product sales through March 2006, revenues from our collaborative agreement with Merck 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. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes (VAT) in foreign jurisdictions, are presented on a net basis in our income statement, in that taxes billed to customers are not included as a component of net product sales, as per 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 our authorized European distributor and also to 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 only approximately 18 months of historical experience with rebates and returns specific to Naglazyme. Until

additional historical experience is obtained to serve as a reasonable basis for our estimates of rebates and returns, management will use, to the extent available, current estimated sales mix of which sales will be eligible for rebates, estimated rebate rates for state Medicaid programs and other government programs, as well as experience obtained through the commercialization of Aldurazyme by our joint venture with Genzyme, which is a similar product. Certain of our customers receive distributor fees based on sales volume. In accordance with EITF Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products),* these fees are presumed to be a reduction of the selling price of Naglazyme and, therefore, are presented as a reduction of revenue on our consolidated statements of operations. The nature and amount of our current estimates of the applicable revenue dilution item that are currently applied to aggregate world-wide gross sales of Naglazyme to derive net sales are described in the table below.

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

We maintain a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of Naglazyme customers to make required payments. We first recorded sales of Naglazyme during the second quarter of 2005 and as of December 31, 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.

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 were evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

We established and maintained reserves for amounts payable to managed care organizations and state Medicaid programs for the reimbursement of a portion of the retail price of prescriptions filled that are covered by the respective plans. The amounts estimated to be paid relating to products sold were recognized as revenue reductions and as additions to accrued expenses at the time of the original sale. The rebate reserves were based on our best estimate of the expected prescription fill rate to these managed care organizations and state Medicaid patients, as well as the rebate rates associated with eligible prescriptions. The estimates were developed using the product s rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. These factors included changes in the mix of prescriptions that were eligible for rebates, changes in the contract rebate rates and the lag time related to the processing of rebate claims by our customers and managed care organizations. The length of time between the period of prescriptions and the processing of the related rebates was consistent historically at between three and nine months, depending on the nature of the rebate. The length of time between the period of original sale by us and the processing of the related rebate is dependent upon both the

33

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 year ended December 31, 2006. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

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

Our estimates for future product returns are primarily based on the actual return history for the product and estimates of future demand related to estimated wholesaler inventory levels. Although we are unable to quantify wholesaler inventory levels of Orapred with any certainty, to the extent necessary based on the expiration date and our estimates of quantity of product in the distribution channel, we adjust our estimate for future returns as appropriate. We estimate wholesaler inventory levels, to the extent possible, based on limited information obtained from certain of our wholesale customers and through other internal analyses. Our internal analyses utilize information such as historical sales to wholesalers, product shelf-life based on expiration dating, estimates of the length of time product is in the distribution channel and historical prescription data, which are provided by a third-party vendor. We also evaluate the current and future commercial market for Orapred and consider factors such as Orapred s performance compared to its existing competitors. Based on actual retail product demand realized during 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 $1.2 million, which were recorded as an increase to net revenue of approximately $0.7 million for returns of product sold by us and $0.5 million of reduced expense for returns of product sold by the previous owner during 2006. As additional information is obtained regarding retail demand and wholesaler inventory levels, additional reserves may be required or reserves may need to be reversed.

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

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%	

34

We periodically evaluated the need to maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. When making this evaluation, we made judgments about the creditworthiness of customers based on ongoing credit evaluations and the aging profile of customer accounts receivable and assess current economic trends that might impact the level of credit losses in the future. The Orapred product had not experienced significant credit losses. We had no allowance for doubtful accounts as of December 31, 2006.

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

Our estimates of the period over which we have an ongoing performance obligation are based on the contractual terms of the underlying arrangement, the level of effort required for us to fulfill our obligation and the anticipated timing of the fulfillment of our obligation. Accordingly, we have deferred the up-front license fee received from Merck Serono and 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 Kuvan, formerly referred to as Phenoptin, for the treatment of PKU, at which point our performance obligations for developing Kuvan 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 2006 by approximately $0.3 million, and the change in estimate is expected to reduce license revenues in 2007 by approximately $0.6 million, and increase license revenues in 2008 by approximately $0.9 million. Our estimate of the Kuvan commercialization period is based on several underlying assumptions about uncertain events, including actions by European regulatory authorities, results of our ongoing clinical trials and successful commercial scale manufacturing of Kuvan. As Kuvan advances through the clinical development and regulatory process, our estimates of our performance obligation period may change. 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 is no cost of sales associated with the amortization of the up-front license fee received from Merck Serono.

Nonrefundable reimbursements received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represented Merck Serono s share of Kuvan development costs under the agreement, which are recorded as research and development expenses.

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 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,

35

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 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 December 31, 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 December 31, 2006. Stock-based compensation of $0 and $1.0 million was capitalized into Naglazyme inventory for the years ended December 31, 2005 and 2006, respectively.

Research and Development

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

A critical accounting assumption by our management is that we believe that regulatory approval of our product candidates is uncertain, and do not assume that product manufactured prior to regulatory approval will be sold commercially. As a result, 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.

36

Clinical Trial Accruals

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

Stock Option Plans

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

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

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

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

Income taxes

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have recorded a full valuation allowance against our net deferred tax assets, the principal amount of which is the tax effect of net operating loss carryforwards of approximately $293.0 million at December 31, 2006. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. If we later determine that it is more likely than not that the net deferred tax assets would be realized, the previously provided valuation allowance would be reversed. In order to realize our deferred tax assets we must be able to generate sufficient taxable income in the tax jurisdictions in which the deferred tax assets are located. This critical accounting assumption has

been historically accurate, as we have not been able to utilize our net deferred tax assets, and we do not expect changes to this assumption in the near future as the ultimate realizability of the deferred tax assets is uncertain.

Recent Accounting Pronouncements

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

Results of Operations

All of the activities related to the manufacture, distribution and sale of Aldurazyme are reported in the results of the joint venture. Because of this presentation and the significance of the joint venture s 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.

BioMarin Results of Operations

Net Loss

Our net loss for the year ended December 31, 2006 decreased by $45.8 million, to $28.5 million, from $74.3 million for the year ended December 31, 2005. Net loss for 2006 decreased primarily as a result of the following (in millions):

Net loss for the period ended December 31, 2005	$ (74.3)
Increased Naglazyme gross profit	33.7
Increased collaborative agreement revenues	6.1
Milestone and license revenue related to sublicense of Orapred franchise	14.0
Increased profits from BioMarin/Genzyme LLC	7.5
Decreased Orapred net operating expenses	6.7
Decreased Naglazyme development expenses	10.9
Increased Naglazyme sales and marketing expenses	(9.0)
Increased Kuvan manufacturing and clinical trial costs	(8.2)
Increased Kuvan commercial preparation costs	(2.2)
Increased 6R-BH4 development costs for endothelial dysfunction	(5.4)
Increased Phenylase development costs	(2.3)
Stock-based compensation expense upon adoption of FAS 123R	(9.6)
Increased interest expense	(4.8)
Increased interest income	11.0
Increase in corporate overhead and other	(2.6)
Net loss for the period ended December 31, 2006	$ (28.5)

The increase in Naglazyme gross profit during 2006 as compared to 2005 is primarily the result of increased Naglazyme sales, primarily in the U.S. and E.U. We also recorded $14.0 million in milestone and license revenue from the sublicense of North American rights of Orapred to a third party. The decrease in Naglazyme development costs is primarily due to decreased clinical trial and manufacturing expenses, after

marketing approval was received in the U.S. in May 2005 and E.U. in January 2006.

Our net loss for the year ended December 31, 2005 decreased by $113.1 million, to $74.3 million, from $187.4 million for the year ended December 31, 2004. Net loss for 2005 decreased primarily as a result of the following (in millions):

Net loss for the period ended December 31, 2004	$ (187.4)
Reduction of expenses associated with Ascent Pediatrics acquisition (includes $31.5 million of non-recurring in-process research and development expense in 2004)	34.7
Absence of impairment of acquired intangible assets	68.3
Increased profits from BioMarin/Genzyme LLC	14.8
Kuvan collaborative agreement revenues	12.6
Increase in Orapred operating loss	(11.3)
Decrease in Naglazyme operating loss	11.0
Increased Kuvan research and development expenses	(14.4)
Increased facility expenses, including depreciation	(3.3)
Absence of separation costs associated with former CEO	2.9
Increased interest expense and decrease in interest income, excluding imputed interest	(2.0)
Net decrease in other operating expenses	(0.2)
Net loss for the period ended December 31, 2005	$ (74.3)

The expenses associated with the Ascent Pediatrics acquisition decreased in 2005 due to the absence of a non-recurring acquired in-process research and development expense of $31.5 million incurred in 2004, $2.8 million related to amortization of acquired intangible assets and a decrease of $0.6 million related to a fair value inventory adjustment, offset by an increase of $0.2 million related to imputed interest expense. The increase in profits from BioMarin/Genzyme LLC during 2005 as compared to 2004 is primarily the result of increased Aldurazyme sales, which are recorded through the joint venture with Genzyme. The increase in Orapred operating net loss is attributable to decrease in gross profit of $10.1 million, which includes a charge for inventory write-offs of $1.1 million, increased spending on research and development for Orapred ODT of $1.5 million, offset by other net operating expenditure decreases of $0.3 million. The decrease in Naglazyme net loss is attributable to increased gross profit of $6.0 million, decreased research and development expenses of $9.3 million, partially offset by increased sales and marketing expenses for commercialization of $4.0 million and other net operating expenditure increases of $0.3 million.

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

Net Product Sales and Gross Profit

Net product sales increased $36.6 million to $49.6 million in 2006 from $13.0 million in 2005. Net product sales in 2006 included $46.5 million of net product sales of Naglazyme and $3.1 million of net product sales of Orapred. Net product sales in 2005 of $13.0 million included $6.9 million of net product sales of Orapred and $6.1 million of net product sales of Naglazyme. We expect net product sales of Naglazyme to increase in future periods, primarily due to additional patients initiating therapy.

We received marketing approval for Naglazyme in the U.S. in May 2005 and began shipping product in June 2005. In January 2006, we received marketing approval for Naglazyme in the E.U. Net product sales for Naglazyme in 2006 were $46.5 million, of which $31.0 million was from customers based outside of the U.S. The impact of foreign currency exchange rates on Naglazyme sales from customers based outside of the U.S. was approximately $2.5 million in 2006. Gross profit was approximately $39.4 million, representing gross margins of approximately 85%. 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

39

product sold in 2006 had an insignificant cost basis and therefore lower cost of goods sold was reported. The majority of inventory with an insignificant cost basis has been sold or used in clinical trials as of December 31, 2006. Net product sales of Naglazyme during 2005 were $6.1 million. As all of the product sold in 2005 had a zero cost basis, gross profit in 2005 was also $6.1 million, as it was manufactured prior to regulatory approval.

Commencing with our acquisition of the Ascent Pediatrics business in May 2004 and continuing through the sublicense in March 2006, our net product sales include sales of Orapred. During 2006, we recognized return reserve reversals totaling $1.2 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. Also as a result of the sublicense, which caused a reduction in our liability for certain rebates, we recognized rebate reserve reversals of $1.3 million during 2006, which were recorded as additional net product sales. During the years ended December 31, 2005 and 2006, we recognized net product sales of $6.9 million and $3.1 million, respectively, related to 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 $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 Merck Serono, which was executed in May 2005. License revenues are related to amortization of the $25.0 million up-front license payment received from Merck Serono and contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. As development spending of the Kuvan, formerly referred to as Phenoptin, and 6R-BH4 for other indications program increases or decreases, contract research revenues will also change proportionately following the completion of Phase 2 clinical trials for each indication. The related costs are included in research and development expenses.

Collaborative agreement revenues in 2005 and 2006 were $12.6 million and $18.7 million, respectively, and includes the amortization of $5.5 million and $7.4 million, respectively, of the up-front license fee received from Merck Serono and recognized as revenue during the period, and $7.1 million and $11.3 million, respectively, of reimbursable Kuvan development costs incurred during the period.

Royalty and License Revenues

Royalty and license revenues, totaling $15.9 million in 2006, 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 in 2006 also include $2.5 million related to the up-front license fee received from the third party. During 2006, we recognized $1.6 million 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 by $10.3 million to $66.7 million for the year ended December 31, 2006, from $56.4 million for the year ended December 31, 2005. Research and development expenses changed for the year ended December 31, 2006 primarily as a result of the following (in millions):

Research and development expenses for the year ended December 31, 2005	$ 56.4
Decreased Naglazyme development expenses	(10.9)
Increased Kuvan clinical trial and manufacturing costs	8.2
Increased 6R-BH4 development costs for endothelial dysfunction	5.4
Increased Phenylase development costs	2.3
Stock-based compensation expense upon adoption of FAS 123R	4.3
Increased research and development on other programs	1.0
Research and development expenses for the year ended December 31, 2006	$ 66.7

The increase in Kuvan clinical trial and manufacturing costs is primarily due to increased clinical trial expenses due to the 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 and peripheral arterial disease. 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. We expect research and development expense to increase in future periods, primarily as a result of spending on our 6R-BH4 program for other indications and on our Phenylase program.

Research and development expenses increased by $6.6 million, to $56.4 million for the year ended December 31, 2005, from $49.8 million for the year ended December 31, 2004. Research and development expenses changed for the year ended December 31, 2005 primarily as a result of the following (in millions):

Research and development expenses for the year ended December 31, 2004	$ 49.8
Decreased Naglazyme development expenses	(9.3)
Increased Kuvan clinical trial and manufacturing costs	10.9
Increased 6R-BH4 development costs for endothelial dysfunction	3.5
Increased Phenylase development costs	1.9
Orapred ODT formulation development costs	1.5
Decreased research and development on other programs	(1.9)
Research and development expenses for the year ended December 31, 2005	$ 56.4

The increase in 6R-BH4 development costs to treat endothelial dysfunction includes $3.3 million for license fees paid to Daiichi Suntory Pharma Co., Ltd. related to obtaining the exclusive worldwide rights, excluding Japan, for the use of 6R-BH4. The increase in Kuvan development costs is primarily due to increased clinical trial expenses due to the continuation of the Phase 3 clinical trial and pre-approval manufacturing expenses. The decrease in Naglazyme development costs is primarily due to decreased clinical trial and manufacturing expenses, after marketing approval was received in May 2005.

Selling, General and Administrative Expense

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

resources; finance, legal and support personnel expenses; and other corporate costs such as insurance, audit and legal expenses. Selling, general and administrative expenses increased by $7.4 million, to $49.0 million for the year ended December 31, 2006, from $41.6 million for the year ended December 31, 2005. The components of the increase for the year ended December 31, 2006 primarily include the following (in millions):

Selling, general and administrative expenses for the year ended December 31, 2005	$ 41.6
Decreased Orapred sales and marketing expenses	(12.3)
Increased Naglazyme sales and marketing expenses	9.0
Stock-based compensation expense upon adoption of FAS 123R	5.3
Increased Kuvan commercial preparation costs	2.2
Net increase in corporate overhead and other administrative costs	3.2
Selling, general and administrative expenses for the year ended December 31, 2006	$ 49.0

We initiated commercial operations in the E.U and Brazil during 2006 and expect additional costs to be incurred in future periods as a result. We expect selling, general and administrative expenses to increase in future periods as a result of the increasing sales for Naglazyme and preparation for the potential commercial launch of Kuvan. The increase in corporate overhead and other administrative costs is primarily related to increases in facilities costs, accounting costs and insurance.

Selling, general and administrative expenses increased by $4.0 million, to $41.6 million for the year ended December 31, 2005, from $37.6 million for the year ended December 31, 2004. The components of the increase for the year ended December 31, 2005 primarily include the following (in millions):

Selling, general and administrative expenses for the year ended December 31, 2004	$ 37.6
Increased sales and marketing for Naglazyme commercialization	4.0
Decreased Orapred sales and marketing expenses	(4.1)
Expenses directly related to reduction of the Ascent Pediatrics sales force	0.9
Absence of former CEO separation costs	(2.9)
Increased Orapred return expense, related to product sold by the previous seller of Orapred	2.9
Decreased Orapred rebate expense, related to product sold by the previous seller of Orapred	(1.4)
Increase in facility expenses, including depreciation	3.3
Increased recruiting and relocation expenses	0.7
Net increase in corporate overhead and other administrative costs	0.6
Selling, general and administrative expenses for the year ended December 31, 2005	$ 41.6

The decrease in Orapred sales and marketing expenses is primarily attributable to the decrease in sales and marketing efforts during 2005, following the reduction in the Orapred sales force, reducing overall expenses for the period by $4.1 million. The increased Orapred return expense includes $2.9 million related to an increase in estimated product returns for sales made by Medicis prior to the acquisition.

In July 2005, we announced that we were reducing the Orapred sales force through the elimination of 52 positions. Severance and related costs and payments of approximately $0.9 million associated with eliminating the 52 sales force positions plus six non-sales force positions were recognized in the third quarter of 2005.

42

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 2006 was $3.7 million, compared to $1.1 million for 2005, 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.

Amortization expense for 2005 was $1.1 million, as compared to $4.0 million for 2004. The decrease in amortization expense for 2005 was primarily attributable to the lower asset value resulting from the impairment charge recognized in the fourth quarter of 2004.

Acquired in-Process Research and Development

Acquired in-process research and development includes the nonrecurring charge for the portion of acquisition consideration attributable to development-stage products in the Orapred product line. Acquired in-process research and development of $31.5 million during 2004 includes the fair value of the two additional development-stage formulations of Orapred that we acquired in the Ascent Pediatrics transaction.

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

Equity in the (Loss)/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 $19.3 million for 2006, compared to $11.8 million for 2005. The increase in profit from BioMarin/Genzyme LLC in 2006 was principally due to increases in Aldurazyme net revenue, which totaled $96.3 million for 2006, compared to $76.4 million for 2005. We expect our equity in the income of BioMarin/Genzyme LLC to increase in future periods, as net revenues for Aldurazyme continue to increase.

Equity in the income of BioMarin/Genzyme LLC was $11.8 million for 2005, compared to a loss of $3.0 million for 2004. The increase in profit from BioMarin/Genzyme LLC in 2005 was principally due to increases in Aldurazyme net revenue, which totaled $76.4 million for 2005, compared to $42.6 million for 2004.

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

Impairment of Acquired Intangible Assets

No impairment of the Orapred acquired intangible assets was recorded for the years ended December 31, 2005 and 2006. Impairment of acquired intangible assets during the year ended December 31, 2004 includes the impairment loss recorded on the Orapred product technology

during the fourth quarter of 2004. In December 2004, we recognized an impairment loss totaling $68.3 million. The primary circumstance leading to the impairment was the introduction of a new generic competitor to Orapred during the fourth quarter of 2004 that resulted in a significant decrease in the Orapred market share. The impairment charge represents the amount by which the carrying value of the Orapred technology exceeded its fair value on December 31, 2004.

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 $12.9 million for 2006, from $1.9 million for 2005, primarily due to higher interest rates and increased levels of cash and investments during 2006.

Interest income decreased to $1.9 million in 2005 from $2.5 million in 2004, primarily due to decreased levels of cash and investments on hand throughout the year.

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 $16.7 million for 2006, as compared to $11.9 million for 2005, representing an increase of $4.8 million. The increase in 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 and lower interest as a result of the conversion of a portion of 3.5% convertible notes due in 2008 in September 2006. The decline in imputed interest expense was due to a lower outstanding balance of the acquisition obligation in 2006. Imputed interest expense totaled $4.7 million for 2006, as compared to $5.4 million for 2005.

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 year ended December 31, 2006. In January 2007, the remaining outstanding balance of $51.4 million for our 3.50% Convertible Senior Subordinated Notes due in 2008 were converted into approximately 3.7 million shares of common stock. As a result, we expect interest expense to decrease in future periods.

Interest expense was $11.9 million and $10.5 million in 2005 and 2004, respectively, representing an increase of $1.4 million. The increase in 2005 is primarily related to increased borrowings on the equipment and facility loans during the year and higher interest rates. In 2005 and 2004, the imputed interest related to the Ascent Pediatrics transaction was $5.4 million and $5.1 million, respectively.

BioMarin/Genzyme LLC Results of Operations

The discussion below gives effect to the inventory capitalization policy that we use for inventory held by the joint venture, which is different from the joint venture s inventory capitalization policy. We began capitalizing Aldurazyme inventory production costs in May 2003, after U.S. regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory production costs in January 2002, when inventory production for commercial sale began. The difference in inventory capitalization policies results in a greater operating expense realized by us prior to regulatory approval, and lower cost of goods sold with higher gross profit realized by us post-regulatory approval as the previously expensed product is sold by the joint venture, as well as lower research and development expense when Aldurazyme is used in on-going clinical trials. These differences will be eliminated when all of the product manufactured prior to regulatory approval has been sold or has been used in clinical trials. The majority of the differences have been eliminated as of December 31, 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 $96.3 million of net revenue for 2006, compared to $76.4 million for 2005. The increase in net revenue of $19.9 million is primarily attributable to an increase in the number of patients receiving therapy. We expect net revenue of Aldurazyme to increase in future periods, primarily due to additional patients initiating therapy.

Gross profit was $73.1 million for 2006, as compared to $60.3 million for 2005, representing an increase of $12.8 million. Gross margins for 2006 were approximately 76%, as compared to gross margins for 2005 of 79%.

The decrease in gross margin during 2006 compared to 2005 is attributable to the recognition of higher cost of sales in 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 $71.9 million, representing a gross margin of 75% for 2006, as compared to a gross profit of $51.9 million, representing a gross margin of 68% for 2005. The increase in gross margin excluding the effect of the difference in inventory cost basis in 2006 is due to improvements in manufacturing yields for Aldurazyme.

Operating Expenses

Operating expenses of the joint venture include the costs associated with the development and commercial support of Aldurazyme and totaled $35.3 million for 2006, as compared to $36.9 million for 2005. Operating expenses in 2006 included $22.2 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme, and $13.1 million of research and development costs, primarily long-term clinical trial and regulatory costs. Operating expenses in 2005 included $22.0 million of selling, general and administrative expenses associated with the commercial launch of Aldurazyme, and $14.9 million of research and development expenses, primarily clinical trial costs.

Operating expenses in 2004 totaled $42.9 million and included $26.9 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme and $16.0 million of research and development costs, primarily long-term clinical trial costs. Selling, general and administrative expenses decreased by $4.9 million to $22.0 million in 2005 due to normalization of sales and marketing efforts for the product following post-launch commercialization.

Liquidity and Capital Resources

Cash and Cash Flow

As of December 31, 2006, our combined cash, cash equivalents, short-term investments and cash balances related to long-term debt totaled $288.8 million, an increase of $224.0 million from $64.8 million at December 31, 2005. The $224.0 million increase in cash, cash equivalents, short-term investments and cash balances related to long-term debt during 2006 includes net proceeds from the public offering of common stock of $127.4 million and concurrent public offering of convertible debt of $167.0 million.

Excluding the net offering proceeds, the decrease in cash, cash equivalents, short-term investments and cash balances related to long-term debt during 2006 was $70.4 million, which was $11.6 million less than the net decrease in cash, cash equivalents, short-term investments and cash balances related to long-term debt during 2005 of $82.0 million. The primary items contributing to the decrease 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	$ 26.5
Increased cash flows from BioMarin/Genzyme LLC	15.2
Net repayments of equipment and facility loans	(21.7)
Increased capital asset purchases	(18.1)
Absence of Merck Serono license payment received in 2005	(25.0)
License proceeds related to sublicense of North American Orapred rights	14.0
Decreased operating spend, net, partially offset by working capital increases	22.3
Other	(1.6)

Total increase in net cash outflow excluding net offering proceeds	$ 11.6

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. Primarily as a result of increased Naglazyme sales, our net accounts receivable increased by $8.8 million during 2006. We expect that our net accounts receivable will continue to increase in the near future. Our inventory increased by $14.2 million during 2006, as a result of the capitalization of manufacturing costs following regulatory approval and continued production of Naglazyme to meet increasing demand. We also expect that our inventory balance will continue to increase in the near future.

We expect that our net cash outflow in 2007 related to capital asset purchases will generally be consistent with the level experienced in 2006. This spending includes continued development of our facilities and information technology systems upgrades.

Pursuant to our settlement of a dispute with Medicis in January 2005, Medicis made available to us a convertible note of up to $25.0 million beginning July 1, 2005 based on certain terms and conditions and provided that the Company does not experience a change of control. Money advanced under the convertible note is convertible into our common stock, at Medicis option, according to the terms of the convertible note. As of December 31, 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.

We have historically financed our operations primarily by the issuance of common stock, convertible debt and by relying on equipment and other commercial financing. During 2007, and for the foreseeable future, we will be highly dependent on our net product revenue and disbursements from BioMarin/Genzyme LLC to supplement our current liquidity and fund our operations. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing.

Funding Commitments

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

Our investment in our product development programs has a major impact on our operating performance. Our research and development expenses for the years ended December 31, 2004, 2005 and 2006 and for the period since inception (March 1997) represent the following (in millions):

	2004	2005	2006	Since Program Inception
Naglazyme	$ 29.8	$ 20.6	$ 9.7	$ 104.2
Kuvan	8.3	22.7	27.4	59.1
6R-BH4 for endothelial dysfunction		3.5	8.9	12.4
Phenylase	0.3	2.2	4.5	7.0
Orapred	1.9	3.9	4.7	10.5
Not allocated to specific major current projects	9.5	3.5	11.5	124.4
	$ 49.8	$ 56.4	$ 66.7	$ 317.6

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-K, 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.*

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

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

- our ability to successfully market and sell Naglazyme 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;
- 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;
- our ability to pay the Medicis acquisition obligation; 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 would have impacted our liquidity due to the semi-annual cash interest payments and the scheduled repayment of the notes in 2008. However, in January 2007, the remaining outstanding balance of $51.4 million for our 3.5% Convertible Senior Subordinated Notes due in 2008 were converted into approximately 3.7 million shares of common stock. As a result, related payments of principal of $51.4 million in 2008 and interest of $1.8 million and $0.9 million in 2007 and 2008, respectively, will not be required.

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 $87.1 million through 2009, of which $7.0 million is payable in 2007. At our option, we may elect to pay Medicis $8.6 million of the amounts due in 2009 through the issuance of our common stock.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of December 31, 2006 is presented below (in thousands).

	Payments Due by Period					
	Total	2007	2008	2009-2010	2011-2012	2013 and Thereafter
Medicis obligations	$ 87,100	$ 7,000	$ 6,500	$ 73,600	$	$
Convertible debt and related interest (1)	254,672	6,113	56,653	8,625	8,625	174,656
Operating leases	24,261	3,234	3,625	7,476	6,934	2,992
Research and development and purchase commitments	24,087	16,758	6,495	100	100	634
Total	$ 390,120	$ 33,105	$ 73,273	$ 89,801	$ 15,659	$ 178,282

(1) Amounts in total and for 2008 include $51.4 million of 3.5% Convertible Senior Subordinated Notes due in 2008, which were converted into approximately 3.7 million shares of common stock in January 2007.

We are also subject to contingent payments related to various development activities totaling approximately $29.8 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

Related Party Transactions

Our Chief Medical Officer, Emil D. Kakkis, M.D., Ph.D. formerly held an adjunct faculty position with LA Biomedical, formerly known as Harbor-UCLA Research Educational Institute, for purposes of conducting research. LA Biomedical licenses certain intellectual property and provides other research services to us. We are also obligated to pay LA Biomedical a minimum annual payment and royalties on future sales of products covered by the license agreement. Our joint venture with Genzyme is subject to a second agreement with LA Biomedical that requires the joint venture to pay LA Biomedical a royalty on sales of Aldurazyme through November 2019. Pursuant to Dr. Kakkis agreements with LA Biomedical, which were entered into prior to his employment by us, Dr. Kakkis is entitled to certain portions of these amounts payable to LA Biomedical. The license agreements were effective before Dr. Kakkis was an officer of our company. Pursuant to Dr. Kakkis agreements with LA Biomedical, he was entitled to approximately $0.9 million and $1.1 million during 2005 and 2006, respectively.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Market Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. By policy, we place our investments with highly rated credit issuers and limit the amount of credit exposure to any

one issuer. As stated in our policy, we seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk.

We mitigate default risk by investing in high credit quality securities and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any investment issuer or guarantor. The portfolio includes only marketable securities with active secondary or resale markets to ensure portfolio liquidity.

Based on our investment portfolio and interest rates at December 31, 2006, we believe that a 100 basis point decrease in interest rates could result in a potential loss in fair value of our investment portfolio of approximately $2.0 million. Changes in interest rates may affect the fair value of our investment portfolio; however, we will not recognize such gains or losses in our consolidated statement of operations unless the investments are sold, or unless the investments are classified as held-for-sale.

The table below presents the carrying value of our cash and investment portfolio, which approximates fair value at December 31, 2006 (in thousands):

	Carrying Value
Cash and cash equivalents	$ 89,162*
Short-term investments	199,685**
Total	$ 288,847

* 6% of cash and cash equivalents invested in money market funds, 50% in commercial paper, 35% in repurchase agreements and 9% of uninvested cash.

** 7% of short-term investments invested in U.S. agency securities, 14% in corporate securities and 79% in commercial paper.

Our debt obligations consist of our convertible debt, which carries a fixed interest rate and, as a result, we are not exposed to interest rate market risk on our convertible debt. The carrying value of our convertible debt approximates its fair value at December 31, 2006.

Foreign Currency Exchange Rate Market Risk

A significant portion of Aldurazyme sales by BioMarin/Genzyme LLC are earned outside of the U.S. and, therefore, our equity in the income of BioMarin/Genzyme LLC is subject to risk of foreign currency rate fluctuations, primarily to the Euro and British pound. The policies and procedures related to the management of foreign currency risk of Aldurazyme sales are maintained and performed by our joint venture partner, Genzyme, which includes foreign currency forward contracts.

A significant portion of Naglazyme sales are earned outside of the U.S. and our related revenues and account receivables are subject to risk of foreign currency rate fluctuations. These risks may be managed with selective use of derivatives. We use derivatives to mitigate or eliminate certain financial and market risks because we conduct business in diverse markets around the world. We periodically enter into foreign currency

forward contracts, which have a maturity of less than one year. These contracts have not been designated as hedges and, accordingly, unrealized gains or losses on these contracts are reported in current earnings. At December 31, 2006, we had net outstanding foreign exchange forward contracts to sell $12.9 million, comprised of sell contracts of $12.9 million of equivalent Euros and $7.5 million of equivalent British Pounds and buy contracts of $3.4 million of equivalent Euros and $4.1 million of equivalent British Pounds, all of which have a term of less than 3 months. As of December 31, 2006, the weighted average settlement rate for our Euro and British Pound denominated contracts was 1.32 and 1.97, respectively. None of our forward exchange contracts are designated as hedges under SFAS No. 133. As a result, the fair value changes of all contracts are reported in earnings as foreign exchange gain or loss. For the year ended December 31, 2006, approximately $0.3 million of

loss has been included in our statement of consolidated earnings with respect to these forward exchange contracts, as compared to income of $33,000 for the year ended December 31, 2005. The notional settlement value of foreign currency forward contracts outstanding was $0.3 million at December 31, 2005.

At December 31, 2006, we had cash of approximately $6.9 million denominated in foreign country currencies, which represented approximately 2% of the total investment portfolio. As a result, our investment portfolio is subject to limited amounts of foreign exchange risk.

Based on our overall currency rate exposures at December 31, 2006, we expect that a near-term 10% depreciation of the U.S. dollar could result in the potential loss of the fair value of our foreign currency sensitive assets and investments by approximately $0.4 million. We also expect that our 2007 net loss would increase by approximately $2.0 million to $4.0 million, depending upon the level of activities denominated in foreign currencies, as a result of a near-term 10% depreciation of the U.S. dollar.

Item 8. Financial Statements and Supplementary Data

The information required to be filed in this item appears on pages F-1 to F-32 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure 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-K was recorded, processed, summarized and reported within the time periods specified in the SEC s rules and instructions for Form 10-K.

Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate internal control structure and procedures for financial reporting. Under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer,

our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2006. Our management s assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, Internal Control-Integrated Framework.

Based on using the COSO criteria, we believe our internal control over financial reporting as of December 31, 2006 was effective.

Our independent registered public accounting firm, KPMG LLP, has audited the financial statements included in this Form 10-K and has issued a report on management s assessment of our internal control over financial reporting as well as on the effectiveness of our internal control over financial reporting. The attestation reports of KPMG on management s assessment of internal control over financial reporting and on the audit of the financial statements are incorporated by reference from Item 8 of this Form 10-K.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter of 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Scope of the Effectiveness of Controls

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of the assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our board of directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Part III

Item 10. Directors and Executive Officers of the Registrant

We incorporate information regarding our directors and executive officers into this section by reference from sections captioned Election of Directors and Executive Officers in the proxy statement for our 2007 annual meeting of stockholders.

Item 11. Executive Compensation

We incorporate information regarding our directors and executive officers into this section by reference from the section captioned Executive Compensation in the proxy statement for our 2007 annual meeting of stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

We incorporate information regarding our directors and executive officers into this section by reference from the section captioned Security Ownership of Certain Beneficial Owners in the proxy statement for our 2007 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions

We incorporate information regarding our directors and executive officers into this section by reference from the section captioned Interest of Insiders in Material Transactions in the proxy statement for our 2007 annual meeting of stockholders.

Item 14. Principal Accountant Fees and Services

We incorporate information regarding our principal accountant fees and services into this section by reference from the section captioned Auditors in the proxy statement for our 2007 annual meeting of stockholders.

Part IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

Exhibit Index

1.1	Notes Purchase Agreement dated March 23, 2006, by and between BioMarin Pharmaceutical Inc. and Merrill Lynch, previously filed with the Commission on March 23, 2006 as Exhibit 1.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
1.2	Equity Purchase Agreement dated March 23, 2006, between BioMarin Pharmaceutical Inc. and the Equity Underwriters, previously filed with the Commission on March 23, 2006 as Exhibit 1.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
2.1	Asset Purchase Agreement dated as of April 20, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
2.2	Securities Purchase Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
2.3	License Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.3 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
2.4	Settlement Agreement and Mutual Release dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.4 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
2.5	Amendment to Securities Purchase Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.5 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
2.6	Amendment to License Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.6 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
3.1	Amended and Restated Certificate of Incorporation, as amended June 12, 2003, previously filed with the Commission on June 23, 2003 as Exhibit 3.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
3.2	Certificate of Correction to Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioMarin Pharmaceutical Inc., previously filed with the Commission on April 4, 2005 as Exhibit 3.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
3.3	Amended and Restated By-Laws of BioMarin Pharmaceutical Inc., previously filed with the Commission on June 26, 2006 as Exhibit 3.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
4.1	Rights Agreement, dated as of September 11, 2002, between BioMarin Pharmaceutical Inc. and Mellon Investor Services LLC, as Rights Agent, previously filed with the Commission on September 13, 2002 as Exhibit 4.1 to the Company s Form 8-A, which is incorporated herein by reference.

4.2	Indenture dated June 23, 2003, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on August 12, 2003 as Exhibit 4.1 to the Company s Quarterly report on Form 10-Q, which is incorporated herein by reference.
4.3	3.50% Convertible Subordinated Note due 2008, in the principal amount of $125,000,000, dated June 23, 2003, previously filed with the Commission on August 12, 2003 as Exhibit 4.2 to the Company s Quarterly report on Form 10-Q, which is incorporated herein by reference.
4.4	Registration Rights Agreement dated June 23, 2003 by and among UBS Securities LLC and CIBC World Markets Corp., as Initial Purchasers, and BioMarin Pharmaceutical Inc., previously filed with the Commission on August 12, 2003 as Exhibit 4.3 to the Company s Quarterly report on Form 10-Q, which is incorporated herein by reference.
4.5	Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
4.6	First Supplemental Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
4.7	Form of 2.5% Senior Subordinated Convertible Notes due 2013, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.1	Form of Indemnification Agreement for Directors and Officers, previously filed with the Commission on May 4, 1999 as Exhibit 10.1 to the Company s Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.2	Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on March 23, 2005, previously filed with the Commission on March 29, 2005 as Exhibit 10.42 to the Company s Annual Report on Form 10-K/A, which is incorporated herein by reference.
10.3	1997 Stock Plan, as amended on December 22, 1998, and forms of agreements, previously filed with the Commission on May 4, 1999 as Exhibit 10.2 to the Company s Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.4	Amendment to 1997 Stock Plan, as amended, as adopted March 20, 2002, previously filed with the Commission on March 21, 2002 as Exhibit 99.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.5	Amendment No. 2 to 1997 Stock Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.6	Amended and Restated BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, as adopted on June 21, 2006, previously filed with the Commission on June 16, 2006 as Exhibit 99.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.7	1998 Director Option Plan and forms of agreements thereunder, previously filed with the Commission on May 4, 1999 as Exhibit 10.3 to the Company s Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.8	Amendment to 1998 Director Plan as adopted March 26, 2003 previously filed with the Commission on May 15, 2003 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.

10.9	Amendment No. 2 to 1998 Director Option Plan, as adopted June 12, 2003 and July 21, 2003, previously filed with the Commission on August 12, 2003 as Exhibit 10.1 to the Company s Quarterly report on Form 10-Q, which is incorporated herein by reference.
10.10	Amendment No. 3 to 1998 Director Option Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.11	Amended and Restated 2006 Employee Stock Purchase Plan, as adopted on June 21, 2006, previously filed with the Commission on August 3, 2006 as Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.12	BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan, as adopted December 1, 2005, previously filed with the Commission on December 2, 2005 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.13	Employment Agreement with Stuart J. Swiedler, M.D., Ph.D., dated May 29, 1998, as amended, previously filed with the Commission on May 4, 1999 as Exhibit 10.12 to the Company s Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.14	Employment Agreement with Emil Kakkis, M.D., Ph.D., dated June 30, 1998, as amended, previously filed with the Commission on May 4, 1999 as Exhibit 10.13 to the Company s Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.15	Employment Agreement with Robert Baffi dated April 20, 2000, previously filed with the Commission on March 20, 2001 as Exhibit 10.29 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
10.16	Employment Agreement with Jean-Jacques Bienaimé, dated May 11, 2005, previously filed with the Commission on May 12, 2005, as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.17	Amendment No. 1 to Employment Agreement dated December 15, 2005 between BioMarin Pharmaceutical Inc. and Jean-Jacques Bienaimé, previously filed with the Commission on December 13, 2005 as Exhibit 10.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.18	Amendment No. 2 to Employment Agreement dated May 10, 2006, between BioMarin Pharmaceutical Inc. and Jean-Jacques Bienaime, previously filed with the Commission on May 9, 2006 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.19	Severance Agreement and Release of All Claims dated August 23, 2005 between BioMarin Pharmaceutical Inc. and Louis Drapeau, previously filed with the Commission on August 23, 2005 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.20	Grant Terms and Conditions Agreement between BioMarin Pharmaceutical Inc. and Harbor-UCLA Research and Education Institute dated April 1, 1997, as amended, previously filed with the Commission on July 21, 1999 as Exhibit 10.17 to the Company s Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.21	License Agreement between BioMarin Pharmaceutical Inc., and Children s Hospital, Adelaide, Australia dated August 14, 1998, previously filed with the Commission July 21, 1999 as Exhibit 10.18 to the Company s Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.

10.22	License Agreement dated July 30, 2004, between BioMarin Pharmaceutical Inc. and Daiichi Suntory Pharma Co., Ltd., as amended by Amendment No. 1 to License Agreement dated November 19, 2004, previously filed with the Commission on March 16, 2005 as Exhibit 10.25 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.23	Supply Agreement dated July 30, 2004, by and among BioMarin Pharmaceutical Inc., Daiichi Suntory Pharma Co., Ltd. and Shiratori Pharmaceutical Co., Ltd., previously filed with the Commission on March 16, 2005 as Exhibit 10.26 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.24	Development, License and Commercialization Agreement dated May 13, 2005, between BioMarin Pharmaceutical Inc. and Ares Trading S.A., previously filed with the Commission on July 6, 2005 as Exhibit 10.1 to the Company s Current Report on Form 8-K/A, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.25	Collaboration Agreement with Genzyme Corporation dated September 4, 1998, previously filed with the Commission on July 21, 1999 as Exhibit 10.24 to the Company s Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.26	Operating Agreement with Genzyme Corporation, previously filed with the Commission on July 21, 1999 as Exhibit 10.30 to the Company s Amendment No. 2 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.27	Purchase Agreement dated July 14, 2005, by and among BioMarin Pharmaceutical Inc. and Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, previously file with the Commission on July 14, 2005 as Exhibit 1.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.28	Agreement dated May 27, 2005, between BioMarin Pharmaceutical Inc. and the Caduceus Group, previously filed with the Commission on May 27, 2005 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.29	Convertible Promissory Note dated January 12, 2005, executed by BioMarin Pharmaceutical Inc. in favor of Medicis Pharmaceutical Corporation as Holder, previously filed with the Commission on March 16, 2005 as Exhibit 10.38 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
10.30	CRO Services Agreement dated September 15, 2004 between BioMarin Pharmaceutical Inc. and Kendle International Inc. as amended by the First Amendment to the CRO Services Agreement dated February 10, 2005, previously filed with the Commission on March 16, 2005 as Exhibit 10.39 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.31	License Agreement dated March 15, 2006 between BioMarin Pharmaceutical Inc. and Alliant Pharmaceuticals, Inc., previously filed with the Commission on May 4, 2006 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.32	Purchase and Sale Agreement and Joint Escrow Instructions dated January 24, 2006 between BioMarin Pharmaceutical Inc. and Wirrulla Novato LLC, previously filed with the Commission on May 4, 2006 as Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q, which is incorporated here by this reference.

10.33	First Amendment to Purchase and Sale Agreement and Joint Escrow Instructions dated February 23, 2006 between BioMarin Pharmaceutical Inc. and Wirrula Novato LLC previously filed with the Commission on May 4, 2006 as Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q, which is incorporated here by this reference.
21.1*	Subsidiaries of BioMarin Pharmaceutical Inc.
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm for BioMarin Pharmaceutical Inc.
23.2*	Consent of PricewaterhouseCoopers, LLP, Independent Registered Public Accounting Firm for BioMarin/Genzyme LLC.
24.1*	Power of Attorney (Included in Signature Page)
25.1	Form T-One Statement of Eligibility under the Trust Indenture Act of 1939, previously filed with the Commission on March 20, 2006 as Exhibit 25.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of The Securities Exchange Act of 1934, as amended.
99.1*	BioMarin/Genzyme LLC Consolidated Financial Statements as of December 31, 2006 and 2005, and for the years ended December 31, 2006, 2005 and 2004.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioMarin Pharmaceutical Inc.

Dated: February 27, 2007

By: /s/ Jeffrey H. Cooper
Jeffrey H. Cooper

Senior Vice President, Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jean-Jacques Bienaimé and Jeffrey H. Cooper, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to the Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Jean-jacques Bienaimé **Jean-Jacques Bienaimé**	Chief Executive Officer (Principal Executive Officer)	February 27, 2007
/s/ Jeffrey H. Cooper **Jeffrey H. Cooper**	Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2007
/s/ Pierre Lapalme **Pierre Lapalme**	Chairman and Director	February 27, 2007
/s/ Elaine Heron **Elaine Heron**	Director	February 27, 2007
/s/ Joseph Klein, III **Joseph Klein, III**	Director	February 27, 2007

/s/ ALAN J. LEWIS **Alan J. Lewis**	Director	February 27, 2007
/s/ MICHAEL G. GREY **Michael G. Grey**	Director	February 27, 2007
/s/ RICHARD A. MEIER **Richard A. Meier**	Director	February 27, 2007

INDEX TO BIOMARIN PHARMACEUTICAL INC.

CONSOLIDATED FINANCIAL STATEMENTS

REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

BioMarin Pharmaceutical Inc.:

We have audited the accompanying consolidated balance sheets of BioMarin Pharmaceutical Inc. and subsidiaries (the Company) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for the each of the years in the three-year period ended December 31, 2006. In connection with our audits of the consolidated financial statements, we also have audited financial statement schedule II. These consolidated financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits. We did not audit the financial statements of BioMarin/Genzyme LLC (a 50 percent owned joint venture) for the years 2006 and 2005. The Company s investment in BioMarin/Genzyme LLC (in thousands) at December 31, 2006 and 2005 was $31,457 and $31,983, respectively, and its equity in income of BioMarin/Genzyme (in thousands) was $19,274 and $11,838 for the years ended December 31, 2006 and 2005, respectively. The financial statements of BioMarin/Genzyme LLC for the years 2006 and 2005 were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for BioMarin/Genzyme LLC for the years 2006 and 2005, is based solely on the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioMarin Pharmaceutical Inc. and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 1 to the Consolidated Financial Statements, effective January 1, 2006, the Company adopted the provision of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of BioMarin Pharmaceutical Inc. s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2007 expressed an unqualified opinion on management s unqualified opinion on management s assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

San Francisco, California

February 27, 2007

The Board of Directors and Stockholders of

BioMarin Pharmaceutical Inc.:

We have audited management s assessment, included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting, that BioMarin Pharmaceutical Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). BioMarin Pharmaceutical Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that BioMarin Pharmaceutical Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, BioMarin Pharmaceutical Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of BioMarin Pharmaceutical Inc. and subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for the each of the years in the three-year period ended December 31, 2006. In connection with our audits of the consolidated financial statements, we also have audited financial statement schedule II. Our report dated February 27, 2007 expressed an unqualified opinion on those consolidated financial statements and related financial statement schedule. Our report was based on our audits and the report of other auditors.

/s/ KPMG LLP

San Francisco, California

February 27, 2007

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2005 and 2006

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

	December 31, 2005	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,092	$ 89,162
Short-term investments	9,700	199,685
Accounts receivable, net	5,860	14,670
Advances to BioMarin/Genzyme LLC	1,071	1,596
Inventory	10,898	25,075
Other current assets	3,320	4,036
Total current assets	68,941	334,224
Cash balances related to long-term debt	17,049	
Investment in BioMarin/Genzyme LLC	31,983	31,457
Property, plant and equipment, net	37,321	55,466
Acquired intangible assets, net	15,306	11,655
Goodwill	21,262	21,262
Other assets	3,441	9,372
Total assets	$ 195,303	$ 463,436
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 20,934	$ 32,166
Current portion of acquisition obligation, net of discount	7,477	6,787
Current portion of deferred revenue	8,096	7,092
Current portion of equipment and facility loans	3,860	
Total current liabilities	40,367	46,045
Convertible debt	125,000	223,940
Long-term portion of acquisition obligation, net of discount	70,873	68,548
Deferred revenue, net of current portion	11,825	5,023
Equipment and facility loan, net of current portion	17,049	
Other long-term liabilities	7,651	2,078
Total liabilities	272,765	345,634
Stockholders equity (deficit):		
Common stock, $0.001 par value: 150,000,000 shares authorized; 74,301,610 and 91,725,528 shares issued and outstanding at December 31, 2005 and December 31, 2006, respectively	75	92
Additional paid-in capital	485,570	709,359
Accumulated other comprehensive loss	(16)	(25)
Accumulated deficit	(563,091)	(591,624)

Total stockholders equity (deficit)	(77,462)	117,802
Total liabilities and stockholders equity (deficit)	$ 195,303	$ 463,436

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2004, 2005 and 2006

(In thousands, except for per share data)

	December 31,		
	2004	**2005**	**2006**
Revenues:			
Net product sales	$ 18,641	$ 13,039	$ 49,606
Collaborative agreement revenues		12,630	18,740
Royalty and license revenues			15,863
Total revenues	18,641	25,669	84,209
Operating expenses:			
Cost of sales (excludes amortization of developed product technology)	3,953	2,629	8,740
Research and development	49,784	56,391	66,735
Selling, general and administrative	37,606	41,556	49,030
Amortization of acquired intangible assets	3,987	1,144	3,651
Acquired in-process research and development	31,453		
Impairment of acquired intangible assets	68,251		
Total operating expenses	195,034	101,720	128,156
Equity in the (loss) income of BioMarin/Genzyme LLC	(2,972)	11,838	19,274
Loss from operations	(179,365)	(64,213)	(24,673)
Interest income	2,466	1,861	12,866
Interest expense	(10,544)	(11,918)	(16,726)
Net loss	$ (187,443)	$ (74,270)	$ (28,533)
Net loss per share, basic and diluted	$ (2.91)	$ (1.08)	$ (0.34)
Weighted average common shares outstanding, basic and diluted	64,354	68,830	84,582

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

For the Years ended December 31, 2004, 2005 and 2006 (in thousands)

	Common stock			Warrants					
	Shares	Amount	Additional paid-in capital	Shares	Amount	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders equity (deficit)
Balance at January 1, 2004	64,156	$ 64	$ 414,110	780	$ 5,219	$ (145)	$ (17)	$ (301,378)	$ 117,853
Amortization of deferred compensation						145			145
Issuance of common stock under ESPP	187		785						785
Exercise of common stock options	158	1	1,016						1,017
Fair market value adjustments of available-for-sale investments							(346)		(346)
Expiration of warrants			5,219	(780)	(5,219)				
Other			11						11
Net loss								(187,443)	(187,443)
Balance at December 31, 2004	64,501	$ 65	$ 421,141		$	$	$ (363)	$ (488,821)	$ (67,978)

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT) (Continued)

For the Years ended December 31, 2004, 2005 and 2006 (in thousands)

	Common stock			Warrants			Accumulated other comprehensive		Total stockholders equity
	Shares	Amount	Additional paid-in capital	Shares	Amount	Deferred compensation	income (loss)	Accumulated deficit	(deficit)
Balance at January 1, 2005	64,501	$ 65	$ 421,141		$	$	$ (363)	$ (488,821)	$ (67,978)
Issuance of common stock in a public offering, net of issuance costs	8,500	8	56,320						56,328
Issuance of common stock under ESPP	251		889						889
Exercise of common stock options	1,050	2	6,893						6,895
Fair market value adjustments of available-for-sale investments							346		346
Stock compensation expense related to modification of awards			327						327
Foreign currency translation adjustment							1		1
Net loss								(74,270)	(74,270)
Balance at December 31, 2005	74,302	$ 75	$ 485,570		$	$	$ (16)	$ (563,091)	$ (77,462)

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT) (Continued)

For the Years ended December 31, 2004, 2005 and 2006 (in thousands)

	Common stock			Warrants					
	Shares	Amount	Additional paid-in capital	Shares	Amount	Deferred compensation	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders equity (deficit)
Balance at January 1, 2006	74,302	$ 75	$ 485,570		$	$	$ (16)	$ (563,091)	$ (77,462)
Issuance of common stock in a public offering, net of issuance costs	10,350	10	127,422						127,432
Issuance of common stock under ESPP	326		1,405						1,405
Exercise of common stock options	1,499	2	11,679						11,681
Conversion of convertible notes	5,249	5	72,687						72,692
Fair market value adjustments of available-for-sale investments							23		23
Stock-based compensation			10,596						10,596
Foreign currency translation adjustment							(32)		(32)
Net loss								(28,533)	(28,533)
Balance at December 31, 2006	91,726	$ 92	$ 709,359		$	$	$ (25)	$ (591,624)	$ 117,802

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2004, 2005 and 2006

(In thousands)

	December 31,		
	2004	**2005**	**2006**
Cash flows from operating activities			
Net loss	$ (187,443)	$ (74,270)	$ (28,533)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,279	9,748	11,958
Imputed interest on acquisition obligation	5,160	5,444	4,685
Equity in the loss (income) of BioMarin/Genzyme LLC	2,972	(11,838)	(19,274)
Stock-based compensation		327	10,596
Acquired in-process research and development	31,453		
Impairment of acquired intangible assets	68,251		
Gain (Loss) on disposals and impairments of property and equipment	(104)	404	
Changes in operating assets and liabilities:			
Accounts receivable	(4,047)	(1,813)	(8,809)
Advances to BioMarin/Genzyme LLC	1,891	1,089	(526)
Inventory		(8,582)	(14,177)
Other current assets	197	(679)	(716)
Notes receivable from officer	1,040		
Other assets	(101)	(59)	(3,091)
Accounts payable and accrued liabilities	11,653	(3,642)	10,399
Other liabilities	1,497	4,799	(4,795)
Deferred revenue		19,921	(7,807)
Net cash used in operating activities	(54,302)	(59,151)	(50,090)
Cash flows from investing activities			
Purchase of property, plant and equipment	(20,821)	(6,486)	(24,583)
Acquisition of Ascent Pediatrics	(14,788)		
Decrease (Increase) in restricted cash	(25,298)	25,180	
Sales of short-term investments	86,306	26,380	29,906
Purchases of short-term investments	(37,435)		(219,891)
Investment in BioMarin/Genzyme LLC	(14,093)		
Distributions from BioMarin/Genzyme LLC		3,000	19,800
Settlement of dispute with Medicis		6,000	
Net cash provided by (used in) investing activities	(26,129)	54,074	(194,768)
Cash flows from financing activities			
Proceeds from equipment and facility loans	19,957	17,543	
Proceeds from ESPP and exercise of stock options	1,813	7,782	13,087
Reclassification of amounts (to) from cash balances related to long-term debt	(16,406)	(643)	17,049
Repayment of equipment and facility loans	(3,258)	(16,723)	(20,909)
Repayment of acquisition obligation	(30,000)	(34,200)	(7,700)

Proceeds from public offering of common stock, net		56,328	127,431
Proceeds from convertible debt offering, net of offering costs			166,979
Net cash provided by (used in) financing activities	(27,894)	30,087	295,937
Effect of foreign currency translation on cash		1	(9)
Net increase (decrease) in cash and cash equivalents	(108,325)	25,011	51,070
Cash and cash equivalents:			
Beginning of year	121,406	13,081	38,092
End of year	$ 13,081	$ 38,092	$ 89,162

See accompanying notes to consolidated financial statements.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2005 and 2006

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin®) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin received marketing approval for Naglazyme ® (galsulfase) in the U.S. in May 2005, and in the E.U. in January 2006. Aldurazyme ® (laronidase) has been approved in the U.S and E.U. and is marketed by the Company and its joint venture partner, Genzyme Corporation (Genzyme). 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 December 31, 2006, the Company had accumulated losses of approximately $591.6 million. Management believes that the Company s cash, cash equivalents and short-term investments at December 31, 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 net future cash needs primarily through its current cash, cash equivalents and short-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners.

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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated.

(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) Cash and Cash Equivalents

The Company treats liquid investments with original maturities of less than three months when purchased as cash and cash equivalents.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(d) Short-Term Investments

The Company records its investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses being included in accumulated other comprehensive income (loss). Short-term investments are comprised mainly of corporate securities, commercial paper, repurchase agreements, federal agency investments and taxable municipal debt securities. As of December 31, 2006, the Company had no available-for-sale investments. See Note 15 for further information.

(e) Inventory

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

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 December 31, 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 December 31, 2006. Stock-based compensation of $0 million and $1.0 million were capitalized into Naglazyme inventory for the years ended December 31, 2005 and 2006, respectively.

During 2005, increased generic competition to Orapred resulted in continued decreases in end-user demand. As a result, the Company revised its estimates of expected inventory requirements and recognized Orapred inventory write-offs of $1.5 million during 2005. The inventory write-off included $1.1 million of commercial inventory, which increased cost of goods sold, and $0.4 million of sample inventory, which increased sales and marketing expense. See Note 8 for further information on inventory balances as of December 31, 2005 and 2006.

(f) 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.

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

The Company accounts for its investment in the joint venture using the equity method. Accordingly, the Company records an increase in its investment for contributions to the joint venture and for its 50% share of the income of the joint venture, and a reduction in its investment for its 50% share of any losses of the joint venture or disbursements of profits from the joint venture. Equity in the Loss/Income of BioMarin/Genzyme LLC includes the Company s 50% share of the joint venture s loss/income for the period. Advances to BioMarin/

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

Genzyme LLC include the current receivable from the joint venture for the reimbursement related to services provided to the joint venture by the Company during the most recent month, and the investment in BioMarin/Genzyme LLC includes the Company s share of the net equity of the joint venture.

(h) 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 December 31, 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 buildings and 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.

(i) Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred. See Note 9 for further information on property, plant and equipment balances as of December 31, 2005 and 2006.

Certain of the Company s operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. The Company accounts for these operating leases in accordance with SFAS No. 13, *Accounting for Leases* , and FASB Technical Bulletin No. 85-3, *Accounting for Operating Leases with Scheduled Rent Increases* . Accordingly, the scheduled increases in rent expense are recognized on a

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

straight-line basis over the lease term. The difference between rent expense and rent paid is recorded as deferred rent and included in other liabilities in the accompanying consolidated balance sheets. The tenant improvement allowances are recognized as a credit to rent expense over the lease term on a straight-line basis.

(j) 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 Merck 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).

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 fees paid to Naglazyme distributors as a reduction of revenue, in accordance with EITF Issue No. 01-09, "*Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor s Products)*".

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns of Naglazyme is required, including market exclusivity of the product based on its orphan drug status, the patient population, the customers limited return rights and the Company s joint venture s experience of returns for Aldurazyme, which is a similar product. Based on these factors, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required. The Company maintains a policy to record allowances for

doubtful accounts for estimated losses resulting from the inability of its Naglazyme customers to make required payments. The Company first recorded sales of Naglazyme during the second quarter of 2005 and as of December 31, 2006, the Company has experienced no bad debts and had no allowance for doubtful accounts.

Orapred product sales The Company does not expect to report Orapred product sales in future periods 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 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 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 of product returns with a customer for an amount less than previous estimates. This adjustment resulted in reserve reductions of approximately $1.2 million, which were recorded as an increase in revenue of $0.7 million for returns of product sold by the Company and $0.5 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 2006, the Company s allowance for doubtful accounts was insignificant.

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue. Nonrefundable up-front license fees where the Company has continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which the Company continues to have a performance obligation. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono s share of Kuvan (sapropterin dihydrochloride), formerly referred to as Phenoptin, development costs under the agreement, which are recorded as research

and development expenses. Collaborative agreement revenues include $5.5 million and $7.4 million of the up-front

license fee received from Merck Serono recognized as revenue during 2005 and 2006, respectively, and $7.1 million and $11.3 million of reimbursable Kuvan development costs incurred during 2005 and 2006, respectively.

In 2005, the up-front license fee received from Merck Serono was being amortized to 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 Kuvan for the treatment of phenylketonuria (PKU), at which point the Company s performance obligations for developing Kuvan 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 2006 by approximately $0.3 million, and the change in estimate is expected to reduce license revenues in 2007 by approximately $0.6 million, and increase license revenues in 2008 by approximately $0.9 million. There is no cost of sales associated with the amortization of the up-front license fee received from Merck 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 based on information received from the sublicensee and when collectibility is reasonably assured.

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

The up-front license fee of $2.5 million received from 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 $2.5 million related to the up-front license fee received from the third party recognized as revenue during 2006. 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.

(k) Research and Development

Research and development expenses include expenses associated with contract research and development provided by third parties, product manufacturing prior to regulatory approval, clinical and regulatory costs, and internal research and development costs. Generally, in instances where we enter into agreements with third

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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

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

(l) 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):

	December 31,	
	2005	2006
Options to purchase common stock	6,969	10,374
Common stock issuable under convertible debt	8,920	14,075
Portion of acquisition payable in common stock	798	525
Total	16,687	24,974

(m) Stock Based Compensation

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

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

As stock-based compensation expense recognized in the consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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.

(n) Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded to reduce deferred tax assets to the amount that is more likely than not to be realized. There is a full valuation allowance against net deferred tax assets of $293.0 million at December 31, 2006. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease income in the period such adjustment was made. See Note 14 for further discussion of the Company s income taxes.

(o) 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. See Note 16 for further discussion of the Company s derivative instruments.

(p) 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.

(q) Accumulated Other Comprehensive Loss

Accumulated Other Comprehensive Loss includes unrealized gains and losses on short-term investments designated as available for sale and foreign currency translation adjustments. There were no tax effects allocated to any components of other comprehensive income during 2004, 2005 and 2006.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(r) Recent Accounting Pronouncements

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

In November 2006, the FASB ratified the EITF consensus reached in EITF Issue No. 06-6 *Debtor s Accounting for a Modification (or Exchange) of Convertible Debt Instruments* , which provides guidance for debtor s accounting for a modification or exchange of convertible debt instruments. This EITF states that a change in the fair value of an embedded conversion option that resulted from an exchange of debt instruments or a modification in the terms of an existing debt instrument should be excluded from the cash flow test of whether the terms of the new debt instrument are substantially different from the terms of the original debt instrument. Management does not expect the adoption of EITF No. 06-6 to have a material effect on the Company s consolidated financial position, results of operations or cash flows.

In November 2006, the FASB ratified the EITF consensus reached in EITF Issue No. 06-7 *Issuer s Accounting for a Previously Bifurcated Conversion Option in Convertible Debt Instrument When the Conversion Option No Longer Meets the Bifurcation Criteria in Paragraph 12 of FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities* , which provides guidance for entities issuing convertible debt with an embedded conversion option that is required to be bifurcated under FAS 133. Management does not expect the adoption of EITF No. 06-7 to have a material effect on the Company s consolidated financial position, results of operations or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements* , which provides guidance on the consideration of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB No. 108 is effective for annual financial statements covering the first fiscal year ending after November 15, 2006, with earlier application encouraged for any interim period of the first fiscal year ending after November 15, 2006. Management does not expect any adjustments resulting from the application of SAB 108.

In June 2006, the FASB issued FASB Interpretation (FIN) No. 48, *Accounting for Income Tax Uncertainties* . FIN No. 48 applies to all tax positions accounted for under FASB No. 109, *Accounting for Income Taxes* , including tax positions acquired in a business combination. The Interpretation defines the threshold for recognizing the benefits of tax return positions in the financial statements as more-likely-than-not . The term more-likely-than-not means there exists a likelihood of more than 50 percent that the position will be sustained upon review by the taxing authority based solely on its technical merits as of the reporting date. FIN No. 48 is effective for interim and annual reporting periods beginning after December 15, 2006. Management does not expect the adoption of FIN No. 48 to have a material effect on the Company s consolidated financial position, results of operations or cash flows.

(s) Reclassifications

Certain amounts in the years ended December 31, 2004 and 2005 as reported in the Consolidated Statements of Cash Flows have been revised to reflect acquisitions of property, plant and equipment included in accrued

liabilities. Specifically, $3.3 million was reclassified from Net Cash Provided By (Used In) Investing Activities to Net Cash Used In Operating Activities for the year ended December 31, 2004 and $3.5 million was reclassified from Net Cash Used In Operating Activities to Net Cash Provided By (Used In) Investing Activities for the year ended December 31, 2005. Certain other items in the prior years consolidated financial statements have been reclassified to conform to the 2006 presentation.

(3) STOCK-BASED COMPENSATION

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

The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the requisite service period of the options using the straight-line method. As a result of the adoption of SFAS No. 123R, the Company s loss from operations and net loss for the year ended December 31, 2006, was $9.6 million higher than under the Company s previous accounting method for stock-based compensation. Prior to adoption of SFAS No. 123R, benefits of tax deductions in excess of recognized compensation costs were required to be reported as operating cash flows. SFAS No. 123R requires that they be recorded as a financing cash inflow rather than as a reduction of taxes paid. For the year ended December 31, 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. Pursuant to the income tax provisions included in SFAS 123R, the Company has elected the long method of computing our hypothetical APIC pool. The Company is in the process of computing the hypothetical excess tax benefits in additional paid-in capital as of the date of adoption of SFAS No. 123R. This analysis is not expected to result in a material change to BioMarin s financial statements.

Stock-based compensation costs for the year ended December 31, 2006 totaled $10.6 million, of which $1.0 million was capitalized into inventory, $5.3 million was included in selling, general and administrative expense and $4.3 million was included in research and development expense. An insignificant amount of stock compensation was included in cost of goods sold for the year ended December 31, 2006. No stock compensation costs were recognized for the year ended December 31, 2005, which was prior to the Company s adoption of SFAS No. 123R.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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:

	Years ended December 31,	
	2004	2005
Net loss as reported	$ (187,443)	$ (74,270)
Add: Total stock based compensation expense determined under intrinsic value based method recognized in net loss as reported		327
Deduct: Total stock-based compensation expense determined under fair value based method for all awards, net of tax	(14,382)	(10,184)
Pro forma net loss	$ (201,825)	$ (84,127)
Net loss per common share as reported, basic and diluted	$ (2.91)	$ (1.08)
Pro forma net loss per common share, basic and diluted	(3.14)	(1.22)

The following summarizes the weighted average assumptions used to determine the fair value of the stock options granted prior to the adoption of SFAS No. 123R, using the Black-Scholes option-pricing model:

Dates of grant	Interest rate	Expected dividend yield	Expected life	Expected volatility
January 1, 2004 to December 31, 2004	4.1%	0.00%	6 years	56%
January 1, 2005 to December 31, 2005	4.4%	0.00%	6 years	54%

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 December 31, 2006, the only awards issued under the 2006 Share Incentive Plan were stock options. The options generally vest over a four-year period on a cliff basis six months after the grant date and then monthly thereafter. The term of the outstanding options is generally ten years. Options assumed under past business acquisitions generally vest over periods ranging from immediately upon grant to five years from the original grant date and have terms ranging from two to ten years.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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 December 31, 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.

Stock Option Valuation Assumptions	Year Ended December 31, 2006
Expected volatility	52.2-57.9%
Dividend yield	0.0%
Expected life	4.9-5.3 years
Risk-free interest rate	4.4-5.1%

The Company has recorded $10.0 million of compensation costs related to stock options for the year ended December 31, 2006, recognized in accordance with SFAS No. 123R. As of December 31, 2006, there was $37.9 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 3.3 years.

A summary of stock option activity under the plans for the year ended December 31, 2006 is presented as follows:

	Shares	Weighted Average Exercise Price	Weighted average fair value of options granted	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
					(in thousands)
Balance as of December 31, 2003	9,681,706	$ 10.37			
Granted	1,795,800	$ 6.19	$ 3.66		
Exercised	(157,879)	$ 6.44			$ 183
Expired and Forfeited	(1,311,602)	$ 8.25			

Balance as of December 31, 2004	10,008,025	$	9.96				
Granted	2,712,471	$	7.02	$	3.92		
Exercised	(1,049,639)	$	6.56			$	2,004
Expired and Forfeited	(4,702,288)	$	11.04				
Balance as of December 31, 2005	6,968,569	$	8.60				
Granted	5,258,071	$	14.67	$	7.66		
Exercised	(1,499,770)	$	7.77			$	9,941
Expired and Forfeited	(352,676)	$	10.23				
Balance as of December 31, 2006	10,374,194	$	11.75		7.9	$	52,090
Options expected to vest as of December 31, 2006	4,875,213	$	13.14		9.2	$	17,782
Exercisable as of December 31, 2006	4,280,939	$	9.76		6.1	$	29,865

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of our common stock as of the end of the period. There were 7.7 million options that were in-the-money at December 31, 2006. The aggregate intrinsic value of options exercised was determined as of the date of option exercise. During the year ended December 31, 2006, the fair value of options vested under our stock option plans was $8.9 million, as compared to $11.3 million and $6.3 million for the years ended December 31, 2004 and 2005, respectively.

At December 31, 2006, an aggregate of 14.5 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 options 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.

As of December 31, 2006, the options outstanding consisted of the following:

	Options outstanding			Options exercisable	
Range of exercise prices	Number of options outstanding	Weighted average remaining contractual life	Weighted average exercise price	Number of options exercisable	Weighted average exercise price
$ 3.50 to 7.00	2,116,093	6.8	$ 5.90	1,266,663	$ 5.71
7.01 to 10.50	2,159,883	6.8	8.69	1,552,109	8.70
10.51 to 14.00	3,015,554	8.3	12.21	1,039,142	12.26
14.01 to 17.50	839,471	9.0	15.88	145,233	15.93
17.51 to 21.00	2,033,193	9.7	17.62	67,792	19.90
21.01 to 24.50	210,000	3.4	22.00	210,000	22.00
	10,374,194			4,280,939	

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 Employee Stock 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 recorded compensation costs related to the Employee Stock Purchase Plan in the year ended December 31, 2006 of $0.6 million. No stock compensation costs was recognized for the year ended December 31, 2005, which was prior to the Company s adoption of SFAS No. 123R. For the years ended December 31, 2005 and 2006, 250,813 shares and 325,119 shares were purchased under the Employee Stock Purchase Plan, respectively.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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

	Year Ended December 31,		
Employee Stock Purchase Plan Valuation Assumptions	**2004**	**2005**	**2006**
Expected volatility	55-76%	54-63%	44-55%
Dividend yield	0.0%	0.0%	0.0%
Expected life	6-24 months	6-24 months	6-24 months
Risk-free interest rate	1.6-2.7%	1.7-3.1%	2.7-5.2%

(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 July 2005, the Company reduced the Orapred sales force through the elimination of 52 positions. 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 December 31, 2006, the Company has not made any draws on the note.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

The amended transaction agreements provided for total acquisition payments of $169.0 million payable to Medicis in specified amounts through 2009, of which $87.1 million remains payable as of December 31, 2006. The remaining payments to Medicis include a payment due in 2009 of $73.6 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 December 31, 2006
2007	$ 7,000
2008	6,500
2009	73,600
Total	$ 87,100

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 2005.

The acquisition was 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

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.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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 $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 year ended December 31, 2006, the Company also recognized $1.6 million in royalty revenues from Orapred product sold by the sublicensee and $2.5 million related to the up-front license fee.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(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 Orapred product technology as of December 31, 2006. The gross and net carrying value of the Orapred product technology as of December 31, 2006 were as follows (in thousands):

Gross value	$ 20,437
Accumulated amortization	(8,782)
Net carrying value	$ 11,655

The Company completed its 2006 annual impairment test during the fourth quarter of 2006 and determined that no impairment of the acquired intangible assets existed as of December 31, 2006. 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.

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

	As of December 31, 2006
2007	$ 4,371
2008	4,371
2009	2,913
Total	$ 11,655

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 year ended December 31, 2006 increased by $2.6 million ($0.03 per share) to $3.7 million, as compared to amortization expense for the year ended December 31, 2005 of $1.1 million.

(b) Goodwill

Goodwill as of December 31, 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, 2006. Following the

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

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.

(7) JOINT VENTURE

(a) Joint Venture Financial Data

The results of the joint venture s operations for the years ended December 31, 2004, 2005 and 2006, are presented in the table below (in thousands). Equity in the Loss/Income of BioMarin/Genzyme LLC represents the Company s 50% share of the joint venture s income. The joint venture s results and summarized assets and liabilities as presented below give effect to the difference in inventory cost basis between the Company and the joint venture. The difference in basis primarily represents the difference in inventory capitalization policies between the joint venture and the Company. The Company began capitalizing Aldurazyme inventory costs in May 2003 after regulatory approval was obtained. The joint venture began capitalizing Aldurazyme inventory costs in January 2002 when inventory production for commercial sale began. The difference in inventory capitalization policies resulted in greater operating expense recognized by the Company prior to regulatory approval compared to the joint venture. Correspondingly, this results in less cost of goods sold recognized by the Company when the previously expensed product is sold by the joint venture and less operating expenses when this previously expensed product is used in clinical trials. The difference will be eliminated when all of the product produced prior to obtaining regulatory approval has been sold or used in clinical trials. The majority of the difference has been eliminated as of December 31, 2006.

	Year ended December 31,		
	2004	2005	2006
Revenue	$ 42,583	$ 76,417	$ 96,291
Cost of goods sold	5,787	16,089	23,173
Gross profit	36,796	60,328	73,118
Operating expenses	42,890	36,906	35,262
(Loss) Income from operations	(6,094)	23,422	37,856
Other income	151	254	692
Net (loss) income	$ (5,943)	$ 23,676	$ 38,548
Equity in the (loss) income of BioMarin/Genzyme LLC	$ (2,972)	$ 11,838	$ 19,274

At December 31, 2005 and 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	2006
Assets	$ 70,436	$ 71,192
Liabilities	(6,470)	(8,278)
Net equity	$ 63,966	$ 62,914
Investment in BioMarin/Genzyme LLC (50% share of net equity)	$ 31,983	$ 31,457

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(b) Joint Venture Critical Accounting Policies

Revenue recognition BioMarin/Genzyme LLC recognizes revenue from product sales when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Revenue transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents.

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

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

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

BioMarin/Genzyme LLC records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the nature of Aldurazyme and its patient population, the customers limited return rights, Genzyme s experience of returns for similar products and BioMarin/Genzyme LLC s estimate of distribution channel inventory, based on sales and inventory level information provided by the primary distributors for Aldurazyme, as described above. Based on these factors, BioMarin/Genzyme LLC has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

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

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(8) SUPPLEMENTAL BALANCE SHEET INFORMATION

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

	December 31,	
	2005	2006
Accounts payable	$ 484	$ 2,285
Accrued accounts payable	10,018	13,901
Accrued vacation	1,581	2,109
Accrued compensation	4,219	6,302
Accrued interest and taxes	372	1,305
Accrued Naglazyme royalties	185	819
Other accrued expenses	150	996
Accrued rebates	1,751	819
Acquired rebates and returns reserve	1,646	906
Short-term returns reserves	330	2,633
Current portion of deferred rent	198	91
	$ 20,934	$ 32,166

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

	December 31,	
	2005	2006
Long-term portion of returns reserve	$ 5,684	$
Long-term portion of deferred rent	1,967	1,234
Deferred compensation liability		844
Total other long-term liabilities	$ 7,651	$ 2,078

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

	December 31,	
	2005	2006
Orapred raw materials	$ 821	$
Naglazyme raw materials	1,717	2,747
Naglazyme work in process	8,032	13,305
Naglazyme finished goods	328	9,023
Total inventory	$ 10,898	$ 25,075

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

A rollforward of our significant estimated revenue dilution reserves is as follows (in thousands):

	Balance at beginning of period	Provision for current period sales	Provision/ (Reversals) for prior period sales	Actual charges related to current period sales	Actual charges related to prior period sales	Balance at end of period
Year ended December 31, 2005:						
Returns reserve	$ 790	$ 279	$ 5,129	$	$ (184)	$ 6,014
Accrued rebates	3,578	1,019	(2,497)	(349)		1,751
Reserve for cash discounts	89	212		(197)	(80)	24
Year ended December 31, 2006:						
Returns reserve	$ 6,014	$ 42	$ 118	$	$ (3,541)	$ 2,633
Accrued rebates	1,751	1,187	(1,323)	(603)	(193)	819
Reserve for cash discounts	24	167		(150)	(20)	21

(9) PROPERTY, PLANT AND EQUIPMENT

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

Category	December 31, 2005	December 31, 2006	Estimated useful lives
Leasehold improvements	$ 57,809	$ 24,733	Shorter of life of asset or lease term
Building and improvements		22,604	20 years
Manufacturing and laboratory equipment	13,938	16,045	5 years
Computer hardware and software	5,055	6,484	3 years
Office furniture and equipment	3,269	3,617	5 years
Land		4,259	
Construction-in-progress	759	4,777	
	$ 80,830	$ 82,519	
Less: Accumulated depreciation	(43,509)	(27,053)	

Total property, plant and equipment, net	$ 37,321	$ 55,466

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 their respective fair values. 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 remaining net book value. 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.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

Depreciation for the years ended December 31, 2004, 2005, and 2006 was, $8.2 million, $7.7 million and $6.8 million, respectively, of which $0, $1.0 million and $1.5 million was capitalized into inventory, 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 $0.6 million of amortization expense during the year ended December 31, 2006.

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 was allowed, at its option, to redeem the notes, in whole or in part, at predetermined prices, plus any accrued and unpaid interest to the redemption date, which it did in two separate transactions in September 2006 and January 2007. The Company would have been required to repay the debt if there was 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 $0.8 million and $0.7 million of amortization expense during the years ended December 31, 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 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 interest 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. In January 2007, the remaining outstanding balance of $51.4 million of the Company s 3.50% Convertible Senior Subordinated Notes due in 2008 were converted into approximately 3.7 million shares of common stock.

Interest expense for the years ended December 31, 2004, 2005, and 2006 was, $10.5 million, $11.9 million and $16.7 million, respectively, and included $5.1 million, $5.4 million and $4.7 million in imputed interest expense, respectively. Interest paid for the years ended December 2004, 2005 and 2006 was, $5.4 million, $5.5 million and $9.6 million, respectively.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(11) COLLABORATIVE AGREEMENTS

(a) Genzyme

In 1998, the Company entered into an agreement with Genzyme to establish a joint venture (BioMarin/Genzyme LLC) for the worldwide development and commercialization of Aldurazyme to treat mucopolysaccharidosis I (MPS I). Under the Aldurazyme joint venture agreement with Genzyme, the Company and Genzyme each provide 50% of the funding for the joint venture, as needed. All manufacturing, research and development, sales and marketing, and other services performed by Genzyme and the Company on behalf of the joint venture are billed to the joint venture at cost. Any profits or losses of the joint venture are shared equally by the two parties.

(b) Merck Serono

In May 2005, the Company entered into an agreement with Merck Serono S.A. (Merck Serono) for the further development and commercialization of BH4, both in Kuvan for PKU and for other indications, and Phenylase (phenylalanine ammonia lyase). Through the agreement, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S. and Japan, and BioMarin retained exclusive rights to market these products in the U.S. The Company and Merck Serono will generally share equally all development costs following successful completion of Phase 2 trials for each product candidate in each indication. BioMarin and Merck Serono are individually responsible for the costs of commercializing the products within their respective territories. Merck Serono will also pay BioMarin royalties on its net sales of these products.

Pursuant to the agreement, Merck Serono paid BioMarin $25.0 million as consideration for executing the agreement, and will make additional milestone payments of up to $232.0 million based on the successful development and approval of both products in multiple indications, including $45.0 million associated with Kuvan for the treatment of PKU. The term of the agreement is the later of 10 years after the first commercial sale of the products or the period through the expiration of all related patents within the territories. As of December 31, 2005 and 2006, deferred revenue included $19.9 million and $12.1 million, respectively, related to the remaining unamortized up-front license fee and accounts receivable included $3.3 million and $3.1 million, respectively, due from Merck Serono for reimbursable Kuvan development costs.

(c) Other Agreements

The Company is engaged in research and development collaborations with various other entities. These provide for sponsorship of research and development by the Company and may also provide for exclusive royalty-bearing intellectual property licenses or rights of first negotiation regarding licenses to intellectual property development under the collaborations. Typically, these agreements can be terminated for cause by either party upon 90 days written notice.

(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.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(13) STOCKHOLDERS EQUITY

(a) Common Stock

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.

In July 2005, the Company completed a public offering of its common stock. In the offering, the Company sold 8,500,000 shares at a price to the public of $7.05 per share, or a total offering price of $59.9 million. The net proceeds were approximately $56.3 million.

During 2004, certain warrants expired resulting in a reclassification of $5.2 million from warrants to additional paid-in capital.

(b) Stockholders Rights Plan

In 2002, the Board of Directors authorized a stockholders rights plan. Terms of the plan provide for stockholders of record at the close of business on September 23, 2002 to receive one preferred share purchase right (a Right) for each outstanding share of common stock held. The Rights will be exercisable if a person or group acquires 15% or more of the Company s common stock or announces a tender offer or exchange offer for 15% or more of the common stock. Depending on the circumstances, the effect of the exercise of the Rights will be to permit each holder of a Right to purchase shares of Series B Junior Participating Preferred Stock of the Company that have significantly superior dividend, liquidation, and voting rights to the common stock. The Company will be entitled to redeem the Rights at $0.001 per Right at any time before a person has acquired 15% or more of the outstanding common stock. The stockholders rights plan expires in 2012.

(14) INCOME TAXES

The Company has operated at a loss for tax purposes since its inception in 1997. As of December 31, 2006, the Company had federal net operating loss carryforwards of approximately $337.2 million and state net operating loss carryforwards of approximately $128.7 million. The Company also had federal research and development and orphan drug credit carryforwards of approximately $71.3 million as of December 31, 2006, and state research credit carryovers of approximately $16.9 million. The federal net operating loss and credit carryforwards expire at various dates beginning in the year 2011 through 2026, if not utilized. The state net operating loss carryforwards began to expire in 2006 and will completely expire in 2016 if not utilized. Certain state research credit carryovers will begin to expire in 2015 if not utilized with others

carrying over indefinitely. The Company also has net operating loss carryforwards of $7.1 million and research credit carryovers of $5.8 million in Canada that it currently does not expect to utilize.

Utilization of the Company s net operating loss carryforwards and credits may be subject to limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets for financial reporting and the amount used for income tax purposes. Significant components of the Company s deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31,	
	2005	2006
Deferred tax assets:		
Net operating loss carryforwards	$ 115,487	$ 132,163
Research and other credits	73,919	93,960
Capitalized research expenses	14,225	16,521
Depreciation and amortization	8,675	8,076
Accrued expenses and reserves	7,103	3,623
Goodwill and intangible assets	29,941	30,161
Deferred revenue	8,734	5,311
Other	3,146	3,167
Total deferred tax assets	$ 261,230	$ 292,982
Valuation allowance	(261,230)	(292,982)
Net deferred tax assets	$	$

A full valuation allowance is maintained to reduce the Company s deferred tax assets to zero, as management believes that it is more likely than not that the deferred tax assets will not be realized, because ultimate profitability of the Company is uncertain as of December 31, 2006. The net valuation allowance increased by $19.6 million and $31.8 million during the years ended December 31, 2005 and 2006, respectively.

As of December 31, 2006, approximately $13.0 million of the Company s valuation allowance against deferred tax assets related to the net operating loss carryforwards that arose from the exercise of employee stock options will be accounted for as an increase to additional paid-in-capital if and when realized.

The Company had no current federal income tax expense and minimal current state income tax expense for the years ended December 31, 2004, 2005 and 2006. The reconciliations between the U.S. federal statutory tax rates to the Company s effective tax rates are as follows:

	December 31,

	2004	2005	2006
Federal tax	35.0%	35.0%	35.0%
Permanent items	(2.1)%	(6.4)%	(10.4)%
General business credits	6.0%	13.6%	26.9%
Other			(0.4)%
Valuation allowance	(38.9)%	(42.2)%	(51.1)%
Effective tax rate			

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(15) SHORT-TERM INVESTMENTS

At December 31, 2006, the principal amounts of short-term investments by contractual maturity are summarized in the table below (in thousands). All short-term investments were classified as held-to-maturity at December 31, 2006.

	Contractual Maturity Date For the Years Ending December 31,		December 31, 2006		
	2007	2008	Total Book Value	Unrealized Gains	Aggregate Fair Value
Corporate securities	$ 27,212	$	$ 27,212	$ 7	$ 27,219
Commercial paper	157,563	$	157,563	15	157,578
U.S. Government agencies	14,910		14,910	5	14,915
Total	$ 199,685	$	$ 199,685	$ 27	$ 199,712

At December 31, 2005, the principal amounts of short-term investments by contractual maturity are summarized in the table below (in thousands). All short-term investments were classified as held-to-maturity at December 31, 2005.

	Contractual Maturity Date For the Years Ending December 31,		December 31, 2005		
	2006	2007	Total Book Value	Unrealized Losses	Aggregate Fair Value
U.S. Government agencies	$ 9,700	$	$ 9,700	$ (71)	$ 9,629

At December 31, 2006, the aggregate amount of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands):

	Less Than 12 Months		12 Months or More		Total	
	Aggregate Fair Value	Unrealized Gains	Aggregate Fair Value	Unrealized Gains	Aggregate Fair Value	Unrealized Gains
Corporate securities	$ 27,219	$ 7	$	$	$ 27,219	$ 7
Commercial paper	157,578	15			157,578	15
U.S. Government Agencies	14,915	5			14,915	5
Total	$ 199,712	$ 27	$	$	$ 199,712	$ 27

The Company completed an evaluation of its investments and determined that it did not have any impairments as of December 31, 2006. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized cost.

At December 31, 2005, the aggregate amount of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands):

	Less Than 12 Months		12 Months or More		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
U.S. Government Agencies	$ 9,629	$ (71)	$	$	$ 9,629	$ (71)

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(16) DERIVATIVE FINANCIAL INSTRUMENTS

The Company periodically enters into foreign currency forward contracts, which have a maturity of less than one year. These contracts have not been designated as hedges and, accordingly, unrealized gains or losses on these contracts are reported in current earnings.

At December 31, 2006, the Company had net outstanding foreign exchange forward contracts to sell $12.9 million, comprised of sell contracts of $12.9 million of equivalent Euros and $7.5 million of equivalent British Pounds and buy contracts of $3.4 million of equivalent Euros and $4.1 million of equivalent British Pounds, all of which have a term of less than 3 months. The notional settlement value of all foreign currency forward contracts outstanding as of December 31, 2005 was $0.3 million.

None of the Company s forward exchange contracts are designated as hedges under SFAS No. 133. As a result, the fair value changes of all contracts are reported in earnings as foreign exchange gain or loss. For the year ended December 31, 2006, approximately $0.1 million of net income has been included in the Company s statement of consolidated earnings with respect to these forward exchange contracts, as compared to $33,000 as of December 31, 2005.

(17) COMMITMENTS AND CONTINGENCIES

(a) Lease Commitments

The Company leases office space and research, testing and manufacturing laboratory space in various facilities under operating agreements expiring at various dates through 2014. Certain of the leases provide for options by the Company to extend the lease for multiple five-year renewal periods and also provide for annual minimum increases in rent, usually based on a Consumer Price Index or annual minimum increases. Minimum lease payments for future years are as follows (in thousands):

2007	$ 3,234
2008	3,625
2009	3,672
2010	3,804
2011	3,562
Thereafter	6,364
	$ 24,261

Rent expense for the years ended December 31, 2004, 2005, and 2006 was $4.4 million, $3.7 million and $3.1 million, respectively. Deferred rent accruals were $1.3 million, of which $0.1 million was current, at December 31, 2006, and $2.2 million, of which $0.2 million was current, at December 31, 2005.

(b) Research and Development Funding and Technology Licenses

The Company uses experts and laboratories at universities and other institutions to perform certain research and development activities. These amounts are included as research and development expenses as services are provided.

The Company has also licensed technology, for which it is required to pay royalties upon future sales, subject to certain annual minimums. As of December 31, 2006, such minimum annual commitments are approximately $0.5 million.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(c) Contingencies

From time to time the Company is involved in legal actions arising in the normal course of its business. The Company is not presently subject to any material litigation nor, to management s knowledge, is any litigation threatened against the Company that collectively is expected to have a material adverse effect on the Company s cash flows, financial condition or results of operations. The Company is also subject to contingent payments totaling approximately $29.8 million upon achievement of certain regulatory and licensing milestones if they occur before certain dates in the future.

(18) RELATED-PARTY TRANSACTIONS

During 2005, an officer of the Company held an adjunct faculty position with LA Biomedical, formerly known as Harbor-UCLA Research Educational Institute, for purposes of conducting research. LA Biomedical licenses certain intellectual property and provides other research services to the Company. The Company is also obligated to pay LA Biomedical royalties on future sales of products covered by the license agreement. The Company s joint venture with Genzyme is subject to a second agreement with LA Biomedical that requires the joint venture to pay LA Biomedical a royalty on sales of Aldurazyme through November 2019, of which the officer is entitled to certain portions, based on the sales level per the terms of the agreement. The license agreement was effective before the officer was a BioMarin employee. Pursuant to these agreements, the officer was entitled to approximately $0.9 million and $1.1 million during 2005 and 2006, respectively.

(19) DAIICHI SUNTORY PHARMA LICENSE

In May 2005, the Company entered into a license agreement with Daiichi Suntory Pharma Co., Ltd. (Daiichi Suntory Pharma) whereby the Company obtained the exclusive worldwide rights, excluding Japan, for the use of tetrahydrobiopterin (6R- BH4) to treat the endothelial dysfunction that causes vascular complications in diabetes, cardiovascular and other diseases. 6R- BH4 is the active pharmaceutical ingredient in Kuvan. BioMarin paid Daiichi Suntory Pharma $3.3 million in connection with the license, which was included in research and development expense during 2005.

(20) COMPENSATION AGREEMENTS AND PLANS

(a) Employment Agreements

The Company has entered into employment agreements with certain officers. Generally, these agreements can be terminated without cause by the Company upon six months prior notice, or by the officer upon three months prior written notice to the Company.

(b) 401(k) Plan

The Company sponsors the BioMarin Retirement Savings Plan (401(k) Plan). Most employees (Participants) are eligible to participate following the start of their employment, at the beginning of each calendar month. Participants may contribute up to the lesser of 100% of their current compensation to the 401(k) Plan or an amount up to a statutorily prescribed annual limit. The Company pays the direct expenses of the 401(k) Plan and matches 100% of Participant s contributions up to a maximum of the lesser of 2% of the employee s annual compensation or $4,000 per year. The Company s matching contribution vests over four years from employment commencement and was approximately $0.5 million, $0.5 million and $0.6 million for the years ended December 31, 2004, 2005 and 2006, respectively. Employer contributions not vested upon employee termination are forfeited.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(c) 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, annual cash bonus and certain forms of equity compensation. 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 $0.8 million as of December 31, 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 year ended December 31, 2006.

(21) SUPPLEMENTAL CASH FLOW INFORMATION

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

	Years Ended December 31,		
	2004	2005	2006
Acquisition obligation, net of discount	$ 151,702	$	$
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
Change in accrued payables related to fixed asset additions	3,254	(3,529)	965
Stock-based compensation capitalized into inventory			1,006

(22) 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 December 31, 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 53% and 7% of net revenues, respectively, or 60% of the Company s total net product sales of Naglazyme in aggregate for the year ended December 31, 2006. For 2006, net product sales of Naglazyme were $15.5 million from customers based in the U.S. and $31.0 million from customers based outside of the U.S.

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 December 31, 2006.

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

December 31, 2005 and 2006

(23) QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

The Company s quarterly operating results have fluctuated in the past and may continue to do so in the future as a result of a number of factors, including, but not limited to, the timing and nature of research and development activities.

The Company s common stock has been traded on the Nasdaq National Market since July 22, 1999. There were 81 common stockholders of record at December 31, 2006. No dividends have ever been paid by the Company.

	Quarter ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2006:				
Total revenue	$ 13,812	$ 23,450	$ 24,927	$ 22,020
Net loss	(9,780)	(1,325)	(7,036)	(10,392)
Net loss per share, basic and diluted	(0.13)	(0.02)	(0.08)	(0.11)
Common stock price per share:				
High	15.29	14.73	16.90	18.40
Low	10.55	11.55	13.38	14.97
2005:				
Total revenue	$ 4,989	$ 3,626	$ 7,579	$ 9,475
Net loss	(22,458)	(21,340)	(15,476)	(14,996)
Net loss per share, basic and diluted	(0.35)	(0.33)	(0.21)	(0.20)
Common stock price per share:				
High	6.41	7.77	9.47	11.70
Low	4.40	4.75	7.02	6.94

SCHEDULE II

BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES VALUATION ACCOUNTS

Years ended December 31, 2005 and 2006

(in thousands)

	Balance at beginning of period	Additions (Deductions) charged to costs and expenses	Additions charged to other accounts(1)	Deductions	Balance at end of period
Year ended December 31, 2005:					
Returns reserve	$ 790	$ 5,408	$	$ (184)	$ 6,014
Accrued rebates	3,578	(1,478)		(349)	1,751
Reserve for cash discounts	89	212		(277)	24
Acquired returns reserve	726		466	(1,092)	100
Acquired rebates reserve	1,020	538	392	(404)	1,546
Year ended December 31, 2006:					
Returns reserve	$ 6,014	$ 160	$	$ (3,541)	$ 2,633
Accrued rebates	1,751	(137)		(795)	819
Reserve for cash discounts	24	167		(170)	21
Acquired returns reserve	100	590		(449)	241
Acquired rebates reserve	1,546	(389)		(491)	666

(1) Amounts relate to changes in estimates of business acquisition-related liabilities originally accounted for as components of purchase consideration and are included as components of goodwill.