BIOMARIN PHARMACEUTICAL INC
Form 10-K
February 28, 2008
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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, 2007

Or

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

Commission file number: 000-26727

BioMarin Pharmaceutical Inc.

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

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

Registrant s telephone number: (415) 506-6700

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $.001 par value	**The NASDAQ Global Market**
Preferred Share Purchase Rights	**The Swiss Main Board**

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, a non-accelerated filer, or a smaller reporting company. 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 ¨ Smaller reporting company ¨

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 97,381,263 shares common stock, par value $0.001, outstanding as of February 19, 2008. The aggregate market value of the voting stock held by non-affiliates of the Registrant as of June 30, 2007 was $1,720.5 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 May 22, 2008, are incorporated by reference into Part III.

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BIOMARIN PHARMACEUTICAL INC.

2007 FORM 10-K ANNUAL REPORT

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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

BioMarin Pharmaceutical Inc. (BioMarin, the Company, we or our) develops and commercializes 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 or offer a significant benefit over existing products. Our product portfolio is comprised of three approved products and multiple investigational product candidates. Approved products include Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride) and Aldurazyme (laronidase).

We are conducting clinical trials on several investigational product candidates for the treatment of genetic diseases including: PEG-PAL, formerly referred to as Phenylase (phenylalanine ammonia lyase), an enzyme substitution therapy for the treatment of phenylketonurics who are not responsive to Kuvan. Effective December, 2007, we began referring to Phenylase as PEG-PAL. 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 conducting 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 some protein-based pharmaceuticals.

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A summary of our various commercial products and development programs, including key metrics as of December 31, 2007, is provided below:

Program	Indication	Orphan Drug Designation	Stage	2007 Total Product Revenue (in millions)	2007 Research & Development Expense (in millions)
Naglazyme	MPS VI	Yes	Approved	$ 86.2	$ 8.8
Aldurazyme	MPS I	Yes	Approved	$ 123.7 (1)	N/A
Kuvan	PKU	Yes	Approved	$ 0.4	$ 19.9
6R-BH4	Cardiovascular Indications	Not yet determined	Clinical	N/A	$ 15.0
PEG-PAL	PKU	Yes	Clinical	N/A	$ 13.2

(1) We developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation (Genzyme) and BioMarin/Genzyme LLC (the LLC), and recognized 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 through December 31, 2007. The revenue noted here is the total product revenue recognized by the joint venture. Effective January 1, 2008, we restructured our relationship with Genzyme, as discussed in *Recent Developments*, below.

Recent Developments

BioMarin/Genzyme Joint Venture Reorganization

On January 3, 2008, we announced the restructuring of our relationship with our joint venture partner, Genzyme, regarding the manufacturing, marketing and sale of Aldurazyme. Under the revised structure, the operational responsibilities for Genzyme and us will not significantly change. As part of this restructuring, we entered into a number of agreements with Genzyme and the LLC (the Restructuring Agreements). Effective January 1, 2008, we entered into a Manufacturing, Marketing and Sales Agreement with Genzyme and the LLC. Genzyme will continue to globally distribute, market and sell Aldurazyme, and is required to purchase its requirements exclusively from us. We will continue to manufacture Aldurazyme. The parties are subject to a non-competition restriction preventing both parties from participating in certain activities related to Aldurazyme and other pharmaceutical compositions of alpha-L-iduronidase (Collaboration Products) for alpha-L-iduronidase deficiencies outside of the Restructuring Agreements. Genzyme will record sales of Aldurazyme and is required to pay us, on a quarterly basis, a tiered royalty ranging from approximately 39.5% to 50% on worldwide net product sales.

Effective January 1, 2008, Genzyme, the LLC and we also amended and restated our Collaboration Agreement. The LLC will no longer engage in commercial activities related to Aldurazyme and will solely (1) hold the intellectual property relating to Aldurazyme and other Collaboration Products and license all such intellectual property on a royalty-free basis to us and Genzyme to allow us to exercise our rights and perform our obligations under the agreements related to the restructuring and (2) engage in research and development activities that are mutually selected and funded by Genzyme and us. Genzyme and we license rights related to Aldurazyme to the LLC, and the LLC sublicenses these rights to Genzyme and us such that each may perform our obligations under the Restructuring Agreements.

Pursuant to a Members Agreement entered into by Genzyme, the LLC and us related to the restructuring, in February 2008 the LLC distributed cash and inventory to us and cash, accounts receivable and certain other assets and liabilities to Genzyme, such that the fair value of the net assets distributed to us and to Genzyme was equivalent to both parties according to the terms of the restructuring. The value of the assets, including cash and inventory, that we received was $43.5 million.

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Purchase of 300 Bel Marin Keys Facility

On January 3, 2008, we purchased our previously leased facility at 300 Bel Marin Keys Boulevard in Novato, California. The purchase price of the building was approximately $12.0 million, which was fully paid in cash. We use this 85,400 square foot facility for our technical operations group s administrative offices and laboratories.

Re-acquisition of Rights to Kuvan in Canada

On December 18, 2007, we announced that we re-acquired the Canadian rights for tetrahydrobiopterin (BH4), including Kuvan, from Merck Serono, a division of Merck KGaA. The terms of the agreement specified a reduction in royalties owed to BioMarin on Merck Serono sales outside the United States and Japan. Based on the structure of the amended agreement, the reduction in royalties cannot exceed an undisclosed amount.

FDA Approval for Kuvan

On December 13, 2007, we announced that the U.S. Food and Drug Administration (FDA) granted marketing approval for Kuvan, an orally administered preparation for the treatment of phenylketonuria (PKU). Kuvan has received orphan drug designation from the FDA, conferring upon it seven years of market exclusivity in the United States, until 2014. We began shipping product to the distribution channel the day after the announcement of Kuvan approval, and immediately began promotion. Our list sales price for Kuvan is $0.29 per mg.

Collaboration with IGAN BioSciences on Development of Enzyme Therapy to Treat IGA Nephropathy

On December 3, 2007, we announced a collaboration with IGAN BioSciences (IGAN) to develop an IgA protease for treating IgA nephropathy or Berger s disease, an orphan kidney disorder with few treatment alternatives. Twenty percent of adults with the disorder progress to end stage renal disease (ESRD). In the U.S., approximately 800 patients per year develop ESRD caused by IgA nephropathy out of the 40,000 patients affected by the disorder.

PEG-PAL FDA Filing

On November 27, 2007, we announced that we filed an investigational new drug application (IND) with the FDA for PEG-PAL for the treatment of PKU. We expect to initiate a clinical study of PEG-PAL in PKU patients in the first quarter of 2008.

MAA submitted to EMEA for European Marketing Authorization of Sapropterin for Hyperphenylalaninemia

On November 8, 2007, we announced that our partner Merck Serono submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for Kuvan as an oral treatment for patients suffering from significant hyperphenylalaninemia (HPA) due to PKU or BH4 deficiency. We received the $15.0 million milestone related to the filing from Merck Serono in December 2007.

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

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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 and even the same active ingredient can be approved for the same condition if the new product has a better safety or efficacy profile than Naglazyme. We market Naglazyme in the U.S., E.U., Latin America and Turkey using our own sales force and commercial organization. Additionally, we use local distributors in several other countries to help us pursue registration and/or market Naglazyme on a named patient basis. Naglazyme net product sales for 2007 totaled $86.2 million, as compared to $46.5 million for 2006. Naglazyme net product sales for 2005 were $6.1 million.

Kuvan

Kuvan was granted marketing approval for the treatment of PKU in the U.S. in December 2007. We market Kuvan in the U.S. using our own sales force and commercial organization. Kuvan has been granted orphan drug status in the U.S., which provides for seven years of market exclusivity. Kuvan net product sales for the approximate two-week period after approval and launch in December 2007 were $0.4 million.

Kuvan is a proprietary synthetic oral form of 6R-BH4, a naturally occurring enzyme co-factor for phenylalanine hydroxylase (PAH) indicated for patients with PKU. Kuvan is the first drug for the treatment of PKU. 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 approximately 30-50% of those with PKU could benefit from treatment with Kuvan. PKU is caused by a deficiency of activity of an enzyme, PAH, which is required for the metabolism of phenylalanine (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.

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. 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 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 maintain blood Phe levels at the recommended levels.

In May 2005, we entered into an agreement with Merck Serono for the further development and commercialization of Kuvan and PEG-PAL 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. On December 8, 2007, we announced that we re-acquired Canadian rights for BH4 from Merck Serono. 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. In November 2007, Merck Serono submitted a MAA to the EMEA for sapropterin dihydrochloride as an oral treatment for patients suffering from HPA due to PKU or BH4 deficiency. Kuvan has received orphan drug designation in the E.U. We are entitled to receive a $30.0 million milestone payment from Merck Serono upon approval of Kuvan in the E.U. We recorded collaborative agreement revenue associated with Kuvan in the amounts of $28.3 million in 2007, $18.7 million in 2006, and $12.6 million in 2005.

Aldurazyme

Aldurazyme has been approved for marketing in the U.S., E.U. 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

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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 and even the same active ingredient can be approved for the same condition if the new product has a better safety or efficacy profile than Aldurazyme. We developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation. Prior to the restructuring of our collaboration with Genzyme, we were responsible for product development, manufacturing and U.S. regulatory submissions while Genzyme was responsible for sales, marketing, distribution, obtaining reimbursement for Aldurazyme worldwide and international regulatory submissions. After the restructuring of our relationship, as discussed in *Recent Developments*, above, the operational responsibilities for us and Genzyme have not significantly changed. Genzyme will continue to globally market and sell Aldurazyme and we will continue to manufacture Aldurazyme. As of January 1, 2008, instead of sharing all costs and profits equally through the 50/50 joint venture, Genzyme will record sales of Aldurazyme and will pay us a quarterly tiered royalty ranging from approximately 39.5 to 50 percent of worldwide net product sales. As a result of the restructuring of the joint venture, we expect to record product revenue related to the royalty as well as product revenue related to incremental product delivered to Genzyme to meet future product demand. 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 2007 totaled $123.7 million, compared to $96.3 million for 2006. Aldurazyme net revenue recorded by our joint venture for 2005 totaled $76.4 million.

Products in Clinical Development

PEG-PAL (formerly referred to as Phenylase) is an investigational enzyme substitution therapy. It is being developed as a subcutaneous injection and is intended for those who do not respond to Kuvan. In preclinical models, PEG-PAL produced a rapid, dose-dependent reduction in blood phenylalanine (Phe) levels, the same endpoint that was used in the Kuvan studies. We plan to conduct additional preclinical studies of PEG-PAL in 2008, and to initiate a Phase 1 open-label, single-dose, dose-escalation clinical trial of PEG-PAL for PKU in 2008, with clinical trial results expected in the first quarter of 2009, depending on trial enrollment rates.

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.

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 fourth quarter of 2008, depending on trial enrollment rates. In May 2007, we announced the initiation of a Phase 2 clinical trial of 6R-BH4 for sickle cell disease, which is a 16-week, multi-center, open label, dose-escalation study. We expect results from the Phase 2 clinical trial in the second half of 2008. We plan to initiate several additional preclinical and clinical studies of BH4 for indications related to endothelial dysfunction in 2008.

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Manufacturing

We manufacture Naglazyme and Aldurazyme, which are both recombinant enzymes, in our approved Good Manufacturing Practices (GMP) production facility located in Novato, California. Vialing and packaging 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 next five years.

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.

Kuvan is manufactured on a contract basis. There are two approved manufacturers of the active pharmaceutical ingredient (API) for Kuvan. In general, we expect to continue to contract with outside service providers for certain manufacturing services, including final product vialing and packaging operations for our recombinant enzymes and API production and tableting for Kuvan. Third-party manufacturers facilities are subject to periodic inspections confirming compliance with applicable law and must be GMP certified. We believe that our current agreements with third party manufacturers provide for ample operating capacity to support the anticipated commercial demand for Kuvan. In certain instances, there is only one approved contract manufacturer for certain aspects of the manufacturing process. In such cases, we attempt to prevent disruption of supplies through supply agreements, maintaining safety stock and other appropriate strategies. Although we have never experienced a disruption in supply from our contract manufacturers, we cannot provide assurance that we will not experience a disruption in the future.

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, Latin America and Turkey. For other selected markets, we have signed agreements with other companies to act as distributors of Naglazyme. Most of these agreements generally grant the distributor the right to market the product in the territory and the obligation to secure all necessary regulatory approvals for commercial or named patient sales. 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. that markets Naglazyme and Kuvan and in the E.U. that markets Naglazyme. We believe that the size of our sales force is appropriate to effectively reach our target audience in markets where Naglazyme and Kuvan are 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.

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

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restructuring of our relationship with Genzyme, effective January 1, 2008, Genzyme has the exclusive right to distribute, market and sell Aldurazyme globally and is required to purchase its requirements exclusively from us. See *Recent Developments* for information regarding the restructuring of our relationship with Genzyme.

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 2007, sales to our three 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	56%
Uno Healthcare	7%
Med Supplies	5%
	68%

Despite the significant concentration of customers, the demand for Naglazyme is driven primarily 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 generally 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.

Our Kuvan customers include a limited number of specialty pharmacies which dispense to patients. Due to the pricing of Kuvan and the limited number of patients, the specialty pharmacies carry a limited inventory.

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 and PEG-PAL

There are currently no other 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 PEG-PAL 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

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PEG-PAL. 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 one other company that produces forms of 6R-BH4 (or BH4) for sale outside of Japan, and that BH4 has been used in certain instances for the treatment of PKU. We do not believe, but cannot know for certain, that this company is 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., this company 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 258, including approximately 37 patents issued by the U.S. Patent and Trademark Office (USPTO). Furthermore, our portfolio of pending patent applications totals approximately 261 applications, including approximately 47 pending U.S. applications.

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 producing and purifying such ultrapure *N*-acetylgalactosamine-4-sulfatase compositions. A second U.S. 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.

We have five 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

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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 Japanese application is still pending and is being prosecuted by the applicants. Claims in the related Canadian application have recently issued. 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.

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.

The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time consuming.

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the

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preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee. In 2008 the application fee for NDAs requiring clinical data will be $1,178,000. Manufacturers and/or sponsors under an approved new drug application are also subject to annual product and establishment user fees. In 2008, product and establishment fees will be $65,030 and $392,700 per product and establishment, respectively. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review,

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evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included. It is not unusual, however, for the FDA to reject an application because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30

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months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Fast Track Designation

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which

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demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor s request.

In addition to other benefits such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track drug s NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under the FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA s criteria for priority review.

Accelerated Approval

Under the FDA s accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2)

applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be

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stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the Food and Drug Administration Amendments Act, or the FDAAA, was enacted into law, amending both the FDC Act and the Public Health Service Act. The FDAAA makes a number of substantive and incremental changes to the review and approval processes in ways that could make it more difficult or costly to obtain approval for new pharmaceutical products, or to produce, market and distribute existing pharmaceutical products. Most significantly, the law changes the FDA s handling of postmarket drug product safety issues by giving the FDA authority to require post approval studies or clinical trials, to request that safety information be provided in labeling, or to require an NDA applicant to submit and execute a Risk Evaluation and Mitigation Strategy, or REMS.

The FDAAA also reauthorized the authority of the FDA to collect user fees to fund the FDA s review activities and made certain changes to the user fee provisions to permit the use of user fee revenue to fund the FDA s drug safety activities and the review of Direct-to-Consumer (DTC) advertisements.

The FDAAA also reauthorized and amended the Pediatric Research Equity Act, or PREA. The most significant changes to PREA are intended to improve FDA and applicant accountability for agreed upon pediatric assessments.

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.

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. 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

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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.

Regulation in the European Union

Drugs are also subject to extensive regulation outside of the United States. In the E.U., for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in Europe). If this procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under two simplified application processes, the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

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 10 years in the E.U.

Employees

As of February 8, 2008, we had 525 full-time employees, 243 of whom are in operations, 130 of whom are in research and development, 81 of whom are in sales and marketing and 71 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.

Other Information

Our principal executive offices are located at 105 Digital Drive, Novato, California 94949 and our telephone number is (415) 506-6700. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, proxy statements, 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 U.S. Securities and Exchange Commission (SEC). Such reports and other information may be obtained by visiting the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. 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 or any other report that we file with or furnish to the SEC.

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 in very substantial research and development and have operated at a net loss for the entire time. Based on our current business plans, we expect to

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continue to operate at an annual net loss at least until 2008. Our future profitability depends on our marketing and selling of Naglazyme and Kuvan, the successful commercialization of Aldurazyme by Genzyme, 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 ability to successfully market and sell Kuvan;
- Genzyme s ability to successfully commercialize Aldurazyme;
- the progress, timing and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems, and to build or acquire manufacturing capabilities;
- the time and cost necessary to respond to technological and market developments;
- any changes made to or new developments in our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and
- whether our convertible debt is converted to common stock in the future.

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, 2007 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

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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.

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

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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. Kuvan has received regulatory approval to be commercially marketed and sold in the U.S. 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

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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 facilities 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. In addition, our third-party manufacturers facilities involved with the manufacture of Naglayzme, Kuvan and Aldurazyme have also been inspected and approved by various regulatory authorities.

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 manner. For the same reason, any potential third-party manufacturer of Naglazyme, Kuvan and 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 and we may lose potential revenue. We also rely on third parties for portions of the manufacture of Naglazyme and Aldurazyme. If

those manufacturers are unwilling or unable to fulfill their contractual obligations, we may be unable to meet demand for these products or sell these products at all 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.

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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 our expected success rate and yield expectations. 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 take corrective action in response to any failure in a timely manner.

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.

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, Kuvan and Aldurazyme commercialization efforts, revenue from the sale of Naglazyme, Kuvan and Aldurazyme could be seriously impaired. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

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.

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Any interruption in the supply of finished products could hinder our ability to distribute finished products to meet commercial demand.

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, Kuvan 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, Kuvan 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.

A significant portion of our international sales are made based on special access programs, and changes to these programs could adversely affect our product sales and revenue in these countries.

We make a significant portion of our international sales of Naglazyme through special access or named patient programs, which do not require full product approval. The specifics of the programs vary from country to country. Generally, special approval must be obtained for each patient. The approval normally requires an

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application or suit accompanied by evidence of medical need. Generally, the approvals for each patient must be renewed from time to time.

These programs are not well defined in some countries and are subject to changes in requirements and funding levels. Any change to these programs could adversely affect our ability to sell product in those countries and delay sales. If the programs are not funded by the respective government, there could be insufficient funds to pay for all patients.

Without the special access programs we would need to seek full product approval to commercially market and sell the products. This can be an expensive and time-consuming process. Because the number of patients is so small in some countries, it may not be economically feasible to seek and maintain a full product approval, and therefore the sales in such country would be permanently reduced or eliminated. For all of these reasons, if the special access programs that we are currently using are eliminated or restricted, our revenues could be adversely affected.

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.

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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 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.

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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 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, Brazil and Turkey. 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 or if foreign jurisdictions successfully challenge our interpretation of local taxation.

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

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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, Kuvan, Aldurazyme or PEG-PAL.

We own or license patents and patent applications related to Naglazyme, Kuvan, Aldurazyme 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

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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 and a related patent has issued in Canada. If we are not able to successfully challenge these patents or a related patent in Japan, if it issues, 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 cover 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. A corresponding Canadian patent recently issued and covers enzyme, pharmaceutical composition, nucleic acid encoding the enzyme, host and cell vector. We believe that these patents, and the Japanese patent application, 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 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. and Canada (or in Japan, should a patent issue in that country.)

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, which was subsequently acquired by Shire PLC, 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.

Pursuant to the restructuring of our relationship Genzyme, either party may terminate the Manufacturing, Marketing and Sales Agreement (MMS Agreement) for specified reasons, including if the other party is in

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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 this agreement and we believe that Genzyme is not currently in breach of this 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 MMS Agreement is terminated for breach, the breaching party will transfer its interest in the LLC to the non-breaching party, and the non-breaching party will pay a specified buyout amount for the breaching party s interest in Aldurazyme and in the LLC. If we are the breaching party, we would lose our rights to Aldurazyme and the related intellectual property and regulatory approvals. If the MMS Agreement 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 Aldurazyme and in the LLC at a specified buyout amount. If such option is not exercised, all rights to Aldurazyme will be sold and the LLC will be dissolved. 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 between Genzyme and us in accordance with our percentage interest in the LLC.

If the MMS Agreement is terminated by either party because the other declared bankruptcy, the terminating party would be obligated to buy out the other and would obtain all rights to Aldurazyme exclusively. If the MMS Agreement 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 Aldurazyme and the LLC 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 Aldurazyme and the LLC on those same terms. The party who buys out the other would then have exclusive rights to Aldurazyme. The Amended and Restated Collaboration Agreement between us and Genzyme will automatically terminate upon the effective date of the termination of the MMS Agreement and may not be terminated independently from the MMS Agreement.

If we were obligated, or given the option, to buy out Genzyme s interest in Aldurazyme and the LLC, 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

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

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

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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, 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. 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

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claims in connection with the commercial use of Orapred, our clinical trials and commercial use of Naglazyme, Kuvan and Aldurazyme, or our clinical trials for BH4 or PEG-PAL, 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 Kuvan;
- manufacture, supply or distribution of Naglazyme, Aldurazyme or Kuvan;
- progress of our product candidates through the regulatory process;
- 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 Global 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.

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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.

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Item 2. Properties

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

Location	Approximate Square Feet	Use	Lease expiration date
Several locations in Novato, California	163,000	Corporate headquarters, office and laboratory	2008-2014
Galli Drive facility, Novato, California	70,000	Clinical and commercial manufacturing and laboratory	NA: owned property
Bel Marin Keys facility, Novato, California	85,400	Technical operations, office and laboratory	NA: owned property

Our administrative office space and plans to develop additional space are expected to be adequate for the foreseeable future. In addition to the above, we also maintain small offices in London, England, Sao Paulo, Brazil and Istanbul, Turkey. During 2008 and beyond, we plan to expand the capacity of our production facilities in order to meet future market demands and product development requirements. We believe that, to the extent required, we will be able to lease or buy 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, 2007.

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Part II

Item 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is listed under the symbol BMRN on both the Nasdaq Global 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 Global Market.

		Prices	
Year	Period	High	Low
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
2007	First Quarter	$ 20.53	$ 15.53
2007	Second Quarter	$ 19.00	$ 15.95
2007	Third Quarter	$ 25.00	$ 17.63
2007	Fourth Quarter	$ 37.17	$ 24.81

On February 19, 2008, the last reported sale price on the Nasdaq Global Market for our common stock was $40.12. We have never paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

Equity Compensation Plans

We incorporate information regarding the securities authorized for issuance under our equity compensation plans into this section by reference from the section captioned Equity Compensation Plans in the proxy statement for our 2008 annual meeting of stockholders.

Issuer Purchase of Equity Securities

We did not make any purchases of our common stock during the three months ended December 31, 2007, which is the fourth quarter of our fiscal year.

Holders

As of February 19, 2008, there were 77 holders of record of 97,381,263 outstanding shares of our common stock. Additionally, on such date, options to acquire 11,404,027 shares of our common stock were outstanding.

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Performance Graph

The following is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation by reference language in such filing.

The following graph compares the cumulative total stockholder return with the cumulative total return of the Nasdaq Composite Index (U.S.) and the Nasdaq Biotechnology Index, assuming a $100 investment in BioMarin s common stock on December 31, 2002 and reinvestment of dividends during the period. Our common stock is traded on the Nasdaq Global Market and is a component of both the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock.

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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, 2003, 2004, 2005, 2006 and 2007 and balance sheet data as of December 31, 2003, 2004, 2005, 2006 and 2007 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)				
	2003	2004	2005	2006	2007
Consolidated statements of operations data:					
Revenues:					
Net product sales	$	$ 18,641	$ 13,039	$ 49,606	$ 86,802
Collaborative agreement revenues	12,100		12,630	18,740	28,264
Royalty and license revenues				15,863	6,515
Total revenues	12,100	18,641	25,669	84,209	121,581
Operating expenses:					
Cost of sales (excludes amortization of developed product technology)		3,953	2,629	8,740	18,359
Research and development	53,932	49,784	56,391	66,735	78,600
Selling, general and administrative	15,278	37,606	41,556	48,507	77,539
Amortization of acquired intangible assets		3,987	1,144	3,651	4,371
Acquired in-process research and development		31,453			
Impairment of acquired intangible assets		68,251			
Total operating expenses	69,210	195,034	101,720	127,633	178,869
Loss from operations	(57,110)	(176,393)	(76,051)	(43,424)	(57,288)
Equity in the (loss) income of BioMarin/Genzyme LLC	(18,693)	(2,972)	11,838	19,274	30,525
Interest income	2,559	2,466	1,861	12,417	25,932
Interest expense	(3,131)	(10,544)	(11,918)	(13,411)	(14,243)
Debt conversion expense				(3,315)	
Net loss from continuing operations	(76,375)	(187,443)	(74,270)	(28,459)	(15,074)
Gain on disposal of discontinued operations	577				
Loss before income taxes	(75,798)	(187,443)	(74,270)	(28,459)	(15,074)
Income taxes				74	729
Net loss	$ (75,798)	$ (187,443)	$ (74,270)	$ (28,533)	$ (15,803)

Net loss per share, basic and diluted:					
Net loss from continuing operations	$ (1.23)	$ (2.91)	$ (1.08)	$ (0.34)	$ (0.16)
Gain on disposal of discontinued operations	0.01				
Net loss per share, basic and diluted	$ (1.22)	$ (2.91)	$ (1.08)	$ (0.34)	$ (0.16)
Weighted average common shares outstanding, basic and diluted	62,125	64,354	68,830	84,582	95,878

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	December 31, (in thousands)				
	2003	2004	2005	2006	2007
Consolidated balance sheet data:					
Cash, cash equivalents and short-term investments	$ 206,357	$ 48,815	$ 47,792	$ 288,847	$ 585,594
Total current assets	213,262	85,159	68,941	334,224	644,297
Total assets	256,340	232,966	195,303	463,436	815,279
Long-term liabilities, net of current portion	125,672	230,890	232,398	299,589	566,010
Total stockholders equity (deficit)	117,853	(67,978)	(77,462)	117,802	187,726

You should read the following tables presenting our unaudited quarterly results of operations in conjunction with the consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. We have prepared this unaudited information on the same basis as our audited consolidated financial statements. 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.

	Quarter ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data) (unaudited)			
2007:				
Total revenue	$ 22,838	$ 28,884	$ 25,006	$ 44,853
Net (loss) income	(9,293)	(3,864)	(5,216)	2,570
Net (loss) income per share, basic	(0.10)	(0.04)	(0.05)	0.03
Net (loss) income per share, diluted	(0.10)	(0.04)	(0.05)	0.03
Common stock price per share:				
High	20.53	19.00	25.00	37.17
Low	15.53	15.95	17.63	24.81
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

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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 three approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, and Kuvan. Additionally, we have rights to receive 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 2007 totaled $86.2 million compared to $46.5 million for 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 2007 totaled $123.7 million, compared to $96.3 million for 2006. Effective January 2008, we restructured our relationship with Genzyme as discussed in Item 1 of this Form 10-K.

Kuvan was granted marketing approval in the U.S. in December 2007. Kuvan net product sales for the approximate two-week period after approval and launch in December 2007 were $0.4 million.

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

We are developing several product candidates for the treatment of genetic diseases including: PEG-PAL, a preclinical enzyme substitution therapy for the treatment of the more severe form of PKU. We are developing PEG-PAL 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 peripheral arterial disease and sickle cell disease.

Key components of our results of operations for the years ended December 31, 2005, 2006 and 2007, include the following:

	2005	2006	2007
Total net product sales	$ 13,039	$ 49,606	$ 86,802
Collaborative agreement revenue	12,630	18,740	28,264
Research and development expense	56,391	66,735	78,600
Selling, general and administrative expense	41,556	48,507	77,539
Net loss	(74,270)	(28,533)	(15,803)
Orapred acquisition-related expenses	6,703	8,336	8,898
Stock-based compensation expense	327	9,590	18,283

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See Results of Operations for discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, short-term investments and cash balances related to long-term debt totaled $585.6 million as of December 31, 2007 compared to $288.8 million as of December 31, 2006.

Critical Accounting Policies and Estimates

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

Impairment of Long-Lived Assets

Our long-lived assets include our investment in BioMarin/Genzyme LLC, property, plant and equipment, 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, 2006 and 2007.

We currently operate in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, we assess whether goodwill should be allocated to operating levels lower than our single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. Currently, we have identified only one reporting unit as per SFAS No. 142, *Goodwill and Other Intangible Assets* . The amount of our goodwill originated from the acquisition of the Orapred business in 2004. 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 triggering events occurred during 2007 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.

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As a result of the restructuring of our joint venture with Genzyme, we have realized most of our investment in the joint venture as of December 31, 2007, through the distribution of cash and inventory in February 2008. We expect that our remaining ongoing investment in the joint venture will include our investment in the joint venture cash on hand to fund certain research and development activities related to Aldurazyme and intellectual property management. Management believes that the ongoing investment in the joint venture will be recoverable.

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 2007 and Orapred product sales through March 2006, revenues from our collaborative agreement with Merck Serono and revenues from our Orapred sublicense agreement.

Naglazyme and Kuvan product sales We recognize revenue from Naglazyme and Kuvan 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. Our 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 and Kuvan are 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 distributors and also to hospitals, which act as end-users. Because of the pricing of our products, the limited number of patients and the customers limited return rights, Naglazyme customers and retailers generally carry a very limited inventory. We also sell our products to certain larger pharmaceutical wholesalers, which, with respect to Naglazyme and Kuvan, act as intermediaries between us and end-users and generally do not stock quantities of Naglazyme and Kuvan. Accordingly, we expect that sales related to our product 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 to Naglazyme. Based on these factors, management has concluded that Naglazyme and Kuvan product returns will

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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, our historical experience with rebates and returns specific to Naglazyme serves as a reasonable basis for our estimates of rebates and returns for both Naglazyme and Kuvan. Management uses, 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 to Naglazyme. 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. We were able to leverage our experience with Naglazyme to determine our estimates for Kuvan, while also considering factors unique to the Kuvan product. 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 and Kuvan to derive net sales are described in the table below.

Revenue Dilution Item	Percentage of Gross Sales	Description
Rebates	2-4%	Rebates payable to state Medicaid, other government programs and certain managed care providers
Distributor fees	3-5%	Fees paid to authorized distributors
Cash Discounts	1-2%	Discounts offered to customers for prompt payment of accounts receivable
Total	6-11%	

We maintain a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of Naglazyme and Kuvan customers to make required payments. As of December 31, 2007, we had not experienced any bad debts and had no allowance for doubtful accounts. However, since we cannot predict changes in the financial stability of our customers, we cannot guarantee that allowances will not be required in the future. If we begin to experience credit losses, our operating expenses would increase.

Orapred product sales As a result of our sublicense of North American rights to 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

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product s rebate history adjusted to reflect known and forecasted changes in the factors that impact such reserves. These factors included changes in the mix of prescriptions that were eligible for rebates, changes in the contract rebate rates and the lag time related to the processing of rebate claims by our customers and managed care organizations. The length of time between the period of prescriptions and the processing of the related rebates was consistent historically at between three and nine months, depending on the nature of the rebate. The length of time between the period of original sale by us and the processing of the related rebate is dependent upon both the length of time that the product is in the distribution channel and the lag time related to rebate processing by third parties. Additionally, we experienced longer than usual rebate processing lag times as a result of the transition of the product from Medicis after the acquisition and high levels of Orapred inventory held by wholesalers. In the first quarter of 2006, our liability for certain rebates was reduced due to the sublicense of North American rights for Orapred to a third party. The decrease in estimated future rebates resulted in reserve reversals and an increase in net revenue of approximately $1.3 million for the year ended December 31, 2006. No significant adjustments were made to these reserves during 2007. To the extent actual rebates differ from our estimates, additional reserves may be required or reserves may need to be reversed.

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

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

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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. The Orapred product had not experienced significant credit losses.

Revenue Dilution Item	Estimated Rate	Description
Sales Returns	3-4%	Provision for returns of product sales, mostly due to product expiration
Rebates	8-9%	Rebates offered to managed care organizations and state Medicaid programs
Cash Discounts	2%	Discounts offered to customers for prompt payment of accounts receivable
Total	13-15%	

Collaborative agreement revenues Collaborative agreement revenues from 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 for 2007 includes the portion of the $25.0 million up-front license fee received from Merck Serono recognized as revenue during the development period and the $15.0 million milestone payment related to the EMEA acceptance of the Kuvan filing. Milestone payments related to our collaborative agreements are recognized in full when the related milestone performance goal is achieved and we have no further performance obligations related to that payment.

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 for the treatment of PKU, at which point our performance obligations to Merck Serono 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 reduced license revenues in 2007 by $0.6 million, and is expected to 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. As Kuvan advances through the European 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.

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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, 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.

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. 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. We also received a milestone payment of $4.0 million in June 2007 for the one-year anniversary of FDA approval of Orapred ODT. Although the receipt of the $4.0 million payment was based solely on the passage of time from FDA approval, the Company did not recognize the payment during the twelve-month period following approval because the fee was not considered to be fixed or determinable until the due and payable date. In making this determination, management considered the extended one-year payment term and the related uncertain future product sales and the Company s lack of experience with Sciele.

Inventory

We value inventories at the lower of cost or net realizable 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 to costs of sales. 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 regulatory approval for Kuvan was received in December 2007, and costs related to the manufacturing of those products 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 and Kuvan, prior to regulatory approval, were not capitalized as inventory. When regulatory approval was obtained in May 2005 for Naglazyme and in December 2007 for Kuvan, we began capitalizing inventory at the lower of cost or fair value for the respective products. Stock-based compensation of $1.0 and $1.7 million was capitalized into Naglazyme and Kuvan inventory for the years ended December 31, 2006 and 2007, respectively.

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Research and Development

Research and development expenses include expenses associated with contract research and development provided by third parties, product manufacturing prior to regulatory approval, clinical and regulatory costs, and internal research and development costs. In instances where 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.

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 Statements 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.

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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 $294.4 million at December 31, 2007. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. 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. However, as our revenues increase and approaches profitability, this assumption may change in the near future as the ultimate realizability of the deferred tax assets becomes more certain.

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, 2007 decreased by $12.7 million, to $15.8 million, from $28.5 million for the year ended December 31, 2006. Net loss for 2007 decreased primarily as a result of the following (in millions):

Net loss for the period ended December 31, 2006	$ (28.5)
Increased Naglazyme gross profit	28.5

Milestone revenue related to the Kuvan EMEA filing	15.0
Decreased other collaborative agreement revenues	(5.5)
Increased profits from BioMarin/Genzyme LLC	11.3
Decreased net Orapred profits, including license revenues	(10.5)
Increased research and development expense	(11.9)
Increased selling, general and administrative expense	(29.0)
Increased interest income	13.5
Absence of debt conversion expense	3.3
Increase in corporate overhead and other	(2.0)
Net loss for the period ended December 31, 2007	$ (15.8)

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The increase in Naglazyme gross profit during 2007 as compared to 2006 is primarily the result of additional patients initiating Naglazyme therapy in the U.S., E.U. and other countries. The decrease in collaborative agreement revenues primarily relates to lower reimbursable Kuvan spend. The increase in selling, general and administrative expense was primarily due to the continued international expansion of our Naglazyme commercialization and preparation for commercializing Kuvan. The decrease in Orapred profits primarily relates to the timing of the milestone payments under the Orapred sublicense. See below for additional information related to the primary net loss fluctuations presented above, including details of our operating expense fluctuations.

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
Increased selling, general and administrative expense	(11.2)
Increased research and development expense	(5.0)
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.

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

Net Product Sales and Gross Profit

Net product sales increased $37.2 million to $86.8 million in 2007 from $49.6 million in 2006. Net product sales in 2007 primarily included $86.2 million of net product sales of Naglazyme and $0.4 million of net product sales of Kuvan. Net product sales in 2006 of $49.6 million included $46.5 million of net product sales of Naglazyme and $3.1 million of net product sales of Orapred. We expect net product sales of Naglazyme and Kuvan 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 2007 were $86.2 million, of which $68.7 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 $4.3 million in 2007. Gross profit from Naglazyme in 2007 was approximately $67.9 million, representing gross margins of approximately 79% as compared to $39.4 million in 2006, 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,

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some of the product sold in 2006 had an insignificant cost basis and therefore lower cost of goods sold was reported. 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. Similarly, a significant amount of Kuvan inventory that will be sold in 2008 was manufactured as part of the development cycle for Kuvan and was previously expensed, and therefore will have either zero or nominal cost of goods sold. Substantially all of the Naglazyme inventory with an insignificant cost basis has been sold or used in clinical trials as of December 31, 2007.

During the year ended December 31, 2006 we recognized net product sales of $3.1 million related to the Orapred product line, as compared to $6.9 million for the year ended December 31, 2005. 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 on Kuvan and 6R-BH4 for other indications increases or decreases, contract research revenues may 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 2006 and 2007 were $18.7 million and $28.3 million, respectively, and includes the amortization of $7.4 million and $6.9 million, respectively, of the up-front license fee received from Merck Serono and recognized as revenue during the period, and $11.3 million and $6.4 million, respectively, of reimbursable Kuvan development costs incurred during the period. Collaborative agreement revenues in 2007 also include the $15.0 million milestone payment received from Merck Serono upon EMEA acceptance of the Kuvan filing that was recognized as revenue during the period.

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 $6.5 million in 2007, include a $4.0 million milestone payment related to the one-year anniversary of FDA approval of the marketing application for Orapred ODT. Royalty and license revenues, 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 2007, we recognized $2.3 million in royalty revenues from Orapred product sold by the sublicensee, as compared to $1.6 million during 2006. There were no royalty and license revenues during 2005.

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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 $11.9 million to $78.6 million for the year ended December 31, 2007, from $66.7 million for the year ended December 31, 2006. Research and development expenses changed for the year ended December 31, 2007 primarily as a result of the following (in millions):

Research and development expenses for the year ended December 31, 2006	$ 66.7
Decreased Naglazyme development expenses	(1.1)
Decreased Kuvan clinical trial and manufacturing costs	(7.6)
Increased 6R-BH4 development costs for endothelial dysfunction	3.6
Increased PEG-PAL development costs	8.4
Increased stock-based compensation expense	3.4
Absence of milestone payments to third party co-developer for approval and launch of Orapred ODT	(3.2)
Increase in research and development expense on early stage programs	2.0
Non-allocated research and development expense and other changes	6.4
Research and development expenses for the year ended December 31, 2007	$ 78.6

The increase in 6R-BH4 development costs is related to increases for the ongoing pre-clinical studies of 6R-BH4 in other indications including endothelial dysfunction and costs related to planning and conducting Phase 2 clinical trials in peripheral arterial disease and sickle cell disease. The increase in PEG-PAL development costs is related to increases for pre-clinical studies and manufacturing costs. The decrease in Kuvan clinical trial and manufacturing costs is primarily due to decreased clinical trial and manufacturing expenses approaching marketing approval, which was received in December 2007. However, we expect to continue incurring significant Kuvan research and development costs for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments. The increase in research and development on other programs primarily includes increases in facilities costs, general research costs and research and development personnel. We expect research and development expense to increase in future periods, primarily as a result of spending on our 6R-BH4 program for other indications and on our PEG-PAL program.

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 PEG-PAL development costs	2.3
Stock-based compensation expense	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 was primarily due to increased clinical trial expenses due to the continuation of the Phase 3 clinical trials. The increase in 6R-BH4 development costs was related to increases for pre-clinical studies of 6R-BH4 in endothelial dysfunction and costs related to a Phase 2

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clinical trial of 6R-BH4 for poorly controlled hypertension and peripheral arterial disease. The decrease in Naglazyme development costs was 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 $29.0 million, to $77.5 million for the year ended December 31, 2007, from $48.5 million for the year ended December 31, 2006. The components of the increase for the year ended December 31, 2007 primarily include the following (in millions):

Selling, general and administrative expenses for the year ended December 31, 2006	$ 48.5
Increased Naglazyme sales and marketing expenses	8.4
Increased stock-based compensation expense	5.3
Increased Kuvan commercial preparation costs	7.8
Net increase in corporate overhead and other administrative costs	7.5
Selling, general and administrative expenses for the year ended December 31, 2007	$ 77.5

We initiated commercial operations in the E.U. and South America during 2006 and incurred related costs during 2007 primarily related to the commercialization of Naglazyme. During 2007, we also incurred significant expenses related to the preparation for the Kuvan commercial launch. The increase in stock-based compensation expense is the result of an increased number of options outstanding and a higher average stock price on the related grant date. The increase in corporate overhead and other administrative costs is primarily related to increases in salaries and benefits due to the company s significant growth in headcount. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme and Kuvan.

Selling, general and administrative expenses increased by $6.9 million, to $48.5 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	5.3
Increased Kuvan commercial preparation costs	2.2
Net increase in corporate overhead and other administrative costs	2.7
Selling, general and administrative expenses for the year ended December 31, 2006	$ 48.5

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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. The increase in Naglazyme sales and marketing expenses relates to additional costs associated with the world-wide commercial launch and increased U.S. commercial activities. The decrease in Orapred sales and marketing expenses is primarily attributable to the decrease in sales and marketing efforts during 2006 following the reduction in the Orapred sales force in July 2005. The increase in corporate overhead and other administrative costs is primarily related to increases in facilities costs, accounting costs and insurance.

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 2007 was $4.4 million, compared to $3.7 million for 2006. The increase in amortization expense is due to the change in expected useful life as the amortization period was revised from 15 years to 3.5 years following the sublicense of North American rights to Orapred in March 2006. Following our expected purchase of the common stock of Ascent Pediatrics from Medicis in August 2009, the underlying intellectual property will be transferred to Sciele. We expect that the annual amortization expense associated with the intangible assets will be approximately $4.4 million in 2008 and $2.9 million through the end of the expected useful life in August 2009.

Equity in the Income of BioMarin/Genzyme LLC

Equity in the Income of BioMarin/Genzyme LLC includes our 50% share of the joint venture s income for the period. Equity in the income of BioMarin/Genzyme LLC was $30.5 million for 2007, compared to $19.3 million for 2006. The increase in profit from BioMarin/Genzyme LLC in 2007 was principally due to increases in Aldurazyme net revenue, which totaled $123.7 million for 2007, compared to $96.3 million for 2006.

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.

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

Interest Income

We invest our cash and short-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income increased to $25.9 million for 2007, from $12.4 million for 2006, primarily due to higher interest rates and increased levels of cash and investments during 2007.

Interest income increased to $12.4 million in 2006, from $1.9 million in 2005, primarily due to higher interest rates and increased 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 $14.2 million for 2007, as compared to $13.4 million for 2006, representing an increase of $0.8 million. The decrease in 2007 is primarily due to the lack of interest expense related to our 3.5% Senior Subordinated Convertible Notes due in 2008, which were converted into common stock in two separate transactions in September 2006 and January 2007. This decreased interest expense was partially offset by

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increased interest expense on our $324.9 million of 1.875% senior subordinated convertible notes due in 2017 that were issued in April 2007.

In April 2007, we sold $324.9 million of 1.875% Senior Subordinated Convertible Notes due 2017. As a result of the Company s net increase in convertible debt balances, we expect interest expense to increase in future periods.

The decline in imputed interest expense was due to a lower outstanding balance of the acquisition obligation in 2007. Imputed interest expense totaled $4.5 million for 2007, as compared to $4.7 million for 2006.

Interest expense was $13.4 million and $11.9 million in 2006 and 2005, respectively, representing an increase of $1.5 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. In 2006 and 2005, the imputed interest related to the Ascent Pediatrics transaction was $4.7 million and $5.4 million, respectively.

Debt Conversion Expense

In September 2006, certain holders of our 3.50% Convertible Senior Subordinated Notes due in 2008 agreed to convert $73.6 million in aggregate principal amount of the notes to approximately 5.25 million shares of our common stock. As a result of the conversion, we agreed to pay an inducement to the holders of approximately $3.3 million, which was recognized as additional expense during 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.

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. Substantially all of the differences have been eliminated as of December 31, 2007. Effective January 1, 2008, the Company restructured its relationship with its joint venture partner, Genzyme, regarding the manufacturing, marketing and sale of Aldurazyme.

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 $123.7 million of net revenue for 2007, compared to $96.3 million for 2006. The increase in net revenue of $27.4 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 $96.8 million for 2007, as compared to $73.1 million for 2006, representing an increase of $23.7 million. Gross margins for 2007 were approximately 78%, as compared to gross margins for 2006 of 76%.

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The increase in gross margin during 2007 compared to 2006 is attributable to exchange rate benefits. The increase in gross margin in 2007 is attributable to the effect of foreign currency rate fluctuations on Aldurazyme sales.

Operating Expenses

Operating expenses of the joint venture include the costs associated with the development and commercial support of Aldurazyme and totaled $36.5 million for 2007, as compared to $35.3 million for 2006. Operating expenses in 2007 included $23.9 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme, and $11.8 million of research and development costs, primarily long-term clinical trial and regulatory costs. Operating expenses in 2006 included $22.2 million of selling, general and administrative expenses associated with the commercial launch of Aldurazyme, and $13.1 million of research and development expenses, primarily clinical trial costs.

Operating expenses in 2005 totaled $36.9 million and included $22.0 million of selling, general and administrative expenses associated with the commercial support of Aldurazyme and $14.9 million of research and development costs, primarily long-term clinical trial costs.

Liquidity and Capital Resources

Cash and Cash Flow

As of December 31, 2007, our combined cash, cash equivalents and short-term investments totaled $585.6 million, an increase of $296.8 million from $288.8 million at December 31, 2006. During 2007, we received $316.4 million of net proceeds from a public offering of convertible senior subordinated notes, distributions from the joint venture of $17.1 million, $4.0 million in milestone payments for the one-year anniversary of the FDA approval of Orapred ODT and $15.0 million in milestone payments for the EMEA acceptance of the Kuvan filing. During 2006, we received $127.4 million of net proceeds from a public offering of common stock, $166.9 million of net proceeds from a public offering of convertible senior subordinated notes, distributions from the joint venture of $19.8 million and $14.0 million of proceeds related to our sublicense of North American rights for Orapred.

The $296.8 million increase in cash, cash equivalents, short-term investments and restricted cash during 2007 includes net proceeds from the public offering of convertible debt of $316.4 million. Excluding the net offering proceeds, the decrease in cash, cash equivalents, and short-term investments during 2007 was $19.5 million, which was $50.9 million less than the net decrease in cash, cash equivalents, short-term investments and restricted cash during 2006 of $70.4 million, excluding net offering proceeds of $294.3 million. The primary items contributing to the decrease in net cash outflow, excluding the net offering proceeds, in 2007 were as follows (in millions):

Decreased capital asset purchases	$ 2.2
Absence of conversion premium and accrued interest payment	4.1
Decreased license proceeds related to sublicense of North American Orapred rights	(10.0)
Absence of milestone payment for the approval and launch of Orapred ODT	3.2
Absence of net repayments of equipment and facility loans	20.9
Decreased cash flows from BioMarin/Genzyme LLC	(2.7)
Increased proceeds from stock option exercises	2.1
Receipt of milestone payment for acceptance of Kuvan MAA filing by the EMEA	15.0

Net decreased operating spend, including net payments for working capital, and other	16.1
Total decrease in net cash outflow excluding net offering proceeds	$ 50.9

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The net decreased operating spend includes increases in cash receipts from net revenues partially offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in the Results of Operations section above. Decreases in net payments for working capital in 2007 primarily include decreased inventory build of $6.8 million, decreased accounts receivable build of $6.5 million and increased accounts payable and accrued liabilities build of $1.2 million.

Our combined cash, cash equivalents, short-term investments and cash balances related to long-term debt increased $224.0 million in 2006 to $288.8 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 included 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 in 2006 included 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 included Naglazyme inventory and accounts receivable.

We expect that our net cash outflow in 2008 related to capital asset purchases will increase significantly compared to 2007. The expected increase in capital asset purchases primarily includes a planned expansion of our manufacturing facility, increased spending on manufacturing and lab equipment, expansion of our corporate campus including leasehold improvements and the continued development of 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, 2007, we have not made any draws on the note. We do not anticipate that we will draw funds from this note.

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 2008, and for the foreseeable future, we will be highly dependent on our net product revenue 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.

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Funding Commitments

We expect to fund our operations with our net product revenues from Naglazyme, Aldurazyme and Kuvan, cash, cash equivalents and short-term investments supplemented by proceeds from equity or debt financings, 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 and for potential licenses and acquisitions of complementary technologies, products and companies.

Our investment in our product development programs has a major impact on our operating performance. Our research and development expenses for the years ended December 31, 2005, 2006 and 2007 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

	2005	2006	2007	Since Program Inception
Naglazyme	$ 20.6	$ 9.7	$ 8.8	$ 113.0
Kuvan	22.7	27.4	19.9	79.0
6R-BH4 for other indications, including endothelial dysfunction	3.5	8.9	15.0	27.4
PEG-PAL	2.2	4.5	13.2	20.2
Not allocated to specific major current projects	7.4	16.2	21.7	156.6
	$ 56.4	$ 66.7	$ 78.6	$ 396.2

We cannot estimate the cost to complete any of our product development programs. Additionally, except as disclosed under Overview above, we cannot estimate the time to complete any of our product development programs or when we expect to receive net cash inflows from any of our product development programs. Please see Risk Factors in 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.

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

- our ability to successfully market and sell Naglazyme and Kuvan;
- Genzyme s ability to successfully market and sell Aldurazyme;
- the progress, timing, scope and results of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems and to build or acquire manufacturing capabilities;
- the time and cost necessary to respond to technological and market developments;
- any changes made to or new developments in our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and
- whether our convertible debt is converted to common stock in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our financial position or results of operations.

Borrowings and Contractual Obligations

In April 2007, we sold approximately $324.9 million of senior subordinated convertible debt due April 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately $20.36 per share, subject to adjustment in certain circumstances. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2017. We also must repay the debt if there is a qualifying change in control or termination of trading of its common stock. In March 2006, we sold approximately $172.5 million of senior subordinated convertible notes due 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2013. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately $16.58 per share, subject to adjustment in certain circumstances. However, we must repay the debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock. Our $497.4 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

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 $80.1 million through 2009, of which $6.5 million is payable in 2008. At our option, we may elect to pay Medicis $8.6 million of the amounts due in 2009 through the issuance of our common stock.

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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, 2007 is presented below (in thousands).

	Payments Due by Period					
	2008	2009	2010-2011	2012-2013	2014 and Thereafter	Total
Medicis obligations	$ 6,500	$ 73,600	$	$	$	$ 80,100
Convertible debt and related interest	10,404	10,404	20,808	191,152	346,195	578,963
Operating leases	2,874	2,898	5,746	4,746	40	16,304
Research and development and purchase commitments	34,139	1,307	541	483	1,185	37,655
Total	$ 53,917	$ 88,209	$ 27,095	$ 196,381	$ 347,420	$ 713,022

The purchase commitments above include $11.5 million, which is net of a $0.5 million deposit paid in 2007, related to a purchase agreement for an office and laboratory facility in January 2008 related to our corporate expansion. We are also subject to contingent payments related to various development activities totaling approximately $62.2 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 $1.1 million and $1.4 million related to Aldurazyme during 2006 and 2007, 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.

As of December 31, 2007, our investment portfolio does not include any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at December 31, 2007, 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 $5.9 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.

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The table below presents the carrying value of our cash and investment portfolio, which approximates fair value at December 31, 2007 (in thousands):

	Carrying Value
Cash and cash equivalents	$ 228.3*
Short-term investments	357.3**
Total	$ 585.6

* 9% of cash and cash equivalents invested in money market funds, 71% in commercial paper, 14% in repurchase agreements and 6% of uninvested cash.

** 3% of short-term investments invested in U.S. agency securities, 25% in corporate securities and 72% 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, 2007.

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, and in the future our royalty on Aldurazyme sales, 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, 2007, we had net outstanding foreign exchange forward contracts to sell $13.7 million, comprised of sell contracts of $15.0 million of equivalent Euros and $4.2 million of equivalent British Pounds and buy contracts of $5.5 million of equivalent Euros, all of which have a term of less than 3 months. As of December 31, 2007, the weighted average settlement rate for our Euro and British Pound denominated contracts was 1.46 and 1.99, 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, 2007, approximately $1.0 million of loss has been included in our statement of consolidated earnings with respect to these forward exchange contracts, as compared to loss of $0.3 million for the year ended December 31, 2006. The notional settlement value of foreign currency forward contracts outstanding was $12.9 million at December 31, 2006.

At December 31, 2007, we had cash of approximately $3.0 million denominated in foreign country currencies, which represented approximately 1% 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, 2007, 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 $0.6 million. We expect to enter into new transactions based in foreign currencies that could be impacted by changes in exchange rates.

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Item 8. Financial Statements and Supplementary Data

The information required to be filed in this item appears on pages F-1 to F-39 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 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, 2007. 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, 2007 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 the effectiveness of our internal control over financial reporting. The attestation report of KPMG LLP is 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 2007 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

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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.

Item 9B. Other Information

None.

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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 2008 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 2008 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 2008 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 2008 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 2008 annual meeting of stockholders.

Part IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

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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-K, which is incorporated herein by reference.

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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	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.
4.4	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.
4.5	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.

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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 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.
10.14	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.
10.15	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.
10.16	Employment Agreement with Jeffrey H. Cooper, dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.17	Employment Agreement with Emil D. Kakkis, M.D., Ph.D., dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.18	Employment Agreement with Robert A. Baffi, Ph.D., dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.19	Employment Agreement with Stephen Aselage, dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.20	Employment Agreement with Stuart J. Swiedler, M.D., Ph.D., dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.21	Employment Agreement with G. Eric Davis, dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by this reference.
10.22	Employment Agreement with Mark Wood, dated July 16, 2007, previously filed with the Commission on August 9, 2007 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by this reference.
10.23	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.
10.24	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.

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10.25	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.
10.26	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.
10.27	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.
10.28	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.
10.29	License Agreement between BioMarin Pharmaceutical Inc. and Women s and Children s Hospital dated February 7, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q, 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.
10.30*	Manufacturing, Marketing and Sales Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.31*	Amended and Restated Collaboration Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.32*	Members Agreement dated as of January 1, 2008 by and among BioMarin Pharmaceutical Inc., Genzyme Corporation, BioMarin Genetics Inc., and BioMarin/Genzyme LLC. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
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.

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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, 2007 and 2006, and for the years ended December 31, 2007, 2006 and 2005.

* Filed herewith.

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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, 2008

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, 2008
/s/ Jeffrey H. Cooper **Jeffrey H. Cooper**	Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2008
/s/ Pierre LaPalme **Pierre LaPalme**	Chairman and Director	February 27, 2008
/s/ Elaine Heron **Elaine Heron**	Director	February 27, 2008
/s/ Joseph Klein, III	Director	February 27, 2008

Joseph Klein, III		
/s/ ALAN J. LEWIS	Director	February 27, 2008
Alan J. Lewis		
/s/ MICHAEL G. GREY	Director	February 27, 2008
Michael G. Grey		
/s/ RICHARD A. MEIER	Director	February 27, 2008
Richard A. Meier		
/s/ V. BRYAN LAWLIS	Director	February 27, 2008
V. Bryan Lawlis		

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INDEX TO BIOMARIN PHARMACEUTICAL INC.

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

BioMarin Pharmaceutical Inc.:

We have audited the accompanying consolidated balance sheets of BioMarin Pharmaceutical Inc. and subsidiaries (the Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, changes in stockholders equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2007. 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 II based on our audits. We did not audit the financial statements of BioMarin/Genzyme LLC (a 50 percent owned joint venture) for the years 2007, 2006 and 2005. The Company s investment in BioMarin/Genzyme LLC (in thousands) at December 31, 2007 and 2006 was $44,881 and $31,457, respectively, and its equity in income of BioMarin/Genzyme (in thousands) was $30,525, $19,274 and $11,838 for the years ended December 31, 2007, 2006 and 2005, respectively. The financial statements of BioMarin/Genzyme LLC for those years 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 those years, 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 audit 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, 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, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule II, 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 3 to the Consolidated Financial Statements, effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2007, 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, 2008, expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

(signed) KPMG LLP

San Francisco, California

February 27, 2008

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

BioMarin Pharmaceutical Inc.:

We have audited BioMarin Pharmaceutical Inc. and subsidiaries (the Company) internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company 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, included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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, BioMarin Pharmaceutical Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

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. as of December 31, 2007 and 2006, and the related consolidated statements of operations, changes in stockholders equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2007, and our report dated February 27, 2008, expressed an unqualified opinion on those consolidated financial statements. Our report was based on our audit and the report of other auditors.

(signed) KPMG LLP

San Francisco, California

February 27, 2008

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2006 and 2007

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

	December 31, 2006	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 89,162	$ 228,343
Short-term investments	199,685	357,251
Accounts receivable, net	14,670	16,976
Advances to BioMarin/Genzyme LLC	1,596	2,087
Inventory	25,075	32,445
Other current assets	4,036	7,195
Total current assets	334,224	644,297
Investment in BioMarin/Genzyme LLC	31,457	44,881
Property, plant and equipment, net	55,466	76,818
Intangible assets, net	11,655	9,596
Goodwill	21,262	21,262
Restricted cash	1,731	2,889
Other assets	7,641	15,536
Total assets	$ 463,436	$ 815,279
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 32,166	$ 49,907
Current portion of acquisition obligation, net of discount	6,787	6,309
Current portion of deferred revenue	7,092	5,327
Total current liabilities	46,045	61,543
Convertible debt	223,940	497,375
Long-term portion of acquisition obligation, net of discount	68,548	66,553
Deferred revenue, net of current portion	5,023	
Other long-term liabilities	2,078	2,082
Total liabilities	345,634	627,553
Stockholders equity:		
Common stock, $0.001 par value: 150,000,000 and 250,000,000 shares authorized at December 31, 2006 and December 31, 2007, respectively; 91,725,528 and 97,114,159 shares issued and outstanding at December 31, 2006 and December 31, 2007, respectively	92	97
Additional paid-in capital	709,359	794,917
Accumulated other comprehensive (loss) income	(25)	139

Accumulated deficit	(591,624)	(607,427)
Total stockholders equity	117,802	187,726
Total liabilities and stockholders equity	$ 463,436	$ 815,279

See accompanying notes to consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2005, 2006 and 2007

(In thousands, except for per share data)

	December 31,		
	2005	2006	2007
Revenues:			
Net product sales	$ 13,039	$ 49,606	$ 86,802
Collaborative agreement revenues	12,630	18,740	28,264
Royalty and license revenues		15,863	6,515
Total revenues	25,669	84,209	121,581
Operating expenses:			
Cost of sales (excludes amortization of developed product technology)	2,629	8,740	18,359
Research and development	56,391	66,735	78,600
Selling, general and administrative	41,556	48,507	77,539
Amortization of acquired intangible assets	1,144	3,651	4,371
Total operating expenses	101,720	127,633	178,869
Loss from operations	(76,051)	(43,424)	(57,288)
Equity in the income of BioMarin/Genzyme LLC	11,838	19,274	30,525
Interest income	1,861	12,417	25,932
Interest expense	(11,918)	(13,411)	(14,243)
Debt conversion expense		(3,315)	
Loss before income taxes	(74,270)	(28,459)	(15,074)
Provision for income taxes		74	729
Net loss	$ (74,270)	$ (28,533)	$ (15,803)
Net loss per share, basic and diluted	$ (1.08)	$ (0.34)	$ (0.16)
Weighted average common shares outstanding, basic and diluted	68,830	84,582	95,878

See accompanying notes to consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT) AND COMPREHENSIVE INCOME (LOSS)

For the Years ended December 31, 2005, 2006 and 2007 (in thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders equity (deficit)
	Shares	Amount				
Balance at January 1, 2005	64,501	$ 65	$ 421,141	$ (363)	$ (488,821)	$ (67,978)
Net loss					(74,270)	(74,270)
Fair market value adjustments of available-for-sale investments				346		346
Foreign currency translation adjustment				1		1
Comprehensive loss						(73,923)
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
Stock compensation expense related to modification of awards			327			327
Balance at December 31, 2005	74,302	$ 75	$ 485,570	$ (16)	$ (563,091)	$ (77,462)
Net loss					(28,533)	(28,533)
Fair market value adjustments of available-for-sale investments				23		23
Foreign currency translation adjustment				(32)		(32)
Comprehensive loss						(28,542)
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
Stock-based compensation			10,596			10,596
Balance at December 31, 2006	91,726	$ 92	$ 709,359	$ (25)	$ (591,624)	$ 117,802
Net loss					(15,803)	(15,803)
Fair market value adjustments of available-for-sale investments				62		62
Foreign currency translation adjustment				102		102
Comprehensive loss						(15,639)
Issuance of common stock under ESPP	275		1,928			1,928

Exercise of common stock options	1,443	1	13,291		13,292
Conversion of convertible notes	3,670	4	50,925		50,929
Stock-based compensation			19,414	&nb	