BIOMARIN PHARMACEUTICAL INC
Form 10-K
February 26, 2010
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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, 2009

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, including area code: (415) 506-6700

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 Select Market
Preferred Share Purchase Rights	

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ 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 the definitions of large accelerated filer accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ (Do not check if a smaller reporting company) 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: 101,131,358 shares common stock, par value $0.001, outstanding as of February 17, 2010. The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2009 was $758.5 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 12, 2010, are incorporated by reference into Part III.

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BIOMARIN PHARMACEUTICAL INC.

2009 FORM 10-K ANNUAL REPORT

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Part I.

FORWARD LOOKING STATEMENTS

This Annual Report on 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, pote and similar expressions. These forward-looking statements may be found in *Risk Factors*, *Business*, and other sections of this Annual Report on 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 Annual Report on 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 Annual Report on 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 Annual Report Form 10-K, investors should carefully consider the following discussion and the information under *Risk Factors* when evaluating us and our business.

Item 1. Business

Overview

BioMarin Pharmaceutical Inc. (BioMarin, we, us or our) develops and commercializes innovative pharmaceuticals 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 four approved products and multiple investigational product candidates. Approved products include Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride) tablets, Aldurazyme (laronidase) and Firdapse (amifampridine phosphate).

We are conducting clinical trials on several investigational product candidates for the treatment of genetic diseases including: GALNS, an enzyme replacement therapy for the treatment of Mucopolysaccharidosis Type IV or Morquio Syndrome Type A, or MPS IV A, PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonurics that are not responsive to Kuvan, and a small molecule for the treatment of Duchenne muscular dystrophy. In September 2009, we initiated a Phase 2 clinical trial to evaluate PEG-PAL in patients with Phenylketonuria, or PKU. Results from this clinical trial are expected in the third quarter of 2010. In the first half of 2009, we initiated a phase 1/2 clinical trial of GALNS for the treatment of MPS IV A. We have completed enrollment in this clinical trial and expect to report initial results from this clinical trial in the first half of 2010. In January 2010, we initiated a Phase 1 trial of our small molecule for the treatment of Duchenne muscular dystrophy. Initial top-line results from this trial are expected in the third quarter of 2010.

We are conducting preclinical development of several other enzyme product candidates for genetic and other metabolic diseases, including BMN-185, an IgA protease for IgA nephropathy, and BMN-103, a glucosidase for Pompe disease.

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A summary of our various commercial products and major development programs, including key metrics as of December 31, 2009, is provided below:

Program	Indication	Orphan Drug Designation	Stage	2009 Total Net Product Revenues (in millions)	2009 Research & Development Expense (in millions)
Naglazyme	MPS VI (1)	Yes	Approved	$ 168.7	$ 9.8
Aldurazyme (2)	MPS I (3)	Yes	Approved	$ 70.2	$ 1.3
Kuvan	PKU (4)	Yes	Approved	$ 76.8	$ 11.5
Firdapse (5)	LEMS (6)	Yes	Approved in the European Union only	N/A	$ 0.5
GALNS for Morquio Syndrome Type A	MPS IVA	Yes	Clinical	N/A	$ 17.7
PEG-PAL	PKU	Yes	Clinical	N/A	$ 11.2
BMN-195 for Duchenne muscular dystrophy	DMD (7)	Not yet determined	Clinical	N/A	$ 3.4

(1) Mucopolysaccharidosis VI, or MPS VI.
(2) The Aldurazyme total product revenue noted above is the total product revenue recognized by us in accordance with the terms of our restructured agreement with Genzyme Corporation (Genzyme). See *Commercial Products Aldurazyme* below for further discussion.
(3) Mucopolysaccharidosis I, or MPS I.
(4) Phenylketonuria, or PKU.
(5) Marketing approval from the European Medicines Agency (EMEA) for Firdapse was granted in December 2009. We expect to begin sales of Firdapse in the European Union in March 2010.
(6) Lambert Eaton Myasthenic Syndrome, or LEMS.
(7) Phase 1 clinical trial initiated in January 2010.

Recent Developments

Acquisition of Huxley Pharmaceuticals, Inc.

On October 20, 2009, BioMarin entered into a stock purchase agreement with Huxley Pharmaceuticals, Inc., or Huxley, and the stockholders of Huxley to acquire all of the outstanding shares of capital stock of Huxley. Huxley had the rights to a proprietary form of 3,4-diaminopyridine, or 3,4-DAP, amifampridine phosphate, which we have branded as Firdapse, for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome, or LEMS. Under the terms of the stock purchase agreement, on October 23, 2009, we purchased all of the capital stock of Huxley for an upfront cash payment to the stockholders of Huxley of $15.0 million and an additional $1.0 million upon receipt of U.S. Food and Drug Administration, or FDA, orphan drug designation for Firdapse in LEMS, and will pay an additional $6.5 million to the Huxley stockholders for final EMEA approval of Firdapse in LEMS granted in December 2009. Additionally, Huxley stockholders are eligible to receive up to approximately $36.0 million in milestone payments if certain annual, cumulative sales and U.S. development milestones are met.

Firdapse Marketing Approval in the European Union and Orphan Drug Designation in the U.S.

In December 2009, the EMEA granted marketing approval for 3,4-DAP for LEMS. We will sell our proprietary form of 3,4-DAP under the brand name Firdapse. Firdapse, which was developed by AGEPS, the pharmaceutical unit of the Paris Public Hospital Authority, or AP-HP, and sublicensed from EUSA Pharma SAS, or EUSA, is the first approved treatment for LEMS, thereby conferring orphan drug protection and providing ten years of market exclusivity in Europe. We expect to begin sales of Firdapse in the European Union, or EU in March of 2010. We also announced in November 2009 that the FDA

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had granted orphan drug designation for Firdapse. We plan to meet with the FDA in the first half of 2010 to determine the regulatory path for Firdapse in the U.S.

Acquisition of LEAD Therapeutics, Inc.

On February 4, 2010, we announced that we entered into a stock purchase agreement with LEAD Therapeutics, Inc., or LEAD, and the stockholders of LEAD to acquire all of the outstanding shares of capital stock of LEAD. LEAD is a small private drug discovery and early stage development company with a key compound LT-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with some genetically defined cancers. Under the terms of the stock purchase agreement, on February 10, 2010, we purchased all of the capital stock of LEAD for an upfront cash payment to the stockholders of LEAD of $18.0 million and will pay the stockholders an additional $11.0 million upon acceptance of the investigational new drug application, or IND filing expected by the end of 2010 and up to $68.0 million for development and launch milestones for LT-673, which we now refer to as BMN-673.

Commercial Products

Naglazyme

Naglazyme is a recombinant form of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) indicated for patients with mucopolysaccharidosis VI, or 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, or 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 EU in January 2006. Naglazyme has been granted orphan drug status in the U.S. and the EU, which confers seven years of market exclusivity in the U.S. and ten years of market exclusivity in the EU 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., EU, Latin America, Turkey, and parts of the Middle East and North Africa 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 2009 totaled $168.7 million, as compared to $132.7 million for 2008. Naglazyme net product sales for 2007 were $86.2 million.

Kuvan

Kuvan is a proprietary synthetic oral form of 6R-BH4, a naturally occurring enzyme co-factor for phenylalanine hydroxylase, or PAH, indicated for patients with PKU. Kuvan is the first drug for the treatment of PKU, which 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, or 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.

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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 confers seven years of market exclusivity in the U.S for the treatment of PKU, expiring in 2014. Kuvan net product sales for 2009 were $76.8 million, as compared to $46.7 million for 2008. Kuvan net product sales for the two-week period after approval and launch in December 2007 were $0.4 million.

In July 2008, we announced that Asubio Pharma Co., Ltd., a subsidiary of Daiichi Sankyo, received marketing approval from the Japanese Ministry of Health, Labour and Welfare for a label extension of biopterin (sapropterin dihydrochloride), which contains the same active ingredient as Kuvan in the U.S., for the treatment of patients with PKU. We received a milestone payment of $1.5 million for this marketing approval and are receiving double-digit royalties on net sales of biopterin for the PKU indication in Japan under an exclusive license that we entered into with Asubio in September 2007 for data and intellectual property contained in the Kuvan new drug application.

In May 2005, we entered into an agreement with Merck Serono for the further development and commercialization of Kuvan (and any other product containing 6R-BH4) and PEG-PAL for PKU. Through the agreement, as amended in 2007, Merck Serono acquired exclusive rights to market these products in all territories outside the U.S., Canada and Japan, and we retained exclusive rights to market these products in the U.S. and Canada. We and Merck Serono currently share equally all development costs following successful completion of Phase 2 clinical trials for each product candidate in each indication. On December 9, 2008, we announced that Merck Serono had received marketing approval in the EU for Kuvan for the treatment of PKU. We earned a $30.0 million milestone payment from Merck Serono in the fourth quarter of 2008 as a result of the approval of Kuvan in the EU. The commercial launch of Kuvan in the EU took place in second quarter of 2009. Over the next several years, we expect to receive from Merck Serono a royalty of approximately 4% on net sales of Kuvan in the EU. We also sell Kuvan to Merck Serono at near cost, and Merck Serono resells the product to end-users outside the U.S., Canada and Japan. The royalty earned from Kuvan product sold by Merck Serono in the EU is included as a component of net product revenues in the period earned. In 2009, we earned $0.3 million in net royalties on net sales of $6.9 million of Kuvan in the EU. We recorded collaborative agreement revenue associated with Kuvan in the amounts of $2.4 million in 2009, $38.9 million in 2008 and $28.3 million in 2007.

Aldurazyme

Aldurazyme has been approved for marketing in the U.S., EU and other countries for patients with mucopolysaccharidosis I, or MPS I. MPS I, a progressive and debilitating life-threatening genetic disease for which no other drug treatment currently exists, is caused by the deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of GAGs. Patients with MPS I typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body. These symptoms include: inhibited growth, delayed and regressed mental development (in the severe form), enlarged liver and spleen, joint deformities and reduced range of motion, impaired cardiovascular function, upper airway obstruction, reduced pulmonary function, frequent ear and lung infections, impaired hearing and vision, sleep apnea, malaise and reduced endurance.

Aldurazyme has been granted orphan drug status in the U.S. and the EU, which gives Aldurazyme seven years of market exclusivity in the U.S. and ten years of market exclusivity in the EU 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 in January 2008, as discussed below, 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.

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On January 3, 2008, we announced the restructuring of our relationship with Genzyme, regarding the manufacturing, marketing and sale of Aldurazyme. Under the previous 50/50 structure, each company shared 50% of the expense associated with the product and received 50% of the profit through its interest in the joint venture.

Effective January 1, 2008, Genzyme, the joint venture limited liability company founded by Genzyme and BioMarin (the LLC) and we amended and restated our collaboration agreement. The LLC no longer engages in commercial activities related to Aldurazyme and its sole activities are to (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.

As a result, Genzyme records sales of Aldurazyme and is required to pay us, on a quarterly basis, a 39.5% to 50% royalty on worldwide net product sales. In addition, we recognize product transfer revenue when product is released to Genzyme and all of our obligations have been fulfilled. Genzyme s return rights for Aldurazyme are limited to defective product. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty when the product is sold by Genzyme.

Aldurazyme net product revenues totaled $70.2 million for 2009, as compared to $72.5 million for 2008. The net product revenues for 2009 and 2008 include $61.8 million and $60.1 million, respectively, of royalty revenue on net Aldurazyme sales by Genzyme. Royalty revenue from Genzyme is based on 39.5% to 44.0% of net Aldurazyme sales by Genzyme, which totaled $155.1 million for 2009 and $151.3 million for 2008. Incremental Aldurazyme net product transfer revenue of $8.4 million and $12.4 million for 2009 and 2008, respectively, reflect incremental shipments of Aldurazyme to Genzyme to meet future product demand. In the future, to the extent that Genzyme Aldurazyme inventory quantities on hand remain consistent, we expect that our total Aldurazyme revenues will approximate the 39.5% to 50% royalties on net product sales by Genzyme.

Firdapse

We acquired the rights to Firdapse in October 2009 by acquiring Huxley Pharmaceuticals, Inc. See *Recent Developments Acquisition of Huxley Pharmaceuticals, Inc.* above for further discussion. Firdapse, a proprietary form of 3,4-DAP (amifampridine phosphate) was developed by AGEPS, the pharmaceutical unit of the Paris Public Hospital Authority, or AP-HP, and sublicensed by Huxley from EUSA in April 2009. Firdapse was granted marketing approval in the EU in December 2009. In addition, Firdapse has been granted orphan drug status for the treatment of LEMS in the EU, which confers ten years of market exclusivity in the EU. We expect to begin sales of Firdapse in the EU in March of 2010.

LEMS is a rare autoimmune disease with the primary symptoms of muscle weakness. Muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels leading to a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at four to ten per million, or approximately 2,000 to 5,000 patients in the EU and 1,200 to 3,100 patients in the U.S. Approximately 50% of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. The weakness is generally more marked in the proximal muscles particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with

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swallowing. Patients often report a dry mouth, impotence, constipation and feelings of light headedness on standing. On occasion these problems can be life threatening when the weakness involves respiratory muscles. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyography testing and the presence of auto antibodies against voltage gated calcium channels. Current treatment of LEMS can consist of strategies directed at the underlying malignancy, if one is present. Unfortunately, therapy of small cell lung cancer is limited and outcomes are generally poor. Immunosuppressive agents have been tried but success is limited by toxicity and difficulty administering the regimens. A mainstay of therapy has been 3,4-DAP, but its use in practice has been limited by the drug s availability.

Products in Clinical Development

We are also developing GALNS, an enzyme replacement therapy for the treatment of MPS IV A. In November 2008, we announced the initiation of a clinical assessment program for patients with MSP IVA Syndrome. We initiated a Phase 1/2 clinical trial of GALNS in the first half of 2009. The Phase 1/2 study is designed as an open-label, within-patient dose escalation trial in approximately 20 patients followed by a treatment continuation phase. During the dose escalation phase of the study, subjects will receive weekly intravenous infusions of GALNS in three consecutive 12-week dosing intervals. The objectives of the Phase 1/2 study will be to evaluate safety, pharmacokinetics, and pharmacodynamics and to identify the optimal dose of GALNS for future studies. We have completed enrollment in this clinical trial and expect to report initial results in the first half of 2010.

PEG-PAL is an investigational enzyme substitution therapy. It is being developed as a subcutaneous injection and is intended for those patients with PKU that do not respond to Kuvan. In preclinical models, PEG-PAL produced a rapid, dose-dependent reduction in blood phenylalanine, or Phe, levels, the same endpoint that was used in the Kuvan studies. In May 2008, we initiated a Phase 1 open-label, single-dose, dose-escalation clinical trial of PEG-PAL for PKU. The primary objective of the study was to assess the safety and tolerability of a single, subcutaneous injection of PEG-PAL in patients with PKU that do not respond to Kuvan. The secondary objectives of the study were to evaluate the pharmacokinetics of single, subcutaneous injections of PEG-PAL administered at escalating doses and to evaluate the effect of PEG-PAL on Phe concentrations in subjects with PKU. Clinical results were announced in June 2009. Significant reductions in blood Phe levels were observed in all patients in the fifth dosing cohort of the Phase 1 trial. In addition, there were no serious immune reactions observed and mild to moderate injection-site reactions were in line with our expectations. In September 2009, we initiated a Phase 2, open-label dose finding clinical trial of PEG-PAL. The primary objective of this clinical trial is to optimize the dose and schedule that produces the most favorable safety profile and Phe reduction. The secondary objectives of the clinical trial are to evaluate the safety and tolerability of multiple dose levels of PEG-PAL, to evaluate the immune response to PEG-PAL, and to evaluate steady-state phamacokinetics in all patients and accumulation of PEG-PAL in a subset of patients enrolled in this clinical trial. We expect clinical trial results in the third quarter of 2010.

We are developing a small molecule for the treatment of Duchenne muscular dystrophy and initiated a clinical trial in January 2010. This study is a Phase 1, single-center, double-blind, placebo-controlled single-dose escalation trial followed by a multiple-dose escalation study of our product administered orally in healthy volunteers. The primary objective is to assess the safety, tolerability and pharmacokinetics of our product in healthy volunteers, and enable subsequent studies in patients with DMD. We expect to receive the initial top-line results from this trial in the third quarter of 2010.

Manufacturing

We manufacture Naglazyme and Aldurazyme, which are both recombinant enzymes, in our approved Good Manufacturing Practices, or 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.

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Our facilities have been licensed by the FDA, the European Commission and health agencies in other countries for the commercial production of Aldurazyme and 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 by a third party. There are two approved manufacturers of the active pharmaceutical ingredient, or API, for Kuvan. Firdapse is manufactured on a contract basis by a third party. There is one approved manufacturer of the API for Firdapse.

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 and Firdapse. Third-party manufacturers facilities are subject to periodic inspections to confirm compliance with applicable law and must be GMP certified. We believe that our current agreements with third-party manufacturers and suppliers provide for ample operating capacity to support the anticipated commercial demand for Kuvan and Firdapse. 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 EU that markets Naglazyme and will market Firdapse. We believe that the size of our sales force is appropriate to effectively reach our target audience in markets where Naglazyme, Kuvan and Firdapse are directly marketed. We utilize third-party logistics companies to store and distribute Naglazyme, Kuvan and Firdapse.

Genzyme has the exclusive right to distribute, market and sell Aldurazyme globally and is required to purchase its requirements exclusively from us.

Customers

Our Naglazyme and Kuvan 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 distributors and to certain larger pharmaceutical wholesalers, which act as intermediaries between us and end-users and generally do not

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stock quantities of Naglazyme. During 2009, 49% of our net Naglazyme and Kuvan product revenues were generated by three customers. Genzyme is our sole customer for Aldurazyme and is responsible for marketing and selling Aldurazyme to third-parties.

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

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, Aldurazyme and GALNS for Morquio Syndrome Type A (MPS IV A)

We know of no active competitive program for enzyme replacement therapy for MPS VI, MPS I or MPS IV A that has entered clinical trials. However, we know of one other company that has a preclinical competitive product for MPS IV A. It is our understanding that this company has suspended its development efforts for technical and financial reasons.

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, MPS I or MPS IV A.

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 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 EU. 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 EU, 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.

Firdapse and LEMS

There are no other approved drugs for the treatment of LEMS. Current options rely on intravenous immunoglobulin, plasmapherisis and/or immuno suppressant drugs. In some countries, 3,4 DAP is available, as a

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base, through various compounding pharmacies or as a special or magistral formulation. Firdapse is the only approved version of 3,4 DAP. One other Aminopyridine, 4AP, is under development by another pharmaceutical company. However, this is for the treatment of fatigue associated with Multiple Sclerosis. The role of 4AP in LEMS is unproven and uncertain.

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 registrations, assignments, confidentiality agreements, material transfer agreements, research collaborations and licenses.

The number of our issued patents now stands at approximately 172, including approximately 35 patents issued by the U.S. Patent and Trademark Office, USPTO. Furthermore, our portfolio of pending patent applications totals approximately 402 applications, including approximately 60 pending U.S. applications.

With respect to Naglazyme, we have five issued patents, including a U.S. 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 own or have licensed a number of patents and pending patent applications that relate generally to formulations and forms of our drug substance, methods of use for various indications under development and dosing regimens. We have three issued U.S. patents with claims to a stable tablet formulation of BH4, methods of treating PKU using a once daily dosing regimen and administration of Kuvan with food.

We have 19 issued patents, including six U.S. 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. Three U.S. patents on alpha-L-iduronidase are owned by an affiliate of Women s and Children s Hospital Adelaide. We have examined such issued U.S. patents, the related U.S. and foreign applications and their file histories, the prior art and other information. Corresponding foreign applications were filed in Canada, Europe and Japan. The European application was rejected and abandoned and cannot be re-filed. After a failure to timely file a court challenge to the Japanese Board of Appeals decision upholding the final rejection of all claims in the corresponding Japanese application, the Japanese application has also lapsed and cannot be re-filed. Claims in the related Canadian application have recently issued. We believe that such patents 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. We believe that these patents and patent applications do not affect our ability to market Aldurazyme in Europe.

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, or FDC Act, the Medicaid rebate program, the Veterans Health Care Act of 1992 and the Occupational Safety and Health Act, among others.

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The FDC 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 FDA. 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 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, as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the 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 objected to 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

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indications, dosage tolerance and optimum dosage, and to 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 the 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 FDA has 60 days from its receipt of an 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 NDAs. 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 new information submitted during the review 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, 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 or cGMPs, 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, or a complete response letter. A complete response letter outlines 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 in a resubmission of the NDA, the FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual, however, for the FDA to issue a complete response letter 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 or FDA approved method of using this 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

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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 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 moiety, 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 evaluation and mitigation strategies, 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 cGMPs after approval. Drug manufacturers and certain of

their subcontractors are required to register their establishments with the FDA and certain state

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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 2007, 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 drug designation has been granted.

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.

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 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 that the FDA 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 submitted, if the drug candidate provides a significant improvement

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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.

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 FDA s finding of safety and efficacy data for an existing product, or published literature, in support of its application.

Section 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 for which the Section 505(b)(2) NDA applicant has submitted data.

To the extent that the Section 505(b)(2) applicant is relying on prior FDA findings of safety and efficacy, 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 Section 505(b)(2) NDA can be delayed 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) NDA 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 post market 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, or DTC, advertisements.

The FDAAA also reauthorized and amended the 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, Kuvan and Firdapse 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

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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 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 EU, for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the EU (which includes most major countries in Europe). If this procedure is not used, approval in one country of the EU can be used to obtain approval in another country of the EU 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 EU. Naglazyme, Aldurazyme and Kuvan received orphan medicinal product designation by the European Committee for Orphan Medicinal Products. Orphan 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 ten years in the EU.

Employees

As of February 6, 2010, we had 720 full-time employees, 331 of whom are in operations, 186 of whom are in research and development, 120 of whom are in sales and marketing and 83 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.

Research and Development

For information regarding research and development expenses incurred during 2007, 2008 and 2009, see Item 7, *Management Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expense* .

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Geographic Area Financial Information

Our chief operating decision maker (i.e., chief executive officer) reviews financial information on a consolidated basis, for the purposes of allocating resources and evaluating financial performance. There are no segment managers who are held accountable by the chief operating decision makers, or anyone else, for operations, operating results and planning for levels or components below the consolidated unit level. Accordingly, we consider ourselves to have a single reporting segment and operating unit structure.

Net product revenues by geography are based on patients locations for Naglazyme and Kuvan, and are based on Genzyme s U.S. location for Aldurazyme. The following table outlines revenues and long-lived assets by geographic area (in thousands):

	Year Ended December 31,		
	2007	2008	2009
Net product revenues:			
United States	$ 18,072	$ 140,418	$ 168,373
Europe	51,878	63,333	76,475
Latin America	6,409	25,250	35,528
Rest of the World	10,443	22,850	35,345
Total net product revenues	$ 86,802	$ 251,851	$ 315,721

Total revenue generated outside the U.S. was $75.1 million, $147.0 million and $150.7 million in the years ended December 31, 2007, 2008 and 2009, respectively.

	Year Ended December 31,	
	2008	2009
Long-lived assets:		
United States	$ 163,278	$ 246,160
International	4,088	33,427
Total long-lived assets	$ 167,366	$ 279,587

Other Information

We were incorporated in Delaware in October 1996 and began operations on March 21, 1997. 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 of 1934, as amended, or the 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, or 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.

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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, Aldurazyme and Kuvan have received regulatory approval to be commercially marketed and sold in the U.S., EU and other countries. Firdapse has received regulatory approval to be commercially marketed only in the EU. 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 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 the patient. 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, the value of our company and our operating results will be adversely affected. Additionally, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased.

If we fail to 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 EU 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 fewer 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 EU with a ten-year period of market exclusivity.

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

Even though we have obtained orphan drug designation for certain of our products and product candidates and even if we obtain orphan drug designation for our future product candidates, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any particular 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.

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 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, the results in humans may be significantly different. After we have conducted preclinical studies, 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 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 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 until 2008. Although we were profitable in 2008, we operated at a

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slight net loss in 2009. Depending on our future investments in research and development for existing and new programs; we could operate at an annual net loss for 2010 and possibly beyond. Our future profitability depends on our marketing and selling of Naglazyme, Kuvan and Firdapse, 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, our spending on our development programs and the impact of any possible future business development transactions. 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 our operations.

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 manufacturers, 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 Naglazyme, Kuvan, Firdapse 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, Aldurazyme and Firdapse or our product candidates may be unable to comply with GMP regulations in a cost effective manner.

If we, or 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 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, Kuvan and Firdapse;

Genzyme s ability to continue to successfully commercialize Aldurazyme;

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

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- 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, 2009 will be sufficient to meet our operating and capital requirements for the foreseeable future based on our current long-term business plans. These estimates are based on assumptions and estimates, which may prove to be wrong. We may need to raise additional funds from equity or debt securities, loans or collaborative agreements if we are unable to satisfy our liquidity requirements. The sale of additional securities may result in additional dilution to our stockholders. Furthermore, additional financing may not be available in amounts or on terms satisfactory to us or at all. This could result in the delay, reduction or termination of our research, which could harm our business.

If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities 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, malfunctions of internal information technology systems, and other events that cannot always be prevented or anticipated. 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

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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.

Although we have entered into contractual relationships with third-party manufacturers to produce the active ingredient in Kuvan and Firdapse, 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. We have contracts for the production of final product for Kuvan and are in final negotiations of a contract for the production of final product for Firdapse. 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 or satisfy demand outside of or in excess of the contractual obligations, we may be unable to meet demand for these products or sell these products at all and we may lose potential revenue. Further, the availability of suitable contract manufacturing capacity at scheduled or optimum times is not certain.

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

If 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 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 or Firdapse.

Our Galli Drive facility located in Novato, California 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 or Firdapse manufactured, could be seriously, or potentially completely impaired, and our Naglazyme, Kuvan, Aldurazyme and Firdapse commercialization efforts and revenue from the sale of Naglazyme, Kuvan, Aldurazyme and Firdapse could be seriously impaired. The insurance that we carry, the inventory that we maintain and our risk mitigation plans 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 harm our business by reducing 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, Kuvan and Firdapse 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 and manufacturing expenses.

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, Aldurazyme and Firdapse is expensive. We expect patients to need treatment for extended periods, and for some products throughout the lifetimes of the patients. 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 our products 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 EU 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 application or a lawsuit accompanied by evidence of medical need. Generally, the approvals for each patient must be renewed from time to time.

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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 our products 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. Further, governments have in the past undertaken and may in the future undertake, unofficial measures to limit purchases of our products, including initially denying coverage for purchasers, delaying orders and denying or taking excessively long to approve customs clearance. Any such actions could materially delay or reduce our revenues from such countries.

Without the special access programs, we would need to seek full product approval to commercially market and sell our products. This can be an expensive and time-consuming process and may subject our products to additional price controls. 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.

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 reimbursement may 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.

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. As part of these cost containment measures, some countries have imposed or threatened to impose revenue caps limiting the annual volume of sales of Naglazyme. To the extent that these caps are significantly below actual demand, our future revenues and gross margins may be adversely affected.

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.

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

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

Many states have adopted laws similar to the federal antikickback statute, some of which apply to referral of patients for health care services reimbursed by any source, not just governmental payers. In addition, California and several other states have passed laws that require pharmaceutical companies to comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the 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, other Latin America countries 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;

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- 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 or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed.

The patent positions of biopharmaceutical products are complex and uncertain. The scope and extent of patent protection for some of our products and product candidates are particularly uncertain because key information on some of our product candidates has existed in the public domain for many years. The composition and genetic sequences of animal and/or human versions of Naglazyme, Aldurazyme, and many of our product candidates have been published and are believed to be in the public domain. The chemical structure of BH4 and 3,4 diaminopyridine have also been published. Publication of this information may prevent us from obtaining or enforcing patents relating to our products and product candidates, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

We own or have licensed patents and patent applications related to Naglazyme, Kuvan, Aldurazyme and Firdapse 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 without limitation the following:

- With respect to pending patent applications, unless and until actually issued, the protective value of these applications is impossible to determine. 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 identical or similar methods, in which case we may not receive a granted patent.

- 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 we cannot practice our technology. Competitors may also contest our patents by showing the patent examiner or a court 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 or are unenforceable for a number of reasons. If a court agrees, we would not be able to enforce 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. We may not have the financial ability to sustain a patent infringement action, or it may not be financially reasonable to do so.

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Receipt of a patent may not provide much practical protection. For example, 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, competition may also seek intellectual property protection for their technology. Due to the amount of intellectual property in our field of technology, we cannot be certain that we do not infringe intellectual property rights of competitors or that we will not infringe intellectual property rights of competitors granted or created in the future. For example, if a patent holder believes our product infringes their patent, the patent holder may sue us even if we have received patent protection for our technology. If someone else claims we infringe their intellectual property, we would face a number of issues, including the following:

Defending a lawsuit, which takes significant time and resources and can be very expensive.

If a court decides that our product infringes a competitor s intellectual property, we may have to pay substantial damages.

With respect to patents, a court may prohibit us from making, selling, offering to sell, importing or using our 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, it may not be available on commercially reasonable terms. For example, we may have to pay substantial royalties or grant cross licenses to our patents and patent applications.

Redesigning our product so it does not infringe the intellectual property rights of competitors may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. 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, such as patent litigation, is expensive and time consuming, requires significant resources and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Furthermore, our competitors may independently develop equivalent knowledge, methods and know-how, in which case we would not be able to enforce our trade secret rights against such competitors.

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.

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 may be prohibited from making, using, importing, offering to sell or selling products requiring these licenses or rights. 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 Women s and Children s Hospital Adelaide 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. Corresponding foreign patent applications were filed in

Europe, Japan and Canada. The European patent application was rejected over prior art, was withdrawn and cannot be re-filed. The corresponding Japanese application was finally rejected by the Japanese Board of Appeals, lapsed after failure to timely file a court challenge, and cannot be re-filed. A corresponding Canadian

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patent issued and covers enzyme, pharmaceutical composition, nucleic acid encoding the enzyme, host cells and vectors. We believe that these patents are invalid or not infringed on a number of grounds. However, 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 marketing of Aldurazyme in the U.S. and Canada.

If our Manufacturing, Marketing and Sales Agreement with Genzyme were terminated, we could be barred from commercializing Aldurazyme or our ability to successfully commercialize Aldurazyme would be delayed or diminished.

Either party may terminate the Manufacturing, Marketing and Sales Agreement, or MMS Agreement, between Genzyme and us related to Aldurazyme for specified reasons, including if the other party is in material breach of the MMS, has experienced a change of control, or has declared bankruptcy and also is in breach of the MMS. Although we are not currently in breach of the MMS and we believe that Genzyme is not currently in breach of the MMS, there is a risk that either party could breach the MMS in the future. Either party may also terminate the MMS 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 party declared bankruptcy, the terminating party would be obligated to buy out the other party 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 party 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 thereby 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

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

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

If we fail to compete successfully with respect to acquisitions, joint ventures or 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, Kuvan and Firdapse. These collaborations include licensing proprietary technology from, and other relationships with, academic research institutions. Our future success will depend, in part, on our ability to identify additional opportunities and to successfully enter into partnering or acquisition agreements for those opportunities. 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 genetic diseases. These companies, including Genzyme, 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.

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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.

If we are unable to obtain an adequate supply of Firdapse or secure pricing and reimbursement for Firdapse in a timely manner, our commercial launch in the EU may be delayed in one or more countries and revenue would be adversely affected.

In December 2009, Firdapse was granted marketing approval in the EU for LEMS. We expect to begin sales of Firdapse in the EU in March of 2010. Firdapse is manufactured on a contract basis by a third party and there is one approved manufacturer of the API for Firdapse and one approved manufacturer for the final product. We do not have an established track record with either of these third parties responsible for the supply of Firdapse. Although we have entered into an agreement with a third party to produce the active ingredient in Firdapse and are in final negotiations of a contract for the production of the final product for Firdapse, we cannot provide assurance that we will not experience a disruption in supply which could cause our launch to be delayed in one or more countries. Further, if we are unable to adequately address supply disruptions after the commercial launch of Firdapse, we may be unable to meet commercial demand for Firdapse and will lose potential revenue. In addition, we have not secured pricing reimbursement for Firdapse in all countries. Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. If we are unable to obtain pricing reimbursement in all countries in the EU, our commercial launch in the EU may be delayed in one or more countries and our revenue would be adversely affected.

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

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

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

Product candidates that we are currently developing or may acquire in the future may be intended for patient populations that are significantly larger than any of MPS I, MPS VI, PKU or LEMS. In order to continue

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development and marketing of 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.

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

Even if our drug products are approved, 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 claims in connection with our clinical trials and commercial use of Naglazyme, Kuvan, Aldurazyme and Firdapse, or our clinical trials for PEG-PAL, GALNS and our small molecule for Duchenne muscular dystrophy, 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 business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases on to our customers due to the process by which health care providers are reimbursed for our products by the government. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations. We purchase or enter into a variety of transactions, including investments in commercial paper, the extension of credit to corporations, institutions and governments and enter into hedging contracts. If any of the issuers or counter parties to these instruments were to default on their obligations, it could materially

reduce the value of the transaction and adversely affect our cash flows.

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Interest rates and the ability to access credit markets could also adversely affect the ability of our customers/distributors to purchase, pay for and effectively distribute our products. Similarly, these macroeconomic factors could affect the ability of our contract manufacturers, sole-source or single-source suppliers to remain in business or otherwise manufacture or supply product. Failure by any of them to remain a going concern could affect our ability to manufacture products.

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, Kuvan and Firdapse;
- manufacture, supply or distribution of Naglazyme, Aldurazyme, Kuvan and Firdapse;
- 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., EU or in other parts of the world;
- 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 the Nasdaq Global Select Market. Listing on the exchange 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. In addition, the current decline in the financial markets and related factors beyond our control, including the credit and mortgage crisis in the U.S. and worldwide, may cause our stock price to decline rapidly and unexpectedly.

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

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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. Our board of directors approved an additional amendment to the stockholder rights plan in February 2009. As long as these rights are attached to our common stock, we will issue one right with each new share of common stock so that all shares of our common stock will have attached rights. When exercisable, each right will entitle the registered holder to purchase from us one two-hundredth of a share of our Series B Junior Participating Preferred Stock at a price of $35.00 per 1/200 of a Preferred Share, subject to adjustment.

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

Location	Approximate Square Feet	Use	Lease Expiration Date
Several locations in Novato, California	201,500	Corporate headquarters, office and laboratory	2011-2019
	70,000		

Galli Drive facility, Novato, California		Clinical and commercial manufacturing and laboratory	NA: owned property
Bel Marin Keys facility, Novato, California	85,400	Technical operations, finance, administration, and laboratory	NA: owned property

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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 Brisbane, California, London, England, Sao Paulo, Brazil, and Istanbul, Turkey. During 2010 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, 2009.

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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 the Nasdaq Global Select Market. The following table sets forth the range of high and low quarterly closing sales prices for our common stock for the periods noted, as reported by Nasdaq.

		Prices	
Year	Period	High	Low
2008	First Quarter	$ 40.39	$ 31.90
2008	Second Quarter	$ 39.72	$ 28.92
2008	Third Quarter	$ 32.55	$ 25.60
2008	Fourth Quarter	$ 26.29	$ 13.59
2009	First Quarter	$ 20.83	$ 10.14
2009	Second Quarter	$ 15.94	$ 11.92
2009	Third Quarter	$ 18.33	$ 13.86
2009	Fourth Quarter	$ 18.98	$ 15.49

On February 17, 2010, the last reported sale price on the Nasdaq Global Select Market for our common stock was $20.71. 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 2010 annual meeting of stockholders.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the year ended December 31, 2009.

Holders

As of February 17, 2010, there were 72 holders of record of 101,131,358 outstanding shares of our common stock. Additionally, on such date, options to acquire 13.8 million 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 we under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation by reference language in such filing.

The following graph shows the value of an investment of $100 on December 31, 2004 in BioMarin common stock, the Nasdaq Composite Index (U.S.) and the Nasdaq Biotechnology Index. All values assume reinvestment of the pretax value of dividends paid by companies included in these indices and are calculated as of December 31 of each year. Our common stock is traded on the Nasdaq Global Select 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.

	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09
BioMarin Pharmaceutical Inc.	100.00	168.70	256.49	553.99	278.56	294.37
NASDAQ Composite	100.00	101.33	114.01	123.71	73.11	105.61
NASDAQ Biotechnology	100.00	117.54	117.37	121.37	113.41	124.58

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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 consolidated statement of operations data for the years ended December 31, 2005, 2006, 2007, 2008 and 2009 and consolidated balance sheet data as of December 31, 2005, 2006, 2007, 2008 and 2009 from audited financial statements. Historical results are not necessarily indicative of results that we may experience in the future.

	Years ended December 31, (in thousands, except for per share data)				
	2005	2006	2007	2008	2009
Consolidated statements of operations data:					
Revenues:					
Net product revenues	$ 13,039	$ 49,606	$ 86,802	$ 251,851	$ 315,721
Collaborative agreement revenues	12,630	18,740	28,264	38,907	2,379
Royalty and license revenues		15,863	6,515	5,735	6,556
Total revenues	25,669	84,209	121,581	296,493	324,656
Operating expenses:					
Cost of sales	2,629	8,740	18,359	52,509	65,909
Research and development	56,391	66,735	78,600	93,291	115,116
Selling, general and administrative	41,556	48,507	77,539	106,566	124,290
Amortization of acquired intangible assets	1,144	3,651	4,371	4,371	2,914
Total operating expenses	101,720	127,633	178,869	256,737	308,229
Income (loss) from operations	(76,051)	(43,424)	(57,288)	39,756	16,427
Equity in the income (loss) of BioMarin/Genzyme LLC	11,838	19,274	30,525	(2,270)	(2,594)
Interest income	1,861	12,417	25,932	16,388	5,086
Interest expense	(11,918)	(13,411)	(14,243)	(16,394)	(14,090)
Debt conversion expense		(3,315)			
Impairment loss on equity investments				(4,056)	(5,848)
Net gain from sale of investments					1,585
Income (loss) before income taxes	(74,270)	(28,459)	(15,074)	33,424	566
Provision for income taxes		74	729	2,593	1,054
Net income (loss)	$ (74,270)	$ (28,533)	$ (15,803)	$ 30,831	$ (488)
Net income (loss) per share, basic	$ (1.08)	$ (0.34)	$ (0.16)	$ 0.31	$ (0.00)
Net income (loss) per share, diluted	$ (1.08)	$ (0.34)	$ (0.16)	$ 0.29	$ (0.00)

Weighted average common shares outstanding, basic	68,830	84,582	95,878	98,975	100,271
Weighted average common shares outstanding, diluted	68,830	84,582	95,878	103,572	100,271

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	December 31, (in thousands)				
	2005	2006	2007	2008	2009
Consolidated balance sheet data:					
Cash, cash equivalents and investments	$ 47,792	$ 288,847	$ 585,594	$ 561,425	$ 470,526
Total current assets	68,941	334,224	644,297	737,696	467,727
Total assets	195,303	463,436	815,279	906,695	917,163
Long-term liabilities, net of current portion	232,398	299,589	566,010	499,939	516,824
Total stockholders equity (deficit)	(77,462)	117,802	187,726	276,675	322,185

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. Our 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 (In thousands, except per share data, unaudited)			
	March 31	June 30	September 30	December 31
2009:				
Total revenue	$ 73,980	$ 82,787	$ 80,807	$ 87,082
Net income (loss)	(13,152)	1,312	6,640	4,712
Net income (loss) per share, basic	(0.13)	0.01	0.07	0.05
Net income (loss) per share, diluted	(0.13)	0.01	0.07	0.05
2008:				
Total revenue	$ 60,396	$ 64,174	$ 72,646	$ 99,277
Net income	1,686	3,810	829	24,506
Net income per share, basic	0.02	0.04	0.01	0.25
Net income per share, diluted	0.02	0.04	0.01	0.21

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

This Annual Report on 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, pote and similar expressions. These forward-looking statements may be found in *Overview*, and other sections of this Annual Report on 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* in this Annual Report on 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 Annual Report on 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 notes to those statements included elsewhere in this Annual Report on Form 10-K.

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 or offer a significant benefit over existing products. Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, Kuvan and Firdapse.

Naglazyme received marketing approval in the U.S. in May 2005, in the EU in January 2006, and subsequently in other countries. Naglazyme net product revenues for 2008 totaled $132.7 million and increased to $168.7 million for 2009.

Aldurazyme, which was developed in collaboration with Genzyme Corporation (Genzyme), has been approved for marketing in the U.S., EU and other countries. Prior to 2008, we developed and commercialized Aldurazyme through a joint venture with Genzyme. Pursuant to our arrangement with Genzyme, Genzyme sells Aldurazyme to third parties and we recognize royalty revenue on net sales by Genzyme. We recognize a portion of the royalty as product transfer revenue when product is released to Genzyme and all obligations related to the transfer have been fulfilled at that point and title to, and risk of loss for, the product is transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalties earned when the product is sold by Genzyme. Aldurazyme net product revenues for 2009 totaled $70.2 million, compared to $72.5 million in 2008.

Kuvan was granted marketing approval in the U.S. and EU in December 2007 and December 2008, respectively. Kuvan net product revenues for 2008 and 2009 totaled $46.7 million and $76.8 million, respectively.

In December 2009, the EMEA granted marketing approval for Firdapse. We expect to launch this product on a country by county basis starting in March 2010.

We are conducting clinical trials on several investigational product candidates for the treatment of genetic diseases, including: GALNS, an enzyme replacement therapy for the treatment of Mucopolysaccharidosis

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Type IV or Morquio Syndrome Type A, or MPS IV A, PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonurics that are not responsive to Kuvan and a small molecule for the treatment of Duchenne muscular dystrophy. In September 2009, we initiated a Phase 2 clinical trial to evaluate PEG-PAL. Results from this clinical trial are expected in the third quarter of 2010. In the first half of 2009, we initiated a Phase 1/2 clinical trial of GALNS. We have completed enrollment in this clinical trial and expect to report initial results in the first half of 2010. In January 2010, we initiated a Phase 1 trial of our small molecule for the treatment of Duchenne muscular dystrophy. Initial top-line results from this trial are expected in the third quarter of 2010.

Key components of our results of operations for the years ended December 31, 2007, 2008 and 2009 include the following (in millions):

	2007	2008	2009
Total net product revenues	$ 86.8	$ 251.9	$ 315.7
Collaborative agreement revenues	28.3	38.9	2.4
Cost of sales	18.4	52.5	65.9
Research and development expense	78.6	93.3	115.1
Selling, general and administrative expense	77.5	106.6	124.3
Net income (loss)	(15.8)	30.8	(0.5)
Stock-based compensation expense	18.3	25.3	34.5

See *Results of Operations* below for a discussion of the detailed components and analysis of the amounts above. Our cash, cash equivalents, short-term investments and long-term investments totaled $470.5 million as of December 31, 2009, compared to $561.4 million as of December 31, 2008, primarily due to the settlement of our Medicis obligation and the acquisition of Huxley Pharmaceuticals, Inc. See *Liquidity and Capital Resources* below for a further discussion of our liquidity and capital resources.

Critical Accounting Policies and Estimates

In preparing our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. (GAAP) and pursuant to the rules and regulations promulgated by the SEC, we make assumptions, judgments and estimates that can have a significant impact on our net income/loss and affect the reported amounts of certain assets, liabilities, revenue and expenses, and related disclosures. 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. We also discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

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, stock-based compensation and business combinations have the greatest 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 polices have not differed materially from actual results.

Business Combinations

We allocate the purchase price of acquired businesses to the tangible and intangible assets acquired and liabilities assumed based upon their estimated fair values on the acquisition date. The purchase price allocation process requires management to make significant estimates and assumptions, especially at acquisition date with respect to intangible assets and in-process research and development.

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Although we believe the assumptions and estimates made are reasonable, they are based in part on historical experience and information obtained from the management of the acquired businesses and are inherently uncertain. Examples of critical estimates in valuing certain of the intangible assets we have acquired or may acquire in the future include but are not limited to:

- the feasibility and timing of achievement of development, regulatory and commercial milestones;
- expected costs to develop the in-process research and development into commercially viable products; and
- future expected cash flows from product sales;

In connection with the purchase price allocations for acquisitions, we estimate the fair value of the contingent payments. The estimated fair value of any contingent payments is determined utilizing a probability-based income approach inclusive of an estimated discount rate.

Unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results.

Impairment of Long-Lived Assets

Our long-lived assets include our investment in BioMarin/Genzyme LLC, long-term investments, property, plant and equipment, intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of our equity investments is measured by available external market data, including quoted prices on public stock exchanges and other relevant information. 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.

The recoverability of long-lived assets, other than goodwill and our long-term investments is measured by comparing the asset s carrying amount to the expected undiscounted future cash flows that the asset is expected to generate.

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 Financial Accounting Standards Board, or FASB Accounting Standards Codification, or ASC Topic 350-20, *Intangibles Goodwill and Other*. The majority 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 unless facts and circumstances warrant a review of goodwill for impairment before that time. We performed our annual impairment test in the fourth quarter of 2009 and determined no impairment of goodwill existed as of December 31, 2009.

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 through the distribution of cash and inventory in February 2008. We expect that our remaining ongoing investment in the joint venture s cash on hand to fund certain research and development activities related to Aldurazyme and intellectual property management.

No significant impairments were recognized for the year ended December 31, 2007. In 2008, we recorded an other-than-temporary impairment charge of $4.1 million for the decline in the value of our equity investment in Summit Corporation plc (Summit). In 2009, we recorded other-than-temporary impairment charges of $1.4 million and $4.5 million for the decline in value of our equity investments in Summit and La Jolla Pharmaceutical (La Jolla), respectively. The determination that the decline was other-than-temporary is, in part, subjective and influenced by several factors including, the length of time and the extent to which the market value of the shares had been less than the value at the time of purchase, Summit and La Jolla s respective financial conditions and near-term prospects, including any events which may influence their respective operations, and our intent and ability to hold the respective investments for a period of time sufficient to allow for the anticipated recovery in market value. Based on the current market conditions, the low volume of trading in Summit and La Jolla s securities, respectively, and their respective current financial conditions, we determined that our investments in Summit and La Jolla were other-than-temporarily impaired as of March 31, 2009 and, adjusted the amount of our investments to the stock s market price on March 31, 2009. In June 2009, we sold our 10.2 million shares of La Jolla common stock through a series of open market trades, ranging in gross proceeds of $0.17 to $0.22 per share, and recognized a loss of $66,000.

The recoverability of the carrying value of buildings, leasehold improvements for our facilities and equipment will depend on the successful execution of our business initiatives and our ability to earn sufficient returns on our approved products and product candidates. We continually monitor events and changes in circumstances that could indicate carrying amounts of our fixed assets may not be recoverable. When such events or changes in circumstances occur, we assess recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, we recognize an impairment loss based on the excess of the carrying amount over the fair value of the assets. Based on management s current estimates, we expect to recover the carrying value of such assets.

Revenue Recognition

We recognize revenue in accordance with ASC Topic 605-15, *Revenue Recognition Products* and ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements.* Our revenues consist of net product revenues from Naglazyme, Kuvan and Aldurazyme, revenues from our collaborative agreement with Merck Serono and other license and royalty revenues. 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.

Net Product Revenues We recognize net product revenue 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. 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 related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in our statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

We receive a 39.5% to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenues in our consolidated statements of operations. We recognize a portion of this amount as product transfer revenue when product is released to Genzyme as all of our performance obligations are fulfilled at that point and title to, and risk of loss for, the product has transferred to

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Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty when the product is sold by Genzyme. We record the Aldurazyme royalty revenue based on net sales information provided by Genzyme and record product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with the terms of the related agreements with Genzyme and when the title and risk of loss for the product is transferred to Genzyme.

We sell Naglazyme worldwide and sell Kuvan in the U.S. and Canada. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. We also sell Kuvan to Merck Serono at a price near our manufacturing cost, and Merck Serono resells the product to end-users outside the U.S., Canada and Japan. The royalty earned from Kuvan product sold by Merck Serono in the EU is included as a component of net product revenues in the period earned. Outside the U.S., Naglazyme is sold to our authorized distributors or directly to government purchasers or hospitals, which act as the end-users. We record reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues are recorded. Our reserve calculations require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update our estimates and assumptions each quarter, and record any necessary adjustments to our reserves. We record fees paid to distributors as a reduction of revenue.

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 products based on their orphan drug status, the patient population, the customers limited return rights and our experience with returns. Because of the pricing of Naglazyme and Kuvan, the limited number of patients and the customers limited return rights, most Naglazyme and Kuvan customers and retailers carry a limited inventory. Certain international customers, usually government entities, tend to purchase larger quantities of product less frequently. Although such buying patterns may result in revenue fluctuations from quarter to quarter, we have not experienced any increased product returns or risk of product returns. We rely on historical return rates for Aldurazyme, Naglazyme and Kuvan to estimate returns. Genzyme s return rights for Aldurazyme are limited to defective product. Based on these factors and the fact that we have not experienced significant product returns to date, management has concluded that product returns will be minimal. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

The nature and amount of our current estimates of the applicable revenue dilution items 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 our customers inability to make required payments. As of December 31, 2009, we have experienced no significant bad debts and have not recorded an allowance for doubtful accounts.

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Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include license revenue and contract research revenue earned under our agreement with Merck Serono, which was executed in May 2005. Nonrefundable up-front license fees where we have continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which we continue to have a performance obligation. Our performance obligation related to the $25.0 million upfront payment from Merck Serono ended in the fourth quarter of 2008. There was no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono s share of Kuvan development costs under the Merck Serono agreement, which are recorded as research and development expenses. Allowable costs during the development period must have been included in the pre-approved annual budget in order to be subject to reimbursement, or must be separately approved by both parties. Milestone payments were recognized in full when the related performance goal was achieved and we no longer had future performance obligations related to the payment.

Royalty and license revenues Royalty revenue includes royalties on net sales of products with which we have no direct involvement and is recognized based on data reported by licensees or sublicensees. Royalties are recognized as earned in accordance with the contract terms when the royalty amount is fixed or determinable based on information received from the sublicensee and when collectibility is reasonably assured.

Due to the significant role we play in the operations of Aldurazyme and Kuvan, primarily the manufacturing and regulatory activities, as well as the rights and responsibilities to deliver the products to Genzyme and Merck Serono, respectively, we elected not to classify the Aldurazyme and Kuvan royalties earned as other royalty revenues and instead to include them as a component of net product revenues.

Inventory

We value our 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, or 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 recognized as cost of sales on the consolidated statements of operations.

Manufacturing costs for product candidates are 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 manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory. When regulatory approval is obtained, we begin capitalizing inventory at the lower of cost or net realizable value.

Stock-based compensation of $5.4 million was capitalized into inventory in the year end December 31, 2009, as compared to $4.6 million and $1.7 million in the years ended December 31, 2008 and 2007, respectively.

Research and Development

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

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deliverables. 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 vendors that perform the activities.

A critical accounting assumption by our management is that we believe that regulatory approval of product candidates is uncertain, and we do not assume that products manufactured prior to regulatory approval will be sold commercially. As a result, inventory costs for product candidates are expensed as research and development until regulatory approval is obtained in a major market, at which time inventory is capitalized at the lower of cost or net realizable value.

Stock-Based Compensation

We use the Black-Scholes option pricing model to determine the fair value of stock options and employee stock purchase plan awards. The determination of the fair value of stock-based payment awards using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period for each such award. Further stock-based compensation expense recognized in the consolidated statements of operations is based on awards expected to vest, therefore the amount of expense has been reduced for estimated forfeitures which are based on historical experience. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods.

If factors change and different assumptions are employed in determining the fair value of stock based awards, the stock based compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 3 of our consolidated financial statements for further information).

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. We record a valuation allowance to reduce deferred tax assets to the amount that is more likely than not to be realized. There was a full valuation allowance against net deferred tax assets of $268.1 million at December 31, 2009. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease net income/loss or additional paid in capital in the period such adjustment was made. During the three years ended December 31, 2007, 2008 and 2009, we recognized income tax expense of $0.7 million, $2.6 million and $1.1 million, respectively. Income tax expense in the years ended December 31, 2007, 2008 and 2009 was primarily related to income earned in certain of our international subsidiaries, California state income tax and U.S. federal alternative minimum tax expense.

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.

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Results of Operations

Net Income (Loss)

Our net loss for the year ended December 31, 2009 was $0.5 million compared to net income of $30.8 million for the year ended December 31, 2008, representing a change of $31.3 million. The change of $31.3 million was primarily a result of the following (in millions):

Net income for the year ended December 31, 2008	$ 30.8
Decreased Kuvan collaborative agreement revenue	(36.5)
Increased research and development expense	(21.8)
Increased selling, general and administrative expense	(17.7)
Decreased interest income	(11.3)
Increased Naglazyme gross profit	27.2
Increased Kuvan gross profit	23.5
Gain on the sale of equity investments	1.6
Increased impairment loss on equity investments	(1.8)
Decreased biopterin license fee revenues	(1.0)
Decreased Aldurazyme gross profit	(0.3)
Decreased interest expense	2.3
Increased Orapred royalty revenue	1.8
Decreased amortization of acquired intangible assets	1.5
Decreased income tax expense	1.5
Other individually insignificant fluctuations	(0.3)
Net loss for the year ended December 31, 2009	$ (0.5)

The decrease in Kuvan collaborative agreement revenue is attributed to our fulfillment of all performance obligations related to the 2005 up-front license payment of $25.0 million from Merck Serono in December 2008 and the absence of the $30.0 million Kuvan EMEA approval milestone earned in 2008. The increase in research and development expense in 2009 is primarily attributed to increases in development expense for our GALNS program for the treatment of MPS IV A, the $8.8 million of up-front costs associated with a product licensed from La Jolla, and increased stock-based compensation expense. The increase in selling, general and administrative expense is primarily due to increased facility and employee related costs and the continued international expansion of Naglazyme and commercialization of Kuvan in the U.S. The increase in Naglazyme gross profit in 2009 as compared to 2008 is primarily a result of additional patients initiating therapy outside the U.S. The increase in Kuvan gross profit in 2009 compared 2008 is primarily a result of additional patients initiating therapy in the U.S. See below for additional information related to the primary net income/loss fluctuations presented above, including details of our operating expense fluctuations.

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Our net income for the year ended December 31, 2008 increased by $46.6 million to $30.8 million, from a net loss of $15.8 million for the year ended December 31, 2007. The increase in net income in 2008 was primarily a result of the following (in millions):

Net loss for the year ended December 31, 2007	$ (15.8)
Increased Naglazyme gross profit	38.9
Increased Aldurazyme gross profit	52.2
Increased Kuvan gross profit	40.0
Increased Kuvan royalty and license revenues	15.3
Increased research and development expenses	(14.7)
Increased selling, general and administrative expenses	(29.0)
Increased losses from BioMarin/Genzyme LLC	(32.8)
Decreased interest income	(9.5)
Impairment charge on Summit investment	(4.1)
Absence of Orapred milestone revenue	(4.0)
Increased interest expense	(2.2)
Increased income tax expense	(1.9)
Other individually insignificant fluctuations	(1.6)
Net income for the year ended December 31, 2008	$ 30.8

The increase in Naglazyme gross profit during 2008 as compared to 2007 is primarily a result of additional patients initiating therapy outside the U.S. and the EU as well as the favorable impact of foreign currency exchange rates on Naglazyme sales from customers outside the U.S. The increase in Aldurazyme gross profit is attributed to the restructuring of our joint venture with Genzyme effective January 1, 2008. Prior to the restructuring we 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. The increase in Kuvan gross profit in 2008 compared to 2007 is attributed to the FDA approval of Kuvan in December 2007, which resulted in approximately two weeks of Kuvan sales in 2007 compared to twelve months in 2008. The increase in Kuvan royalty and license revenues is primarily attributed to the $30.0 million milestone received in 2008 from Merck Serono for the EMEA approval of Kuvan offset by the absence of the $15.0 million milestone received in 2007 for the acceptance of the Kuvan EMEA filing. The increase in selling, general and administrative expense was primarily due to the continued international expansion of Naglazyme and commercialization of Kuvan in the U.S. The increase in research and development expense was primarily due to increases in development expense for GALNS, a licensed product for the treatment of Duchenne muscular dystrophy, and other early stage programs. See below for additional information related to the primary net income/loss fluctuations presented above, including details of our operating expense fluctuations.

Net Product Revenues, Cost of Sales and Gross Profit

The following table shows a comparison of net product revenues for the years ended December 31, 2007, 2008 and 2009 (in millions):

	Year Ended December 31,				
	2007	2008	2009	2007 vs. 2008	2008 vs. 2009
Naglazyme	$ 86.2	$ 132.7	$ 168.7	$ 46.5	$ 36.0

Kuvan	0.4	46.7	76.8	46.3	30.1
Aldurazyme		72.5	70.2	72.5	(2.3)
Orapred	0.2			(0.2)	
Total Net Product Revenues	$ 86.8	$ 251.9	$ 315.7	$ 165.1	$ 63.8

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2009 as Compared to 2008

Net product revenues for Naglazyme in 2009 totaled $168.7 million, of which $138.9 million was earned from customers based outside the U.S. The negative impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was approximately $4.4 million in 2009. Gross profit from Naglazyme sales in 2009 was approximately $134.0 million, representing gross margins of 79%, compared to gross profits of $106.8 million in 2008, representing gross margins of approximately 81%. The slight decrease in gross margins during 2009 as compared to 2008 is attributed to the negative foreign currency impact on revenue during 2009.

Net product revenue for Kuvan during 2009 was $76.8 million, compared to $46.7 million during 2008. With the commercial launch of Kuvan in the EU during the first half of 2009, we began receiving a royalty of approximately 4% on net sales of Kuvan from Merck Serono. During 2009, we earned $0.3 million in royalties from Merck Serono on net sales of $6.9 million. Gross profit from Kuvan in 2009 was approximately $63.9 million, representing gross margins of approximately 83%, compared to 2008 when gross profit totaled $40.4 million, representing gross margins of approximately 86%. Both periods reflect royalties paid to third parties of 11%. In accordance with our inventory accounting policy, we began capitalizing Kuvan inventory production costs after U.S. regulatory approval was obtained in December 2007. As a result, the product sold in 2008 had an insignificant cost basis. The cost of sales for Kuvan in 2008 is primarily comprised of royalties paid to third parties based on Kuvan net sales. We expect U.S. gross margins for Kuvan for the foreseeable future to be in the lower 80% range as the previously expensed inventory has been mostly depleted.

Pursuant to our relationship with Genzyme, we record a 39.5% to 50% royalty on worldwide net product sales of Aldurazyme. We also recognize product transfer revenue when product is released to Genzyme and all of our obligations have been fulfilled. Genzyme s return rights for Aldurazyme are limited to defective product. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay us if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty rate when the product is sold by Genzyme.

	Year Ended December 31,		
	2008	2009	Change
Aldurazyme Revenue reported by Genzyme	$ 151.3	$ 155.1	$ 3.8
Royalties due from Genzyme	60.1	61.8	1.7
Incremental Aldurazyme product transfer revenue	12.4	8.4	(4.0)
Total Aldurazyme Net Product Revenues	$ 72.5	$ 70.2	$ (2.3)
Gross Profit	$ 52.2	$ 51.9	$ (0.3)

In January 2008, we transferred existing finished goods on-hand to Genzyme under the restructured terms of the BioMarin/Genzyme LLC agreements, resulting in the recognition of significant incremental product transfer revenue during 2008. In the future, to the extent that Genzyme Aldurazyme inventory quantities on hand remain flat, we expect that our total Aldurazyme revenues will approximate the 39.5% to 50% royalties on net product sales by Genzyme. In 2009, Aldurazyme gross margins were 74%, compared to 72% in 2008. Aldurazyme gross margins reflect the profit earned on royalty revenue and net incremental product transfer revenue. The change in gross margins is attributed to a shift in revenue mix between royalty revenue and net product transfer revenues. In 2009, the revenue mix was 88% royalty revenues and 12% net product transfer revenues, compared to 2008, where the revenue mix was 83% royalty revenues and 17% net product transfer revenues. Aldurazyme gross margins are expected to fluctuate depending on the mix of royalty revenue, from which we earn higher gross profit, and product transfer revenue, from which we earn a lower gross profit.

Total cost of sales in 2009 was $65.9 million, compared to $52.5 million in 2008. The increase in cost of sales in 2009 compared to 2008 is attributed to the increase in Naglazyme and Kuvan product sales.

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2008 as Compared to 2007

Net product revenues for Naglazyme in 2008 totaled $132.7 million, of which $111.2 million was earned from end-user customers based outside the U.S. The positive impact of foreign currency exchange rates on Naglazyme sales from customers based outside the U.S. was approximately $5.7 million in 2008 compared to $4.3 million in 2007. Gross profit from Naglazyme in 2008 was approximately $106.8 million, representing gross margins of approximately 81%, as compared to $67.9 million in 2007, representing gross margins of approximately 79%. The increase in gross margins is attributed to both foreign currency benefits and improved manufacturing yields.

We received marketing approval for Kuvan in the U.S. in December 2007 and began shipping product that same month. Net product sales for Kuvan in the U.S. for 2008 were $46.7 million. Gross profit from Kuvan in 2008 was approximately $40.4 million, representing gross margins of approximately 86%, which reflect royalties paid to third parties of 11%. In accordance with our inventory accounting policy, we began capitalizing Kuvan inventory production costs after U.S. regulatory approval was obtained in December 2007. As a result, the product sold in 2008 had an insignificant cost basis. The cost of sales for Kuvan for 2008 is principally comprised of royalties paid to third parties based on Kuvan net sales.

Prior to the restructuring of BioMarin/Genzyme LLC effective January 2008, we did not record Aldurazyme revenue and instead recorded our share of the net profits from the joint venture.

Total cost of sales during 2008 was $52.5 million, a significant increase compared to $18.4 million in 2007. The increase is primarily due to the increased net product revenues discussed above, as well as the restructuring of the joint venture with Genzyme, prior to which we did not recognize Aldurazyme net product revenues and the related cost of sales that were recognized by the joint venture.

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. Our performance obligations related to the initial $25.0 million up-front license payment were completed in December 2008. Therefore, periods subsequent to December 31, 2008 do not include amortization amounts related to this payment. As shared development spending increases or decreases, contract research revenues will also change proportionately. Reimbursable revenues are expected to increase if PEG-PAL successfully completes Phase 2 clinical trials and Merck Serono exercises its option to co-develop it. The related costs are included in research and development expenses. The following table details the components of collaborative agreement revenues for the three years ended December 31, 2007, 2008 and 2009 (in millions):

	Year Ended December 31,		
	2007	2008	2009
Amortization of the $25.0 million up-front license payment from Merck Serono	$ 6.9	$ 5.2	$
Reimbursable Kuvan development costs	6.4	3.7	2.4
Kuvan EMEA approval milestone from Merck Serono		30.0	

Kuvan EMEA filing acceptance milestone from Merck Serono	15.0		
Total	$ 28.3	$ 38.9	$ 2.4

Royalty and License Revenues

Royalty and license revenues for 2009 include $5.6 million of Orapred product royalties, a product we acquired in 2004 and sublicensed in 2006, and $1.0 million of 6R-BH4 royalty revenues for product sold in

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Japan. Royalty and license revenues for 2008 included $3.8 million of Orapred product royalties, a $1.5 million milestone payment related to the Japanese approval of biopterin, which contains the same active ingredient as Kuvan, for the treatment of patients with PKU and 6R-BH4 royalty revenues of $0.4 million for product sold in Japan. Royalty and license revenues in 2007 included Orapred product royalty revenues of $2.3 million and a $4.0 million milestone payment related to the one-year anniversary of FDA approval of the marketing application for Orapred ODT. There is no cost of sales associated with the royalty and license revenues recorded during the periods and no related costs are expected in future periods.

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 $21.8 million to $115.1 million for the year ended December 31, 2009, from $93.3 million for the year ended December 31, 2008. The change in research and development expenses for the year ended 2009 was primarily a result of the following (in millions):

Research and development expense for year ended December 31, 2008	$ 93.3
License payment related to collaboration with La Jolla Pharmaceutical Company	8.8
Increased GALNS for Morquio Syndrome Type A development expense	5.2
Increased stock-based compensation expense	3.3
Increased depreciation expense	2.1
Increased Duchenne muscular dystrophy program development expense	1.6
Decreased 6R-BH4 development expenses for indications other than PKU	(8.9)
Increased Prodrug development expenses	0.8
Increased Kuvan development expenses	0.8
Increased Naglazyme development expenses	0.2
Increased research and development expenses on early development stage programs	0.2
Increase in non-allocated research and development expenses and other net changes	7.7
Research and development expense for the year ended December 31, 2009	$ 115.1

During the first quarter of 2009, we paid La Jolla an up-front license fee for the rights to develop and commercialize their investigational drug, Riquent. In February 2009, the results of the first interim efficacy analysis for the Phase 3 ASPEN Study were announced, and the Independent Data Monitoring Board determined that the continuation of the trial was futile. Based on the results of this interim efficacy analysis, we and La Jolla decided to stop the study and in March 2009, we terminated the license agreement. As such, there will not be any additional development expense for Riquent. The increase in GALNS development expenses is primarily attributed to an increased costs related to the Phase 1/2 clinical trial that was initiated in April 2009. The increase in stock-based compensation expense is a result of an increased number of options outstanding due to an increased number of employees. The increase in Duchenne muscular dystrophy program development expense is primarily attributed to increased pre-clinical activities related to the product candidate. The decrease in 6R-BH4 development expense expenses for indications other than PKU is primarily due to a decline in clinical studies in 2009. The increase in Kuvan research and development expense is attributed to long-term clinical activities related to post-approval regulatory commitments. The increase in non-allocated research and development expense primarily includes increases in general research costs and research and development personnel costs that are not allocated to specific programs. We expect to continue incurring significant research and development expense for the foreseeable future due to long-term clinical activities related to post-approval

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regulatory commitments related to our products and spending on our GALNS, PEG-PAL, Duchenne muscular dystrophy and Firdapse programs and our other product candidates.

Research and development expenses increased by $14.7 million to $93.3 million for the year ended December 31, 2008, from $78.6 million for the year ended December 31, 2007. The change in research and development expenses for the year ended December 31, 2008 was primarily as a result of the following (in millions):

Research and development expenses for the year ended December 31, 2007	$ 78.6
Increased GALNS for Morquio Syndrome Type A development expenses	11.2
Decreased PEG-PAL development costs	(2.1)
Increase in research and development expense on other early stage programs	5.7
Increased Aldurazyme development expenses	1.6
Increased stock-based compensation expense	1.6
License payment related to collaboration with Summit Corporation plc	1.4
Decreased Kuvan clinical trial and manufacturing costs	(9.1)
Decreased 6R-BH4 development costs for indications other than PKU	(0.6)
Increase in non-allocated research and development expense and other net changes	5.0
Research and development expenses for the year ended December 31, 2008	$ 93.3

The increase in GALNS development costs is primarily attributed to an increase in pre-clinical studies and manufacturing costs. The increase in Aldurazyme development costs relate to certain development costs that are no longer charged to the joint venture. The decrease in Kuvan clinical trial and manufacturing costs was primarily related to the capitalization of these costs into inventory during 2008 whereas in 2007 these costs were expensed prior to the FDA approval in December 2007. The decrease in PEG-PAL development costs was primarily due to a decline in pre-clinical studies in 2008. The increase in stock-based compensation expense was a result of an increased number of options outstanding due to increased headcount and a higher average stock price on the related grant date. The increase in non-allocated research and development primarily includes increases in facilities costs, general research costs and research and development personnel.

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; human resources; finance; legal and support personnel expenses; and other external corporate costs such as insurance, audit and legal fees.

Selling, general and administrative expenses increased by $17.7 million to $124.3 million for the year ended December 31, 2009, from $106.6 million for the year ended December 31, 2008. The components of the change for the year ended 2009 primarily include the following (in millions):

Selling, general and administrative expense for the year ended December 31, 2008	$ 106.6
Increased Naglazyme sales and marketing expenses	2.9

Increased Kuvan commercialization expenses	3.7
Increased stock-based compensation expense	3.4
Increased depreciation expense	2.3
Increased information technology expense	1.9
Increased foreign exchange gains on un-hedged transactions	(2.1)
Net increase in corporate overhead and other administrative expenses	5.6
Selling, general and administrative expense for the year ended December 31, 2009	$ 124.3

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The increase in Naglazyme sales and marketing expenses in 2009 was attributed to continued expansion of our international activities. The increase in stock-based compensation expense for the twelve months ended December 31, 2009 was the result of an increased number of outstanding stock options due to an increase in the number of employees. We incurred increased Kuvan commercialization expenses as a result of increased commercialization efforts in the U.S. and Canada. The increase in corporate overhead and other administrative costs during 2009 is primarily comprised of increased employee related costs. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme, the European launch of Firdapse and the U.S. commercialization activities for Kuvan.

Selling, general and administrative expenses increased by $29.1 million, to $106.6 million for the year ended December 31, 2008, from $77.5 million for the year ended December 31, 2007. The components of the change for the year ended December 31, 2008 primarily include the following (in millions):

Selling, general and administrative expense for the year ended December 31, 2007	$ 77.5
Increased Naglazyme sales and marketing expenses	7.6
Increased stock-based compensation expense	4.4
Increased Kuvan commercialization expenses	9.8
Increased foreign exchange losses on un-hedged transactions	2.0
Net increase in corporate overhead and other administrative costs	5.3
Selling, general and administrative expenses for the year ended December 31, 2008	$ 106.6

Naglazyme sales and marketing expenses increased in 2008, primarily due to the expansion of our international commercial activities. We also incurred increased commercialization expenses related to the Kuvan commercial launch. The increase in stock-based compensation expense was the result of an increased number of outstanding options and a higher average stock price on the related grant date. The increase in corporate overhead and other administrative costs was primarily related to increases in salaries and benefits due to our growth in administrative employee headcount, consulting fees, travel, facilities and non-income taxes.

Amortization of 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. In June 2009, we completed the purchase of all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis Pediatrics, Inc.), a wholly-owned subsidiary of Medicis Pharmaceutical Corporation (Medicis) as required by the original transaction agreements from 2004 for $70.6 million. Medicis sole substantive asset was the intellectual property related to the Orapred franchise. Subsequently, we transferred the exclusive intellectual property rights to our sublicense in July 2009.

Amortization expense related to the Orapred intangible assets totaled $2.9 million in 2009, compared to $4.4 million in both 2008 and 2007. Amortization expense in 2009 included seven months of expense, compared to 2008 and 2007 which included twelve months of expense, which accounts for the decrease in amortization expense in 2009 compared to 2008 and 2007.

Kuvan license payments, recorded as intangible assets, made to third parties as a result of the FDA approval of Kuvan in December 2007 and the EMEA approval of Kuvan in December 2008 are being amortized over approximately 7.0 years and 10.0 years, respectively. Amortization of the Kuvan intangible assets is recorded as a component of cost of sales and is expected to approximate $0.6 million annually through 2014 and $0.3

million annually through 2018. Amortization expense related to the Kuvan intangible assets for the years ended 2008 and 2009 was $0.4 million and $0.6 million, respectively. Amortization expense related to the Kuvan intangible asset was insignificant in 2007. The increase in Kuvan related amortization expense in 2009 is attributed to the EMEA approval milestone paid to us in December 2008.

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

Equity in the loss of BioMarin/Genzyme LLC includes our 50% share of the joint venture s loss for the period. Effective January 2008, we and Genzyme restructured BioMarin/Genzyme LLC regarding the manufacturing, marketing and sale of Aldurazyme. As of January 1, 2008, BioMarin/Genzyme LLC s operations consist primarily of certain research and development activities and the intellectual property which continues to be managed by the joint venture with costs shared equally by BioMarin and Genzyme.

Equity in the loss of the joint venture totaled $2.6 million for the years ended December 31, 2009, compared to $2.3 million for the year ended December 31, 2008. In 2007, equity in the income of the joint venture was $30.5 million; the decrease in 2008 and 2009 years is attributed to the restructuring of the joint venture which became effective January 1, 2008. Prior to the restructuring of the joint venture in 2008, all Aldurazyme sales were recognized by the joint venture, which resulted in $30.5 million of income to us in 2007.

Interest Income

We invest our cash, short-term and long-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income totaled $5.1 million, $16.4 million and $25.9 million in 2009, 2008 and 2007, respectively. The reduced interest yields during 2009 and 2008 were due to lower market interest rates and decreased levels of cash and investments. We expect that interest income will decline during 2010 as compared to 2009 due to reduced interest yields and lower cash and investment balances.

Interest Expense

We incur interest expense on our convertible debt. Interest expense also includes imputed interest expense on the discounted acquisition obligation for the Ascent Pediatrics transaction. Interest expense in 2009 was $14.1 million and included imputed interest of $2.6 million. Interest expense in 2008 and 2007 totaled $16.4 million and $14.2 million, respectively, and included imputed interest of $4.4 million and $4.5 million, respectively. Imputed interest will not be incurred in future periods as the Medicis obligation has been paid in full.

Changes in Financial Position

December 31, 2009 Compared to December 31, 2008

From December 31, 2008 to December 31, 2009, our cash, cash equivalents, and short-term and long-term investments decreased by $90.9 million, primarily as a result of the settlement the Medicis obligation, the acquisition of Huxley Pharmaceuticals and increased capital expenditures. These decreases in cash and investments were substantially offset by the receipt of the $30.0 million milestone for Kuvan EMEA approval and cash flows from operating activities. Our accounts receivable increased by $19.2 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Other current assets decreased approximately $35.6 million from December 31, 2008 to December 31, 2009, primarily as a result of the receipt of the $30.0 million related to the EMEA milestone earned from Merck Serono in December 31, 2008 that was paid in January 2009, and the reclassification of $6.2 million in cash which

was restricted from use until June 2009 when we paid the remaining acquisition obligation resulting from the Ascent Pediatrics transaction to Medicis. Our net property, plant and equipment increased by approximately $74.2 million from December 31, 2008 to December 31, 2009, primarily as a result of continued expansion and improvements to our facilities during the period. We expect property, plant and equipment to increase in future periods, due to several ongoing facility improvement projects, and we expect depreciation expense to increase as the assets are placed into service.

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Liquidity and Capital Resources

Cash and Cash Flow

As of December 31, 2009, our combined cash, cash equivalents, short-term and long-term investments totaled $470.5 million, a decrease of $90.9 million from $561.4 million at December 31, 2008.

The decrease in our combined cash, cash equivalents, short-term investments and long-term investments during 2009 was $90.9 million, which was $66.7 million more than the net decrease in 2008 of $24.2 million. The primary items contributing to the decrease in net cash outflow in 2009 were as follows (in millions):

Decreased distributions from Genzyme/BioMarin LLC	$ (16.7)
Increased Orapred acquisition payments, primarily the final balloon payment of the Medicis obligation	(67.1)
Increased capital asset purchases	(33.4)
Acquisition of Huxley Pharmaceuticals, Inc.	(15.5)
Decreased proceeds from ESPP and stock option exercises	(17.6)
Net increased proceeds from the sale of equity investments and net decreased investments in equity investments	1.4
Milestone payment received for Kuvan EMEA approval	30.0
Net increase in cash provided by operating activities, including net payments for working capital, and other	52.2
Total decrease in net cash outflow	$ (66.7)

The net decrease in 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 *Results of Operations* above. Increased capital purchases primarily relate to continued expansion of corporate and manufacturing facilities at our Novato, California campus. Net payments for working capital in 2009 primarily include decreased inventory build of $8.4 million, which excluded the inventory distribution from the joint venture and the decreased accounts receivable build of $18.1 million, and the receipt of the Merck Serono $30.0 million milestone payment earned in December 2008 related to the EMEA approval of Kuvan.

On October 23, 2009, we acquired Huxley Pharmaceuticals, Inc. which has rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate for the treatment of the rare autoimmune disease LEMS for a total purchase price of $37.2 million, of which $15.0 million was paid in cash and $22.2 million is contingent purchase price, of which $1.0 million was paid in the fourth quarter of 2009. In connection with the acquisition, we agreed to pay Huxley stockholders additional consideration in future periods of up to $42.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and U.S. development milestones are met.

We purchased all of the outstanding shares of capital stock of BioMarin Pediatrics II (formerly known as Ascent Pediatrics, Inc. and Medicis Pediatrics, Inc.) (Pediatrics) a wholly-owned subsidiary of Medicis Pharmaceutical Corporation (Medicis) as required by the original transaction agreements from 2004 for $70.6 million in cash. Pediatrics sole substantial asset was the intellectual property related to the Orapred franchise. The stock purchase was substantially completed in accordance with the terms of the previously disclosed Securities Purchase Agreement dated May 18, 2004 and amended on January 12, 2005, by and among BioMarin, Medicis and Pediatrics. As a result of the completion of the transaction with Medicis, $9.1 million in cash was released from escrow pursuant to the sublicense and was reclassified from restricted cash to cash and cash equivalents in June 2009.

We expect that our net cash outflow in 2010 related to capital asset purchases will decrease significantly compared to 2009. The expected decrease in capital asset purchases primarily reflects the substantial completion of our manufacturing facility and the related spending on manufacturing and lab equipment.

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We have historically financed our operations primarily by the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. During 2010, 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. Further, depending on market conditions, our financial position and performance and other factors, in the future we may choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

Funding Commitments

We expect to fund our operations with our net product revenues from our commercial products; cash; cash equivalents; short-term and long-term investments supplemented by proceeds from equity or debt financings; and loans or collaborative agreements with corporate partners, each to the extent necessary. We expect our current cash, cash equivalents, and short-term and long-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 and continued development of our existing commercial products has a major impact on our operating performance. Our research and development expenses for the three years ended December 31, 2007, 2008 and 2009 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

	Year Ended December 31,			
	2007	2008	2009	Since Program Inception
Naglazyme	$ 8.8	$ 9.6	$ 9.8	$ 132.4
Kuvan	19.9	10.8	11.5	101.3
GALNS for Morquio Syndrome Type A	2.2	12.6	17.7	34.1
6R-BH4 for indications other than PKU	15.0	14.7	4.4	46.5
PEG-PAL	13.2	11.0	11.2	42.4
Not allocated to specific major current projects	19.5	28.4	35.5	222.0
	$ 78.6	$ 87.1	$ 90.1	$ 578.7

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 Annual Report on 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 this Annual Report on Form 10-K *If we fail to maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased; To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain; If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities 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*

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adversely affected; and *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.*

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, Kuvan and Firdapse; preclinical studies and clinical trials for our other product candidates; potential licenses and other acquisitions of complementary technologies, products and companies; general corporate purposes; and working capital.

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

- our ability to successfully market and sell Naglazyme, Kuvan and Firdapse;
- Genzyme s ability to continue to successfully market and commercialize 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 our 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 $497.1 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

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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, 2009 is presented below (in thousands).

	Payments Due by Period					
	2010	2011	2012 -2013	2014-2015	2016 and Thereafter	Total
Convertible debt and related interest	$ 10,401	$ 10,401	$ 190,853	$ 12,183	$ 334,012	$ 557,850
Operating leases	4,283	4,037	6,495	2,238	2,378	19,431
Research and development and purchase commitments	47,973	9,798	3,925	3,104	3,269	68,069
Total	$ 62,657	$ 24,236	$ 201,273	$ 17,525	$ 339,659	$ 645,350

We are also subject to contingent payments related to various development activities totaling approximately $167.5 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 former Chief Medical Officer, Emil D. Kakkis, M.D., Ph.D., once 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 our joint venture partner 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 $1.4 million and $1.8 million related to Aldurazyme during 2007 and 2008, respectively. There were no related party transactions in 2009.

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, 2009, our investment portfolio did not include any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at December 31, 2009, 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 $4.7 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, 2009 (in thousands):

	Carrying Value
Cash and cash equivalents	$ 167,171*
Short-term investments	133,506**
Long-term investments	169,849***
Total	$ 470,526

* 89% of cash and cash equivalents invested in money market instruments and 11% in uninvested cash.

** 44% of short-term investments invested in corporate securities, 26% invested in U.S. government treasuries, 23% in certificates of deposit, 6% in commercial paper and 1% in equity securities.

*** 28% of long-term investments invested in U.S. government treasuries, 61% in corporate securities and 11% in certificates of deposit.

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, 2009.

Foreign Currency Exchange Rate Market Risk

We transact business in various foreign currencies, primarily in certain European countries. Accordingly, we are subject to exposure from movements in foreign currency exchange rates, primarily related to Euro and British Pound revenue from sales of our products in Europe. Our operating expenses in the United Kingdom and other European counties are in British Pounds and Euros, respectively. Both serve to mitigate a portion of the exposure related to the above-mentioned revenue in both markets.

We hedge a portion of our net position in assets and liabilities denominated in Euros and British Pounds using primarily forward contracts. We also hedge a percentage of our forecasted international revenue with forward contracts. Our hedging policy is designed to reduce the impact of foreign currency exchange rate movements.

In the second quarter of 2008, we commenced hedging a portion of our forecasted revenues denominated in currencies other than the U.S. dollar to help mitigate short-term exposure to fluctuations of the currency by entering into foreign exchange forward rate contracts. These contracts have maturities of less than 12 months.

Our hedging programs are expected to reduce, but do not entirely eliminate, the short-term impact of currency exchange rate movements in operating expenses. As of December 31, 2009, we had foreign currency forward contracts to sell approximately $74.1 million in Euros and $4.0 million in British Pounds. As of December 31, 2009, our outstanding foreign currency forward contracts had a fair value of $0.9 million, of which $0.1 million is included in other current assets, and $0.8 million is included in accrued expenses.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exposure in a manner that entirely offsets the effects of changes in foreign exchange rates. The counterparty to these forward contracts is a creditworthy multinational commercial bank, which minimizes the risk of counterparty nonperformance. We currently do not use financial instruments to hedge local currency operating expenses in Europe. Instead, we believe that a natural hedge exists, in that local currency revenue substantially offsets the local currency operating expenses. We regularly review our hedging program and may, as part of this review, make changes to the program.

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Based on our overall currency rate exposures at December 31, 2009, we expect that a near-term 10% fluctuation of the U.S. dollar could result in the potential change in the fair value of our foreign currency sensitive assets and investments by approximately $4.7 million. We expect to enter into new transactions based in foreign currencies that could be impacted by changes in exchange rates.

At December 31, 2009, we had cash of approximately $10.2 million denominated in foreign country currencies, which represented approximately 2% of the total investment portfolio. As a result, our investment portfolio is subject to limited amounts of foreign exchange risk.

Item 8. Financial Statements and Supplementary Data

The information required to be filed in this item appears on pages F-1 to F-42 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 Exchange Act 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 and procedures are effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

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 our internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act as of December 31, 2009. 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, 2009 was effective.

Our independent registered public accounting firm, KPMG LLP, has audited the financial statements included in this Annual Report on Form 10-K and has issued a report on the effectiveness of our internal control over financial reporting. The report of KPMG LLP is incorporated by reference from Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during our most recently completed quarter that have materially affected or are reasonably likely to materially affect our internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act.

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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 our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our board of directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

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

Item 9B. Other Information

None

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Part III

Item 10. Directors and Executive Officers and Corporate Governance

We incorporate information regarding our directors, executive officers and corporate governance into this section by reference from sections captioned Election of Directors and Executive Officers in the proxy statement for our 2010 annual meeting of stockholders.

Item 11. Executive Compensation

We incorporate information regarding executive compensation into this section by reference from the section captioned Executive Compensation in the proxy statement for our 2010 annual meeting of stockholders.

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

We incorporate information regarding security ownership of our beneficial owners, management and related stockholder matters into this section by reference from the section captioned Security Ownership of Certain Beneficial Owners in the proxy statement for our 2010 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions and Director Independence

We incorporate information regarding certain relationships, related transactions and director independence into this section by reference from the section captioned Interest of Insiders in Material Transactions in the proxy statement for our 2010 annual meeting of stockholders.

Item 14. Principal Accounting 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 2010 annual meeting of stockholders.

Part IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statements

In accordance with Rule 3-09 of Regulation S-X, the comparative audited 2007 and 2009 and unaudited 2008 consolidated financial statements and accompanying notes of BioMarin/Genzyme LLC, which constituted a significant subsidiary in 2009, will be filed subsequently as an amendment to this Form 10-K.

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Exhibit Index

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 February 27, 2009 as Exhibit 3.3 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
4.1	Amended and Restated Rights Agreement, dated as of February 27, 2009, between BioMarin Pharmaceutical Inc. and Mellon Investor Services LLC, as Rights Agent, previously filed with the Commission on February 27, 2009 as Exhibit 4.1 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
4.2	Indenture dated June 23, 2003, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on August 12, 2003 as Exhibit 4.1 to the Company s Quarterly report on Form 10-Q, which is incorporated herein by reference.
4.3	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.

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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	Amended and Restated Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on May 12, 2009, previously filed with the Commission on July 31, 2009 as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q, which is incorporated by reference herein.
10.3	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.
10.4	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.
10.5	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.
10.6	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.
10.7	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.
10.8	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.
10.9	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.
10.10	Amended and Restated 2006 Employee Stock Purchase Plan, as adopted on June 21, 2006, previously filed with the Commission on August 3, 2006 as Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.11	Amended and Restated BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan, as adopted on December 1, 2005 and as amended and restated on January 1, 2009, previously filed with the Commission on December 23, 2008 as Exhibit 10.8 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.12	Amended and Restated Employment Agreement with Jean-Jacques Bienaimé dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.

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10.13	Amended and Restated Employment Agreement with Stephen Aselage dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.14	Amended and Restated Employment Agreement with Robert A. Baffi dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.3 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.15	Amended and Restated Employment Agreement with Emil D. Kakkis, M.D., Ph.D. dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.4 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.16	Severance Agreement with Dr. Emil D. Kakkis, dated May 28, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.17	Consulting Agreement between the Company and Dr. Emil D. Kakkis, dated July 1, 2009 previously filed with the SEC on June 3, 2009 as Exhibit 10.2 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.18	Amended and Restated Employment Agreement with Jeffrey H. Cooper dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.5 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.19	Amended and Restated Employment Agreement with G. Eric Davis dated January 1, 2009, previously filed with the Commission on December 23, 2005 as Exhibit 10.6 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.20	Amended and Restated Employment Agreement with Mark Wood dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.7 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.21	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.
10.22	Employment Agreement with Henry Fuchs, dated March 18, 2009, previously filed with the Commission on March 23, 2009 as Exhibit 10.1 to the Company s Current Report on Form 8-K, which is incorporated herein by 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 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.

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10.25	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.
10.26	Operating Agreement with Genzyme Corporation, previously filed with the Commission on July 21, 1999 as Exhibit 10.30 to the Company s Amendment No. 2 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
10.27	2009 Technical Amendments to BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, effective January 1, 2009, previously filed with the Commission on December 23, 2008, as Exhibit 10.9 to the Company s Current Report on Form 8-K, which is incorporated herein by reference.
10.28	Amended and Restated 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.
10.29	Manufacturing, Marketing and Sales Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2008 as Exhibit 10.30 to the Company s 2007 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.
10.30	Amended and Restated Collaboration Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.31 to the Company s 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
10.31	Members Agreement dated as of January 1, 2008 by and among BioMarin Pharmaceutical Inc., Genzyme Corporation, BioMarin Genetics Inc., and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.32 to the Company s 2007 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.
10.32	Development and Commercialization Agreement dated as of January 4, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.29 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.
10.33	Securities Purchase Agreement dated as of January 4, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.30 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.
10.34	Amendment No. 1 to the Development and Commercialization Agreement dated as of January 16, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.31 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.

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10.35	Amendment No. 1 to the Securities Purchase Agreement dated as of January 16, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.32 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
10.36	Summary of Bonus Plan, previously filed with the Commission on February 27, 2009 as Exhibit 10.33 to the Company s Annual Report on Form 10-K, which is incorporated herein by reference.
10.37*#	Stock Purchase Agreement by and between BioMarin Pharmaceutical Inc., Huxley Pharmaceuticals, Inc., and the stockholders of Huxley Pharmaceuticals, Inc., dated October 20, 2009. 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)
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.
99.1*	BioMarin/Genzyme LLC Consolidated Financial Statements as of December 31, 2008, and for the years ended December 31, 2008 and 2007.

* Filed herewith
Management contract or compensatory plan or arrangement
\# Confidential treatment requested for a portion of this agreement

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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 25, 2010

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 25, 2010
/s/ Jeffrey H. Cooper **Jeffrey H. Cooper**	Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2010
/s/ Pierre Lapalme **Pierre LaPalme**	Chairman and Director	February 25, 2010
/s/ Elaine Heron **Elaine Heron**	Director	February 25, 2010
/s/ Joseph Klein, III	Director	February 25, 2010

Joseph Klein, III		
/s/ Alan J. Lewis	Director	February 25, 2010
Alan J. Lewis		
/s/ Michael G. Grey	Director	February 25, 2010
Michael G. Grey		
/s/ Richard A. Meier	Director	February 25, 2010
Richard A. Meier		
/s/ V. Bryan Lawlis	Director	February 25, 2010
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, 2009 and 2008, 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, 2009. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the financial statements of BioMarin/Genzyme LLC (a 50 percent owned joint venture) for 2007. The Company s equity in income of BioMarin/Genzyme LLC (in thousands) was $30,525 for the year ended December 31, 2007. The financial statements of BioMarin/Genzyme LLC for 2007 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 2007, 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, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

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, 2009, 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 25, 2010 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

San Francisco, California

February 25, 2010

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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, 2009, 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 in Item 9A. 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, 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. and subsidiaries as of December 31, 2009 and 2008, 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, 2009, and our report dated February 25, 2010 expressed an unqualified opinion on those consolidated financial statements. Our report refers to the report of other auditors.

/s/ KPMG LLP

San Francisco, California

February 25, 2010

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2008	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 222,900	$ 167,171
Short-term investments	336,892	133,506
Accounts receivable, net	54,298	73,540
Inventory	73,162	78,662
Other current assets	50,444	14,848
Total current assets	737,696	467,727
Investment in BioMarin/Genzyme LLC	915	441
Long-term investments	1,633	169,849
Property, plant and equipment, net	124,979	199,141
Intangible assets, net	7,626	40,977
Goodwill	21,262	23,722
Other assets	12,584	15,306
Total assets	$ 906,695	$ 917,163
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable, accrued liabilities and other current liabilities	$ 59,033	$ 78,068
Acquisition obligation, net of discount	70,741	
Deferred revenue	307	86
Total current liabilities	130,081	78,154
Convertible debt	497,083	497,083
Other long-term liabilities	2,856	19,741
Total liabilities	630,020	594,978
Stockholders equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at December 31, 2008 and 2009; 99,868,145 and 100,961,922 shares issued and outstanding at December 31, 2008 and 2009, respectively	100	101
Additional paid-in capital	852,947	899,950
Company common stock held by deferred compensation plan	(882)	(1,715)
Accumulated other comprehensive income	1,106	933
Accumulated deficit	(576,596)	(577,084)
Total stockholders equity	276,675	322,185

Total liabilities and stockholders equity	$ 906,695	$ 917,163

See accompanying notes to the consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2007, 2008 and 2009

(In thousands, except for per share data)

	December 31,		
	2007	2008	2009
Revenues:			
Net product revenues	$ 86,802	$ 251,851	$ 315,721
Collaborative agreement revenues	28,264	38,907	2,379
Royalty and license revenues	6,515	5,735	6,556
Total revenues	121,581	296,493	324,656
Operating expenses:			
Cost of sales	18,359	52,509	65,909
Research and development	78,600	93,291	115,116
Selling, general and administrative	77,539	106,566	124,290
Amortization of acquired intangible assets	4,371	4,371	2,914
Total operating expenses	178,869	256,737	308,229
Income (Loss) from operations	(57,288)	39,756	16,427
Equity in the income (loss) of BioMarin/Genzyme LLC	30,525	(2,270)	(2,594)
Interest income	25,932	16,388	5,086
Interest expense	(14,243)	(16,394)	(14,090)
Impairment loss on equity investments		(4,056)	(5,848)
Net gain from sale of investments			1,585
Income (Loss) before income taxes	(15,074)	33,424	566
Provision for income taxes	729	2,593	1,054
Net income (loss)	$ (15,803)	$ 30,831	$ (488)
Net income (loss) per share, basic	$ (0.16)	$ 0.31	$ (0.00)
Net income (loss) per share, diluted	$ (0.16)	$ 0.29	$ (0.00)
Weighted average common shares outstanding, basic	95,878	98,975	100,271
Weighted average common shares outstanding, diluted	95,878	103,572	100,271

See accompanying notes to the consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

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

Years ended December 31, 2007, 2008 and 2009 (In thousands)

	Common stock		Additional Paid-in	Company Common Stock held by Deferred Compensation	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders Equity
	Shares	Amount	Capital	Plan	(Loss)	Deficit	(Deficit)
Balance at January 1, 2007	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				19,414
Balance at December 31, 2007	97,114	$ 97	$ 794,917		$ 139	$ (607,427)	$ 187,726
Net income						30,831	30,831
Fair market value adjustments of available-for-sale investments					1,201		1,201
Unrealized loss on foreign currency hedges					(212)		(212)
Foreign currency translation adjustment					(22)		(22)
Comprehensive income							31,798
Issuance of common stock under ESPP	209		2,634				2,634
Exercise of common stock options	2,489	3	25,813				25,816
Excess tax benefit from stock option exercises			960				960
Restricted stock vested during the period	39						
Common stock held by nonqualified deferred compensation plan				(882)			(882)
Conversion of convertible notes	17		288				288
Stock-based compensation			28,335				28,335
Balance at December 31, 2008	99,868	$ 100	$ 852,947	$ (882)	$ 1,106	$ (576,596)	$ 276,675
Net loss						(488)	(488)
Fair market value adjustments of available-for-sale investments					299		299
Unrealized loss on foreign exchange forward contracts					(477)		(477)
Foreign currency translation adjustment					5		5
Comprehensive loss							(661)
Issuance of common stock under ESPP	287		3,230				3,230

Exercise of common stock options	730	1	7,655				7,656
Excess tax benefit from stock option exercises			113				113
Restricted stock vested during the period	77						
Common stock held by nonqualified deferred compensation plan				(833)			(833)
Stock-based compensation			36,005				36,005
Balance at December 31, 2009	100,962	$ 101	$ 899,950	$ (1,715)	$ 933	$ (577,084)	$ 322,185

See accompanying notes to the consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Three Years ended December 31, 2007, 2008 and 2009

(In thousands)

	Years Ended December 31,		
	2007	2008	2009
Cash flows from operating activities:			
Net income (loss)	$ (15,803)	$ 30,831	$ (488)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	13,654	17,616	20,975
Amortization of discount (premium) on investments	(12,453)	(6,487)	1,443
Imputed interest on acquisition obligation	4,527	4,378	2,577
Equity in the (income) loss of BioMarin/Genzyme LLC	(30,525)	2,270	2,594
Stock-based compensation	19,415	28,336	36,005
Impairment loss on equity investments		4,056	5,848
Net gain from sale of investments			(1,585)
Unrealized foreign exchange (gain) loss on forward contracts	165	(228)	602
Excess tax benefit from stock option exercises		(960)	(113)
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,306)	(37,322)	(19,242)
Inventory	(7,371)	(13,938)	(5,500)
Other current assets	(3,649)	(41,143)	37,415
Other assets	(4,745)	925	(1,286)
Accounts payable, accrued liabilities and other current liabilities	10,850	7,433	8,021
Other liabilities	3	78	687
Deferred revenue	(6,788)	(5,020)	(221)
Net cash provided by (used in) operating activities	(35,026)	(9,175)	87,732
Cash flows from investing activities:			
Purchase of property, plant and equipment	(22,413)	(56,368)	(89,801)
Maturities and sales of investments	693,814	761,178	475,312
Purchase of investments	(838,864)	(733,131)	(439,299)
Investments in BioMarin/Genzyme LLC		(1,750)	(2,120)
Distributions from BioMarin/Genzyme LLC	17,100	16,683	
Investment in Summit Corporation plc		(5,689)	
Acquisition of Huxley Pharmaceuticals, Inc.			(14,517)
Investment in La Jolla Pharmaceutical Company			(6,250)
Payment to LEAD Therapeutics, Inc.			(3,000)
Net cash used in investing activities	(150,363)	(19,077)	(79,675)
Cash flows from financing activities:			
Proceeds from ESPP and exercise of stock options	15,220	28,443	10,886
Excess tax benefit from stock option exercises		960	113
Net proceeds from convertible debt offering	316,350		
Repayment of acquisition obligation	(7,000)	(6,500)	(73,600)
Repayment of capital lease obligations		(94)	(185)
Payment of contingent acquisition payable			(1,000)

Net cash provided by (used in) financing activities	324,570	22,809	(63,786)
Net increase (decrease) in cash and cash equivalents	139,181	(5,443)	(55,729)
Cash and cash equivalents:			
Beginning of year	89,162	228,343	222,900
End of year	$ 228,343	$ 222,900	$ 167,171
Supplemental cash flow disclosures:			
Cash paid for interest, net of interest capitalized into fixed assets	$ 7,358	$ 10,401	$ 9,700
Cash paid for income taxes	296	1,277	2,824
Stock-based compensation capitalized into inventory	1,710	4,612	5,423
Depreciation capitalized into inventory	1,941	2,782	4,432
Supplemental non-cash investing and financing activities disclosures:			
Conversion of convertible notes	51,440	292	
Distribution of inventory resulting from the joint venture restructure		26,780	
Changes in accrued liabilities related to fixed assets	6,726	4,462	185
Equipment acquired through capital lease		546	
Deferred offering costs reclassified to additional paid in capital as a result of convertible notes	512	9	
Common shares transferred to Nonqualified Deferred Compensation Plan		(882)	(833)

See accompanying notes to the consolidated financial statements.

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BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2008 and 2009

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin®) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin selects 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. The Company s product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme® (galsulfase), Kuvan® (sapropterin dihydrochloride), Firdapse™ (amifampridine phosphate) and Aldurazyme® (laronidase).

There were 73 common stockholders of record at December 31, 2009. No dividends have ever been paid by the Company. The Company is incorporated in the state of Delaware.

Through December 31, 2009, the Company had accumulated losses of approximately $577.1 million. Management believes that the Company s cash, cash equivalents and short-term and long-term investments at December 31, 2009 will be sufficient to meet the Company s obligations for the foreseeable future based on management s current long-term business plans and assuming that the Company achieves its long-term goals. If the Company elects to increase its spending on development programs significantly above current long-term plans or enter into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital. The Company expects to continue to finance net future cash needs that exceed its operating revenues primarily through its current cash, cash equivalents, short-term and long-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners.

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of BioMarin and its wholly owned subsidiaries. All significant intercompany transactions have been eliminated. Management performed an evaluation of the Company s activities through the date of filing of this Annual Report on Form 10-K, and has concluded that there are no subsequent events requiring disclosure through that date except for the transaction discussed in Note 21.

(b) Use of Estimates

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

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(c) Cash and Cash Equivalents

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

(d) Investments

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company s securities are classified as either held-to-maturity or available-for-sale and reported in cash equivalents, short-term investments or long-term investments. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investments are recorded at fair market value, with unrealized gains or losses included in accumulated other comprehensive income or loss, exclusive of other-than-temporary impairment losses, if any. Short-term and long-term investments are comprised of corporate securities, commercial paper, U.S. federal government agency securities, money market funds, equity securities and certificates of deposit. As of December 31, 2009, the Company had no held-to-maturity investments.

(e) Inventory

The Company values inventories at the lower of cost or net realizable value. The Company determines the cost of inventory using the average-cost method. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or 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 recognized as cost of sales in the consolidated statements of operations.

Manufacturing costs for product candidates are expensed as research and development expenses. The Company considers regulatory approval of product candidates to be uncertain, and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory. When regulatory approval is obtained, the Company begins capitalizing inventory at the lower of cost or net realizable value.

In the first quarter of 2008, the Company received $26.8 million of inventory distributed by the Company s joint venture with Genzyme Corporation (Genzyme) pursuant to the terms of the joint venture restructuring (see Note 20 for further information). The inventory distribution was recorded at the historical production cost, which represented the lower of cost or market value.

Stock-based compensation capitalized into inventory for the years ended December 31, 2009, 2008 and 2007 was $5.4 million, $4.6 million and $1.7 million, respectively.

(f) Investment in BioMarin/Genzyme LLC and Equity in the Loss of BioMarin/Genzyme LLC

Effective January 1, 2008, the Company restructured its relationship with Genzyme (see Note 20 for further information). The Company accounts for its remaining investment in the joint venture using the equity method. Accordingly, the Company records an increase in its investment for contributions to the joint venture and a reduction in its investment for its 50% share of any losses of the joint venture or disbursements of profits from the joint venture. Equity in the loss of BioMarin/Genzyme LLC includes the Company s 50% share of the joint venture s loss for the period. The investment in BioMarin/Genzyme LLC includes the Company s share of the net equity of the joint venture.

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(g) Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term. Significant additions and improvements are capitalized, while repairs and maintenance are charged to expense as incurred. Property and equipment purchased for specific research and development projects with no alternative uses are expensed as incurred. See Note 8 for further information on property, plant and equipment balances as of December 31, 2008 and 2009.

Certain of the Company s operating lease agreements include scheduled rent escalations over the lease term, as well as tenant improvement allowances. Scheduled increases in rent expense are recognized on a straight-line basis over the lease term. The difference between rent expense and rent paid is recorded as deferred rent and included in other liabilities in the accompanying consolidated balance sheets. The tenant improvement allowances and free rent periods are recognized as a credit to rent expense over the lease term on a straight-line basis.

(h) Revenue Recognition

The Company recognizes revenue in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopics ASC 605-15, *Revenue Recognition Products* and ASC 605-25, *Revenue Recognition Multiple-Element Arrangements.* The Company s revenues consist of net product revenues from Naglazyme, Kuvan and Aldurazyme, revenues from its collaborative agreement with Merck Serono and other license and royalty revenues. Milestone payments are recognized in full when the related milestone performance goal is achieved and the Company has no future performance obligations related to that payment.

Net Product Revenues The Company recognizes net product revenue 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. 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 related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in the Company s consolidated statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

BioMarin receives a 39.5% to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenues in the consolidated statements of operations. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme as all of the Company s performance obligations are fulfilled at that point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty rate when the product is sold by Genzyme. The Company records the Aldurazyme royalty revenue based on net sales

information provided by Genzyme and records product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with the terms of the related agreements with Genzyme and when the title and risk of loss for the product is transferred to Genzyme. As of December 31, 2009, accounts receivable included $20.3 million of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

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The Company sells Naglazyme worldwide and sells Kuvan in the U.S. and Canada. In the U.S., Naglazyme and Kuvan are generally sold to specialty pharmacies or end-users, such as hospitals, which act as retailers. The Company also sells Kuvan to Merck Serono at a price near its manufacturing cost, and Merck Serono resells the product to end users outside the U.S., Canada and Japan. The royalty earned from Kuvan product sold by Merck Serono in the EU is included as a component of net product revenues in the period earned. Outside the U.S., Naglazyme is sold to the Company s authorized distributors or directly to government purchasers or hospitals, which act as the end-users. The Company records reserves for rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues are recorded. The Company s reserve calculations require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions each quarter, and records any necessary adjustments to its reserves. The Company records fees paid to distributors as a reduction of revenue.

The Company records allowances for product returns, if appropriate, as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including market exclusivity of the products based on their orphan drug status, the patient population, the customers limited return rights and the Company s experience with returns. Because of the pricing of Naglazyme and Kuvan, the limited number of patients and the customers limited return rights, most Naglazyme and Kuvan customers and retailers carry a limited inventory. Certain international customers, usually government entities, tend to purchase larger quantities of product less frequently. Although such buying patterns may result in revenue fluctuations from quarter to quarter, the Company has not experienced any increased product returns or risk of product returns. The Company relies on historical return rates to estimate returns for Aldurazyme, Naglazyme and Kuvan. Genzyme s return rights for Aldurazyme are limited to defective product. Based on these factors, management has concluded that product returns will be minimal, and the Company has not experienced significant product returns to date. In the future, if any of these factors and/or the history of product returns changes, an allowance for product returns may be required.

The Company maintains a policy to record allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. As of December 31, 2009, the Company has experienced no significant bad debts and the recorded allowance for doubtful accounts was insignificant.

Collaborative agreement revenues Collaborative agreement revenues from Merck Serono include both license revenue and contract research revenue under the Company s agreement with Merck Serono, which was executed in May 2005. Nonrefundable up-front license fees where the Company has continuing involvement through research and development collaboration are initially deferred and recognized as collaborative agreement license revenue over the estimated period for which the Company continues to have a performance obligation. The Company s performance obligation related to the $25.0 million upfront payment from Merck Serono ended in the fourth quarter of 2008. There was no cost of sales associated with the amortization of the up-front license fee received from Merck Serono. Nonrefundable amounts received for shared development costs are recognized as revenue in the period in which the related expenses are incurred. Contract research revenue included in collaborative agreement revenues represents Merck Serono s share of Kuvan development costs under the Merck Serono agreement, which are recorded as research and development expenses in the consolidated statements of operations. Allowable costs during the development period must have been included in the pre-approved annual budget in order to be subject to reimbursement, or must be separately approved by both parties.

Collaborative agreement revenues totaled $28.3 million, $38.9 million and $2.4 million in the years ended December 31, 2007, 2008 and 2009, respectively. Collaborative agreement revenues in 2009 included $2.4 million

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of reimbursable development costs for Kuvan. Collaborative revenue agreement revenues in 2008 included $3.7 million of reimbursable development costs for Kuvan, recognition of $5.2 million of the up-front license fee received from Merck Serono and a $30.0 million milestone payment from Merck Serono for the marketing approval of Kuvan in the EU. In 2007, collaborative agreement revenue included $6.4 million of reimbursable development costs for Kuvan, recognition of $6.9 million of the up-front license fee and a $15.0 million milestone payment received from Merck Serono upon the acceptance of the Kuvan filing by the EMEA.

Royalty and license revenues Royalty revenue includes royalties on net sales of products with which the Company has no direct involvement and is recognized based on data reported by licensees or sublicensees. Royalties are recognized as earned in accordance with the contract terms when the royalty amount is fixed or determinable based on information received from the sublicensee and when collectibility is reasonably assured.

Due to the significant role the Company plays in the operations of Aldurazyme and Kuvan, primarily the manufacturing and regulatory activities, as well as the rights and responsibilities to deliver the products to Genzyme and Merck Serono, respectively, the Company elected not to classify the Aldurazyme and Kuvan royalties earned as other royalty revenues and instead to include them as a component of net product revenues.

Royalty and license revenues for 2009 include $5.6 million of Orapred product royalties, a product the Company acquired in 2004 and sublicensed in 2006, and $1.0 million of royalty revenues for 6R-BH4, the active ingredient in Kuvan, product sold in Japan. Royalty and license revenues for 2008 included $3.8 million of Orapred product royalties and a $1.5 million milestone payment related to the Japanese approval of 6R-BH4, for the treatment of patients with PKU. Royalty and license revenues in 2007 included Orapred product royalty revenues of $2.3 million and a $4.0 million milestone payment related to the one-year anniversary of FDA approval of the marketing application for Orapred ODT.

(i) Research and Development

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

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

(j) Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income/loss by the weighted average shares of common stock outstanding during the period. Diluted net income (loss) per share reflects the potential dilution

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that would occur if securities or other contracts to issue common stock were exercised or converted into common stock; however, potential common equivalent shares are excluded if their effect is anti-dilutive. Potential shares of common stock include shares issuable upon the exercise of outstanding employee stock option awards, common stock issuable under the Company s 2006 Employee Stock Purchase Plan (ESPP), restricted stock, contingent issuances of common stock related to convertible debt and through the first quarter of 2009, the portion of acquisition costs that was payable in shares of the Company s common stock at the Company s option. For 2007 and 2009, such potential shares of common stock were excluded from the computation of diluted net loss per share, as their effect is antidilutive.

Potentially dilutive securities for the year ended December 31, 2007 and 2009, excluded from the diluted net loss per share (in thousands) include:

	December 31,	
	2007	2009
Options to purchase common stock	11,413	14,047
Common stock issuable under convertible debt	26,361	26,343
Portion of acquisition payable in common stock at the option of the Company	243	
Unvested restricted stock units	117	333
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method		91
Potentially issuable common stock for ESPP purchases	311	281
Total	38,445	41,095

The following represents a reconciliation from basic weighted shares outstanding to diluted weighted shares outstanding and the earnings per share for the year ended December 31, 2008 (in thousands, except per share data):

	For the Year Ended December 31, 2008		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Earnings Per Share:			
Net Income	$ 30,831	98,975	$ 0.31

Effect of dilutive shares:			
Stock options using the treasury method		3,837	
Portion of acquisition obligation payable in common stock at the option of the Company		483	
Potentially issuable common stock for ESPP purchases		245	
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method	(308)	32	
Diluted Earnings Per Share:			
Net Income	$ 30,523	103,572	$ 0.29

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In addition to the equity instruments included in the table above, the following potential shares of common stock were excluded from the computation as they were anti-dilutive for the year ended December 31, 2008 using the treasury stock method for stock options and potentially issuable restricted stock and the if-converted method for the Company s convertible debt (in thousands):

	Year Ended December 31, 2008
Options to purchase common stock	5,285
Common stock issuable under convertible debt	26,343
Potentially issuable restricted stock units	225
Total	31,853

(k) Stock-Based Compensation

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options and ESPP awards. The determination of the fair value of stock-based payment awards using an option-pricing model is affected by the Company s stock price as well as assumptions regarding a number of complex and subjective variables. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period for each award. Further, stock-based compensation expense recognized in the consolidated statements of operations is based on awards expected to vest, therefore the amount of expense has been reduced for estimated forfeitures, which are based on historical experience. If actual forfeitures differ from estimates at the time of grant they will be revised in subsequent periods.

If factors change and different assumptions are employed in determining the fair value of stock based awards, the stock based compensation expense recorded in future periods may differ significantly from what was recorded in the current period (see Note 3 for further information).

(l) Nonqualified Deferred Compensation Plan

The Company s Nonqualified Deferred Compensation Plan allows eligible employees, including management and certain highly-compensated employees as designated by the plan s administrative committee and members of the Board of Directors, to make voluntary deferrals of compensation to specified dates, retirement or death. Participants are permitted to defer portions of their salary, annual cash bonus and restricted stock. The Company is not allowed to make additional direct contributions to the Nonqualified Deferred Compensation Plan on behalf of the participants without further action by the Board of Directors.

Other current assets and other non-current assets include $0.9 million and $1.8 million, respectively, of investments held in trust related to the Company s Nonqualified Deferred Compensation Plan for certain employees and directors as of December 31, 2008 and December 31, 2009, respectively. All of the investments held in the Nonqualified Deferred Compensation Plan are classified as trading securities and recorded at fair value with changes in the investments fair values recognized in earnings in the period they occur. Restricted stock issued into the Nonqualified Deferred Compensation Plan is accounted for similarly to treasury stock in that the value of the employer stock is determined on the date the restricted stock vests and the shares are issued into the Nonqualified Deferred Compensation Plan. The restricted stock issued into the Nonqualified Deferred Compensation Plan is recorded in equity and changes in the fair value of the corresponding liability are recognized in earnings as incurred. The corresponding liability for the Nonqualified Deferred Compensation Plan is included in other current liabilities and other long-term liabilities.

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(m) Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred taxes are determined based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded to reduce deferred tax assets to the amount that is more likely than not to be realized. There was a full valuation allowance against net deferred tax assets of $268.1 million at December 31, 2009. Future taxable income and ongoing prudent and feasible tax planning strategies have been considered in assessing the need for the valuation allowance. An adjustment to the valuation allowance would increase or decrease net income/loss in the period such adjustment was made or additional paid in capital. For the years ended December 31, 2007, 2008 and 2009, the Company recognized income tax expense of $0.7 million, $2.6 million and $1.1 million, respectively. Income tax expense for the years ended December 31, 2007, 2008 and 2009 was primarily related to income earned in certain of the Company s international subsidiaries, California state income tax and U.S. Federal Alternative Minimum Tax expense.

(n) Foreign Currency and Other Hedging Instruments

The Company has transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. The Company manages some of these exposures on a consolidated basis, which results in the netting of certain exposures to take advantage of natural offsets and through the use of foreign currency forward contracts. Gains or losses on net foreign currency hedges are intended to offset losses or gains on the underlying net exposures in an effort to reduce the earnings and cash flow volatility resulting from fluctuating foreign currency exchange rates.

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. Derivatives that are not defined as hedging instruments are adjusted to fair value through earnings. Gains and losses resulting from changes in fair value are accounted for depending on the use of the derivative and whether it is designated and qualifies for hedge accounting (see Note 12 for further information).

(o) Fair Value of Financial Instruments

The Company discloses the fair value of financial instruments for assets and liabilities for which it is practicable to estimate that value. The carrying amounts of all cash equivalents, investments and forward exchange contracts approximate fair value based upon quoted market prices or discounted cash flows. The fair value of trade accounts receivables, accounts payable and other financial instruments approximates carrying value due to their short-term nature.

(p) Comprehensive Income (Loss) and Accumulated Other Comprehensive Income (Loss)

Comprehensive income (loss) includes net income/loss and certain changes in stockholders equity that are excluded from net income/loss, such as changes in unrealized gains and losses on the Company s available-for-sale securities, unrealized gains/losses on foreign currency hedges, and changes in the Company s cumulative foreign currency translation account. There were no tax effects allocated to any components of other comprehensive income (loss) during 2007, 2008 and 2009 due to a full valuation allowance.

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In 2009, comprehensive net loss was approximately $0.7 million, compared to comprehensive net income of $31.8 million for the year ended December 31, 2008. The fluctuation in accumulated other comprehensive income (loss) is comprised of the following (in thousands):

	Year Ended December 31,	
	2008	2009
Net unrealized gain (loss) on available-for-sale securities	$ 869	$ (421)
Net unrealized gain (loss) on foreign currency hedges	(212)	(477)
Net unrealized gain (loss) on equity investments	332	720
Net foreign currency translation gain (loss)	(22)	5
Change in accumulated other comprehensive income (loss)	$ 967	$ (173)

(q) Restricted Cash

The Company s balance of restricted cash amounted to $7.3 million and $2.0 million at December 31, 2008 and 2009, respectively. The December 31, 2008 balance included $6.2 million related to cash received for royalties earned pursuant to the Orapred sublicense agreement, which was restricted from use until June 2009 when the Company paid the remaining acquisition obligation resulting from the Ascent Pediatrics transaction to Medicis (see Note 4). The $6.2 million was included in other current assets on the December 31, 2008 consolidated balance sheet. Restricted cash also includes investments of $0.9 million and $1.8 million held by the Company s Nonqualified Deferred Compensation Plan as of December 31, 2008 and 2009, respectively, which is included in other current assets and other non-current assets.

(r) Recent Accounting Pronouncements

The FASB issued the ASC, which defines the new hierarchy for U.S. GAAP. The ASC is now the sole source for all authoritative non-governmental accounting guidance, with the exception of grandfathered guidance, SEC rules and interpretive releases and Statement of Financial Accounting Standards No. 166 and No. 167. The ASC did not change U.S. GAAP. The ASC was effective for all reporting periods that ended after September 15, 2009. The Company adopted the ASC in the third quarter of 2009.

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-6, *Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements,* which expands fair value disclosure requirements. Transition will be in two phases with

expanded disclosures regarding activity for Level 1 and 2 applicable for the Company on January 1, 2010 and expanded disclosures for Level 3 activity effective on January 1, 2011.

In December 2009, the FASB issued ASU 2009-17, *Consolidations (Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*. This ASU amends the FASB Accounting Standards Codification for Statement 167. In June 2009, the FASB issued Statement of Financial Accounting Standards No.167, *Amendments to FASB Interpretation No. 46(R)* (SFAS No. 167). SFAS No.167 eliminates FASB Interpretation No. 46(R) s exceptions to consolidating qualifying special-purpose entities, contains new criteria for determining the primary beneficiary, and increases the frequency of required reassessments to determine whether a company is the primary beneficiary of a variable interest entity. SFAS No. 167 is effective for fiscal years beginning after November 15, 2009, which for the Company is January 1, 2010, with earlier adoption prohibited. The Company does not expect the adoption of ASU 2009-17 to have a material effect on its consolidated financial statements.

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In September 2009, the FASB issued ASU 2009-13, *Multiple Deliverable Revenue Arrangements* (ASU 2009-13), which amended the accounting standards for multiple element arrangements to:

- provide updated guidance on whether multiple deliverables exist, how the elements in an arrangement should be separated, and how the consideration should be allocated;
- require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of each element if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and
- eliminate the use of the residual method and require a vendor to allocate revenue using the relative selling price method.

ASU 2009-13 is effective for fiscal years beginning after June 15, 2010, which for the Company is January 1, 2011, with early application permitted. The Company is currently evaluating the impact, if any, ASU 2009-13 will have on the Company s consolidated financial statements.

In August 2009, the FASB issued ASU 2009-05, *Fair Value Measurements and Disclosures* (ASU 2009-05), which amends ASC Topic 820, *Fair Value Measurements* (ASC 820). The update addresses practice difficulties caused by tension between fair-value measurements based on the price that would be paid to transfer a liability to a new obligor and contractual or legal requirements that prevent such transfers from taking place. ASC 820 is effective for interim and annual periods beginning after August 27, 2009, which for the Company is October 1, 2009. The adoption of ASU 2009-05 resulted in the expansion of the Company s fair value disclosures.

In December 2009, the FASB issued ASU 2009-16, *Accounting for Transfers of Financial Assets*. This ASU amends the FASB Accounting Standards Codification for Statement 166. In June 2009, the FASB issued Statement of Financial Accounting Standards No. 166, *Accounting for Transfers of Financial Assets an amendment of FASB Statement No. 140* (SFAS No. 166). SFAS No. 166 eliminates the concept of a qualifying special-purpose entity, creates more stringent conditions for reporting a transfer of a portion of a financial asset as a sale, clarifies other sale-accounting criteria, and changes the initial measurement of a transferor s interest in transferred financial assets. SFAS No. 166 will be effective for transfers of financial assets in fiscal years beginning after November 15, 2009, which for the Company is 2010, and in interim periods within those fiscal years, with earlier adoption prohibited. The Company does not expect the adoption of ASU 2009-16 to have a material effect on its consolidated financial statements.

ASC Topic 805, *Business Combinations* (ASC 805) requires an entity to recognize the assets acquired, liabilities assumed, contractual contingencies and contingent consideration at their fair value on the acquisition date. Subsequent changes to the estimated fair value of contingent consideration will be reflected in earnings until the contingency is settled. ASC 805 also requires acquisition-related costs and restructuring costs to be expensed as incurred rather than treated as part of the purchase price. The provisions of ASC 805 are effective for business combinations initiated on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which for the Company was January 1, 2009. The adoption of ASC 805 is reflected in the Company s accounting treatment of the Huxley Pharmaceuticals,

Inc. acquisition discussed in Note 5.

(s) Reclassifications and Adjustments

Certain items in the prior year s consolidated financial statements have been reclassified to conform to the current year s presentation in the consolidated balance sheet and statements of cash flows. The previously

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reported balances for total assets and total liabilities and classifications of net cash provided by (used in) operating activities, investing activities and financing activities for any period presented were not affected by these reclassifications.

(3) STOCKHOLDERS EQUITY

(a) Share Incentive Plan

BioMarin s 2006 Share Incentive Plan (Share Incentive Plan), which was approved in June 2006 and replaces the Company s previous stock option plans, provides for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date, as well as other forms of equity compensation. As of December 31, 2009, awards issued under the 2006 Share Incentive Plan include both stock options and restricted stock units. Stock option awards granted to employees generally vest over a four-year period on a cliff basis six months after the grant date and then monthly thereafter. The term of the outstanding options is generally ten years. Options assumed under past business acquisitions generally vest over periods ranging from immediately upon grant to five years from the original grant date and have terms ranging from two to ten years. Restricted stock units granted to employees generally vest in a straight-line, annually over a four-year period after the grant date. Restricted stock units granted to directors generally vest in full one year after the grant date. As of December 31, 2009, options to purchase approximately 10.7 million and 3.3 million shares were outstanding under the Share Incentive Plan, and the Company s previous plans, respectively.

(b) Employee Stock Purchase Plan

Under BioMarin s Employee Stock Purchase Plan (ESPP), which was approved in June 2006 and replaced the Company s previous plan, employees meeting specific employment qualifications are eligible to participate and can purchase shares on established dates semi-annually through payroll deductions at the lower of 85% of the fair market value of the stock at the commencement or each purchase date of the offering period. Each offering period will span up to two years. The ESPP permits eligible employees to purchase common stock through payroll deductions for up to 10% of qualified compensation, up to an annual limit of $25,000. The ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code. As of December 31, 2009, 1,094,202 shares had been issued under the Employee Stock Purchase Plan, and approximately 1.6 million shares had been reserved for future issuance.

(c) Board of Director Grants

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

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(d) Stock-based Compensation

A summary of stock option activity under all plans, including plans that were suspended upon adoption of the 2006 Share Incentive Plan, for the year ended December 31, 2009 is presented as follows:

	Options	Weighted Average Exercise Price	Weighted Average Fair Value of Options Granted	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance as of December 31, 2008	12,075,152	$ 19.94			
Granted	3,151,911	$ 14.30	$ 7.48		
Exercised	(730,046)	$ 10.47			$ 4,579,963
Expired and Forfeited	(450,122)	$ 23.80			
Balance as of December 31, 2009	14,046,895	$ 19.04		6.5	$ 48,325,020
Options expected to vest as of December 31, 2009	5,182,590	$ 20.61			$ 12,138,813
Exercisable as of December 31, 2009	7,940,065	$ 17.43			$ 33,391,588

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company s common stock as of the last trading day of fiscal 2009. The total intrinsic value of options exercised during the years ended December 31, 2007 and 2008 was $19.2 million and $61.7 million, respectively. There were 10.9 million options that were in-the-money at December 31, 2009. The aggregate intrinsic value of options exercised was determined as of the date of option exercise. Upon the exercise of the options, the Company issues new common stock from its authorized shares.

At December 31, 2009, an aggregate of approximately 14.1 million unissued shares were authorized for future issuance under the Share Incentive Plan.

The following table presents the composition of options outstanding and exercisable as of December 31, 2009:

	Options Outstanding			Options Exercisable	
Range of exercise prices	Number of Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price
$ 0.00 to 7.34	641,472	4.77	$ 6.19	638,763	$ 6.19
7.35 to 10.55	701,738	4.06	8.85	701,293	8.85
10.56 to 14.06	2,190,449	6.29	12.22	1,814,969	12.22
14.07 to 17.58	6,463,453	8.05	16.02	2,997,155	16.77
17.59 to 21.10	986,853	8.32	18.07	369,823	18.14
21.11 to 24.61	348,427	4.42	22.41	250,245	22.25
24.62 to 28.13	195,667	7.70	26.76	93,933	26.66
28.14 to 31.65	38,650	8.58	28.94	13,238	28.94
31.66 to 35.17	95,700	8.17	33.75	43,805	33.83
35.17 to 40.99	2,384,486	8.35	38.51	1,016,841	38.51
Total	14,046,895			7,940,065	

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The weighted average grant date fair value of options granted during the years ended December 31, 2007, 2008 and 2009, was $9.22, $15.71 and $7.48 per share, respectively.

Determining the Fair Value of Stock Options and Stock Purchase Rights

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the tables below. The expected life of options is based on observed historical exercise patterns. Groups of employees that have similar historical exercise patterns were considered separately for valuation purposes, but none were identified that had distinctly different exercise patterns as of December 31, 2009. The expected volatility of stock options is based upon proportionate weightings of the historical volatility of the Company s common stock and the implied volatility of traded options on the Company s common stock for fiscal periods in which there is sufficient trading volume in options on the Company s common stock. The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future. The assumptions used to estimate the per share fair value of stock options granted and stock purchase rights granted under the Company s 2006 Share Incentive Plan and ESPP for the years ended December 31, 2007, 2008 and 2009, respectively, are as follows:

	Year Ended December 31,		
Stock Option Valuation Assumptions	**2007**	**2008**	**2009**
Expected volatility	44-51%	45-51%	53-55%
Dividend yield	0.0%	0.0%	0.0%
Expected life	5.2-5.5 years	5.2-5.8 years	6.0 -6.1 years
Risk-free interest rate	3.7-5.1%	1.4-3.2%	1.9-2.6%

The Company recorded $17.5 million, $25.3 million and $31.6 million of compensation costs related to current period vesting of stock options for the years ended December 31, 2007, 2008, and 2009, respectively. As of December 31, 2009, there was $61.2 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 2.5 years.

	Year Ended December 31,		
Employee Stock Purchase Plan Valuation Assumptions	**2007**	**2008**	**2009**
Expected volatility	44-54%	47-51%	55%
Dividend yield	0.0%	0.0%	0.0%

Expected life	6-24 months	6-24 months	6-24 months
Risk-free interest rate	3.8-5.2%	1.1-2.4%	0.2-0.9%

The Company recorded $1.6 million, $1.5 million, and $2.2 million of compensation costs related to options granted under the ESPP for the years ended December 31, 2007, 2008, and 2009, respectively. As of December 31, 2009, there was $3.2 million of total unrecognized compensation cost related to unvested stock options. These costs are expected to be recognized over a weighted average period of 1.7 years.

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A summary of non-vested restricted stock unit activity under the plan for the year ended December 31, 2009 is presented as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested units as of December 31, 2008	225,255	$ 31.06
Granted	197,295	
Vested	(76,707)	
Forfeited	(12,519)	
Non-vested units as of December 31, 2009	333,324	$ 21.07

The Company recorded $0.4 million, $1.6 million and $2.1 million of compensation costs related to restricted stock units for the years ended December 31, 2007, 2008 and 2009, respectively. As of December 31, 2009, there was $5.6 million of total unrecognized compensation cost related to unvested restricted stock units. These costs are expected to be recognized over a weighted average period of 2.9 years.

During the third quarter of 2009, the Company granted 54,000 stock options to non-employees. The non-employee grants vest over periods of nine months up to two years. The unvested portion of the stock options will be re-measured at each reporting period. Total stock-based compensation expense for non-employee stock option grants for the year ended December 31, 2009 was approximately $142,000.

The compensation expense that has been included in the Company s consolidated statement of operations for stock-based compensation arrangements was as follows (in thousands):

	December 31,		
	2007	2008	2009
Cost of sales	$ 578	$ 1,521	$ 3,948
Research and development expense	6,978	8,584	11,919
Selling, general and administrative expense	10,727	15,145	18,681
Total stock-based compensation expense	$ 18,283	$ 25,250	$ 34,548

There was no income tax benefit associated with stock-based compensation for 2007, 2008 and 2009 because any deferred tax asset resulting from stock-based compensation was offset by additional valuation allowance.

Stock-based compensation of $1.7 million, $4.6 million and $5.4 million was capitalized into inventory for the years ended December 31, 2007, 2008 and 2009, respectively. Capitalized stock-based compensation is recognized into cost of sales when the related product is sold.

At December 31, 2009, an aggregate of approximately 15.7 million unissued shares was authorized for future issuance under the Company s stock plans, which include shares issuable under the Share Incentive Plan and the Company s ESPP. Under the Share Incentive Plan, awards that expire or are cancelled without delivery of shares generally become available for issuance under the plan. Awards that expire or are cancelled under the Company s suspended 1997 Stock Plan or 1998 Director Option Plan may not be reissued.

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(e) Stockholders Rights Plan

In 2002, the Board of Directors authorized a stockholders rights plan, which was amended and restated on February 27, 2009. Terms of the plan provide for stockholders of record at the close of business on September 23, 2002 to receive one preferred share purchase right (a Right) for each outstanding share of common stock held. The Rights will be exercisable if a person or group acquires 15% or more of the Company s common stock or announces a tender offer or exchange offer for 15% or more of the common stock. Depending on the circumstances, the effect of the exercise of the Rights will be to permit each holder of a Right to purchase shares of the Company s Series B Junior Participating Preferred Stock that have significantly superior dividend, liquidation and voting rights compared to the Company s common stock, at a price of $35.00 per share. The Company will be entitled to redeem the Rights at $0.001 per Right at any time before a person has acquired 15% or more of the outstanding common stock. Additionally, the Company s Board of Directors has the authority to issue an additional 249,886 shares of preferred stock and to determine the terms of those shares without any further action by the Company s stockholders. The stockholders rights plan expires in 2012. As of December 31, 2009, no stock rights have been granted under this plan.

(4) INTANGIBLE ASSETS AND GOODWILL

As of December 31, 2008 and December 31, 2009, intangible assets consisted of the following (in thousands):

	December 31,	
	2008	**2009**
Orapred	$ 20,437	$
Kuvan	5,093	5,016
Firdapse		36,933
Gross intangible assets	25,530	41,949
Less: Accumulated amortization	(17,904)	(972)
Net carrying value	$ 7,626	$ 40,977

The following table represents the changes in goodwill for the year ended December 31, 2009 (in thousands):

Balance at December 31, 2008	$ 21,262
Additional goodwill related to the acquisition of Huxley Pharmaceuticals, Inc. (See Note 5)	2,460
Balance at December 31, 2009	$ 23,722

(a) Orapred

In 2004, the Company acquired the Orapred product line from Ascent Pediatrics, a wholly owned subsidiary of Medicis Pharmaceutical Corporation (Medicis). The acquisition was accounted for as a business combination. In June 2009, the Company settled the remaining acquisition obligation for $70.6 million in cash. The stock purchase was completed substantially in accordance with the terms of the previously disclosed Securities Purchase Agreement dated May 18, 2004 and amended on January 12, 2005, by and among BioMarin, Medicis and Pediatrics.

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The transaction resulted in a purchase price allocation of $21.3 million to goodwill, representing the financial, strategic and operational value of the transaction to BioMarin. Goodwill is subject to an annual impairment analysis under the provisions of ASC Subtopic 350-20, *Intangibles Goodwill and Other* (ASC 350-20).

The Company completed its 2009 annual impairment test during the fourth quarter of 2009 and determined that no impairment of goodwill existed as of December 31, 2009.

In March 2006, the Company entered into a license agreement with a third party for the continued sale and commercialization of Orapred and other Orapred formulations then under development. Through the agreement, the third party acquired exclusive rights to market these products in North America, and BioMarin retained exclusive rights to market these products outside of North America. Through a second agreement in 2009, the third-party acquired the remaining world-wide rights.

In July 2009, the Company transferred all of the North American intellectual property relating to the Orapred product to Shionogi Pharma, Inc. (formerly known as Scièle Pharma, Inc.) (Shionogi), a U.S.-based group company of Shionogi & Co., the third party who holds a license to sell and commercialize the Orapred product line world-wide. The transfer of the intellectual property was made in accordance with the terms of the previously disclosed License Agreement dated March 15, 2006 between the Company and Scièle Pharma, Inc. (formerly Alliant Pharmaceuticals, Inc.). As a result of the completion of the transaction with Medicis, $9.1 million in cash was released from escrow pursuant to the sublicense and was reclassified from restricted cash to cash and cash equivalents by the Company in June 2009.

The Orapred intangible assets consist of the Orapred product technology as of December 31, 2008 and 2009. The gross and net carrying value of the Orapred product technology was as follows (in thousands):

	December 31,	
	2008	2009
Gross value	$ 20,437	$
Accumulated amortization	(17,524)	( )
Net carrying value	$ 2,913	$

The product technology was the only intangible asset subject to amortization and represented the rights to the proprietary knowledge associated with Orapred. These rights included the right to develop, use and market Orapred. The product technology was being amortized over Orapred s estimated economic life of 3.5 years using the straight-line method of amortization through July 2009 and included no estimated residual value.

Amortization expense related to the Orapred intangible for the years ended December 31, 2007, 2008 and 2009 was $4.4 million, $4.4 million and $2.9 million, respectively. The imputed discount on the purchase obligation represents the gross value of the future cash payments to Medicis, discounted to their present value at a rate of 6.1%. The discount was amortized and recorded as interest expense over the life of the obligation using the effective interest rate method.

(b) Kuvan Intangible Assets

Kuvan intangible assets relate to license payments made to third parties as a result of the FDA approval of Kuvan in December 2007 and the EMEA approval in December 2008, which resulted in a $2.7 million addition

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to the Kuvan intangible assets. At December 31, 2009, Kuvan intangible assets totaled a gross value of $5.0 million. Amortization expense related to the Kuvan intangible assets is included as a component of cost of sales in the consolidated statements of operations, and totaled $0.4 million and $0.6 million for the years ended December 31, 2008 and 2009, respectively. Amortization expense for the year ended December 31, 2007 was insignificant.

The following table summarizes the annual amortization of the Kuvan intangible assets through 2018 (in thousands):

	Net Balance at December 31, 2009	Remaining Life	Annual Amortization
License payment for FDA Approval	$ 1,646	5 years	$ 332
License payment for EMEA Approval	2,398	9 years	277
Total	$ 4,044		$ 609

(c) Firdapse

The Firdapse intangible assets consist of the Firdapse product technology purchased as part of the Huxley Pharmaceuticals, Inc. acquisition. As of December 31, 2009, the gross and net carrying value of the Firdapse product technology was comprised of $30.2 million and $6.7 million related to marketing rights in Europe and the U.S., respectively, which were both in process research and development assets with indefinite lives as of the purchase date. Subsequently, in December 2009, the EMEA granted marketing approval for Firdapse in the EU, changing the useful life of the European rights from indefinite to 10 years, which corresponds to the period of market exclusivity conferred through the orphan drug protection. Commencing in 2010, the Company will amortize the European product technology at an annual rate of $3.0 million.

The $2.5 million of Huxley goodwill represents the assets recognized in connection with the deferred tax liability and did not result from excess purchase price. See Note 5 for additional discussion.

(5) ACQUISITION OF HUXLEY PHARMACEUTICALS, INC.

On October 23, 2009, the Company acquired Huxley Pharmaceuticals, Inc. (Huxley), which has rights to a proprietary form of 3,4-diaminopyridine (3,4-DAP), amifampridine phosphate, for the rare autoimmune disease Lambert Eaton Myasthenic Syndrome (LEMS) for a total purchase price of $37.2 million. As a result of the acquisition, the Company will be the first to market an approved treatment for LEMS in Europe.

In connection with its acquisition of Huxley, the Company paid $15.0 million upfront for all of the outstanding common stock of Huxley. The Company has also agreed to pay Huxley stockholders additional consideration in future periods up to $42.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and development milestones are met. The fair value of the contingent consideration payments was $22.2 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as Level 3 inputs. Key assumptions include: (1) a discount rate of 6.3%; and (2) a probability adjusted contingency. As of December 31, 2009, the range of outcomes and assumptions used to develop these estimates have not changed. In November 2009, the FDA granted Firdapse U.S. orphan status, resulting in a payment of $1.0 million. In December 2009, the EMEA granted marketing approval for Firdapse, which will result in a payment of $6.5 million.

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The following table presents the allocation of the purchase consideration, including the contingent consideration, based on fair value:

Cash and cash equivalents	$ 483
Intangible assets	36,933
Other assets	179
Goodwill	2,460
Accounts payable and accrued expenses	(387)
Deferred tax liability	(2,460)
Net Assets Acquired	$ 37,208

Huxley s results of operations prior to and since the acquisition date were insignificant compared to the Company s consolidated financial statements.

The deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes. The $2.5 million of goodwill represents the assets recognized in connection with the deferred tax liability and did not result from excess purchase price. See Note 14 for additional discussion.

Intangible Assets

A substantial portion of the assets acquired consisted of intangible assets related to Huxley s in-process research and development (IPR&D) assets for the treatment of LEMS. The Company determined that the estimated acquisition-date fair values of the intangible assets related to the marketing rights for the European and U.S. IPR&D projects were $30.2 million and $6.7 million, respectively. Intangible assets related to IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development (R&D) efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D assets below their respective carrying amounts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. The Company did not recognize amortization expense related to the Firdapse intangible assets during 2009.

In estimating fair value of the IPR&D assets, the Company compensated for the differing phases of development of each asset by probability-adjusting its estimation of the expected future cash flows associated with each asset. The Company then determined the present value

of the expected future cash flows. The projected cash flows from the IPR&D assets were based on key assumptions such as estimates of revenues and operating profits related to the feasibility and timing of achievement of development, regulatory and commercial milestones, expected costs to develop the IPR&D into commercially viable products, and future expected cash flows from product sales.

Marketing approval EMEA for 3,4-DAP, the first approved treatment for LEMS, was granted by the EMEA in December 2009, thereby conferring orphan drug protection and providing ten years of market exclusivity in Europe. The Firdapse-EU intangible assets will be amortized using the straight-line method over their estimated useful life of ten years, which corresponds to the period of market exclusivity conferred through the orphan drug protection.

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(6) SHORT-TERM AND LONG-TERM INVESTMENTS

At December 31, 2008, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity For the Year Ending December 31, 2009 Total Book Value	Unrealized Gain (Loss)	December 31, 2008 Aggregate Fair Value
Corporate securities	$ 55,270	$ (100)	$ 55,170
Commercial paper	33,076	48	33,124
Equity securities	3,633	332	3,965
U.S. Government agency securities	220,914	977	221,891
U.S. Government backed commercial paper	24,370	5	24,375
Total	$ 337,263	$ 1,262	$ 338,525

At December 31, 2009, the principal amounts of short-term and long-term investments by contractual maturity are summarized in the table below (in thousands):

	Contractual Maturity Date For the Years Ending December 31,					
	2010	2011	2012	Total Book Value	Unrealized Gain (Loss)	Aggregate Fair Value
Certificates of deposit	$ 30,924	$ 18,833	$	$ 49,757	$ (120)	$ 49,637
Corporate securities	57,973	64,735	38,096	160,804	461	161,265
Commercial paper	7,981			7,981	12	7,993
Equity securities	701			701	1,052	1,753
U.S. Government agency securities	34,861	47,724		82,585	122	82,707
Total	$ 132,440	$ 131,292	$ 38,096	$ 301,828	$ 1,527	$ 303,355

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of December 31, 2009. The investments are placed in financial institutions with strong credit ratings and management expects full recovery of the amortized costs.

At December 31, 2008, the aggregate amount of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands). All investments were classified as available-for-sale at December 31, 2008.

	Less Than 12 Months To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate securities	$ 44,941	$ (147)	$ 44,941	$ (147)
Commercial paper	1,992	(6)	1,992	(6)
U.S. Government agency securities	6,928	(12)	6,928	(12)
U.S. Government back commercial paper	9,947	(31)	9,947	(31)
Total	$ 63,808	$ (196)	$ 63,808	$ (196)

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At December 31, 2009, the aggregate amounts of unrealized losses and related fair value of investments with unrealized losses were as follows (in thousands). All investments were classified as available-for-sale at December 31, 2009.

	Less Than 12 Months To Maturity		12 Months or More To Maturity		Total	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	$ 23,744	$ (55)	$ 14,358	$ (69)	$ 38,102	$ (124)
Corporate securities	12,265	(16)	45,488	(186)	57,753	(202)
U.S. Government agency securities	5,325	(1)	20,010	(93)	25,335	(94)
Total	$ 41,334	$ (72)	$ 79,856	$ (348)	$ 121,190	$ (420)

(7) SUPPLEMENTAL BALANCE SHEET INFORMATION

As of December 31, 2008 and December 31, 2009, inventory consisted of the following (in thousands):

	December 31, 2008	December 31, 2009
Raw materials	$ 10,314	$ 7,692
Work in process	29,998	40,416
Finished goods	32,850	30,554
Total inventory	$ 73,162	$ 78,662

As of December 31, 2008 and December 31, 2009, other current assets consisted of the following (in thousands):

	December 31, 2008	December 31, 2009
Kuvan European Medicines Agency (EMEA) approval milestone receivable	$ 30,000	$
Non-trade receivables	4,828	7,083
Prepaid expenses	3,013	5,202
Deferred cost of sales	3,879	2,232
Short-term restricted cash	6,202	
Other	2,522	331
Total other current assets	$ 50,444	$ 14,848

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As of December 31, 2008 and December 31, 2009, accounts payable, accrued liabilities and other current liabilities consisted of the following (in thousands):

	December 31, 2008	December 31, 2009
Accounts payable	$ 922	$ 7,567
Accrued accounts payable	26,214	28,353
Accrued vacation	3,798	4,652
Accrued compensation	11,737	14,544
Accrued interest and taxes	2,684	2,859
Accrued royalties	3,401	4,740
Other accrued expenses	6,094	1,525
Accrued rebates	3,194	4,786
Contingent acquisition consideration payable		8,124
Other	989	918
Total accounts payable and accrued liabilities	$ 59,033	$ 78,068

As of December 31, 2008 and December 31, 2009, other long-term liabilities consisted of the following (in thousands):

	December 31, 2008	December 31, 2009
Long-term portion of deferred rent	$ 1,176	$ 983
Long-term portion of capital lease liability	270	85
Long-term portion of contingent acquisition consideration payable		13,089
Long-term portion of deferred compensation liability	1,410	3,124
Long-term deferred tax liability		2,460
Total other long-term liabilities	$ 2,856	$ 19,741

A roll forward of significant estimated revenue dilution reserves is as follows (in thousands):

	Balance at Beginning of Period	Provision for Current period Sales	Provision/ (Reversals) for Prior Period Sales	Actual Charges Related to Current Period Sales	Actual Charges Related to Prior Period Sales	Balance at End of Period
Year ended December 31, 2008:						
Returns reserve	$ 61	$	$ 1	$	$ (62)	$
Accrued rebates	1,816	3,357		(1,684)	(295)	3,194
Acquired returns reserve	122		(122)			
Acquired rebates reserve	621					621
Reserve for cash discounts	34	1,412		(1,182)	(21)	243
Year ended December 31, 2009:						
Accrued rebates	$ 3,194	$ 5,571	$ 187	$ (3,323)	$ (843)	$ 4,786
Acquired rebates reserve	621		(311)		(310)	
Reserve for cash discounts	243	2,170		(2,017)	(137)	259

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(8) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2008 and December 31, 2009 consisted of the following (in thousands):

Category	December 31, 2008	December 31, 2009	Estimated Useful Lives
Leasehold improvements	$ 27,544	$ 38,059	Shorter of life of asset or lease term
Building and improvements	61,183	69,564	20 years
Manufacturing and laboratory equipment	26,996	34,228	5 years
Computer hardware and software	13,088	28,695	3 to 5 years
Office furniture and equipment	4,602	5,529	5 years
Land	10,056	10,056	Not applicable
Construction-in-progress	27,589	74,914	Not applicable
Total property, plant and equipment, gross	$ 171,058	$ 261,045	
Less: Accumulated depreciation	(46,079)	(61,904)	
Total property, plant and equipment, net	$ 124,979	$ 199,141	

Depreciation for the years ended December 31, 2007, 2008 and 2009 was $7.8 million, $11.4 million and $15.9 million, respectively. Depreciation capitalized into inventory for the years ended December 31, 2007, 2008 and 2009 was $1.9 million, $2.8 million and $4.4 million, respectively.

Capitalized interest related to the Company s property, plant and equipment purchases during 2009 was $0.7 million. Capitalized interest related to the Company s property, plant and equipment purchases during 2008 and 2007 was insignificant.

(9) INVESTMENT IN SUMMIT CORPORATION PLC

In July 2008, the Company entered into an exclusive worldwide licensing agreement with Summit Corporation plc (Summit) related to Summit s preclinical drug candidate SMT C1100 and follow-on molecules (2008 Summit License), which are being developed for the treatment of Duchenne muscular dystrophy. The Company paid Summit $7.1 million for an equity investment in Summit shares and licensing rights to SMT C1100. The initial equity investment represented the acquisition of approximately 5.1 million Summit shares with a fair value at the time of acquisition of $5.7 million, based on public market quotes. The Company s investment in Summit represents less than 10% of Summit s outstanding shares. The $1.4 million paid in excess of the fair value of the shares acquired was allocated to the license fee using the residual method and expensed in the third quarter of 2008, as the asset acquired did not have an alternative use. Under the terms of the 2008 Summit License, the Company was obligated to make future development and regulatory milestone payments totaling $51.0 million, contingent on future development and regulatory milestones, as well as tiered royalties based on future net sales. All payments pursuant to the Company s investment in, and license from, Summit were denominated in British pounds.

In March 2009, the Company entered into an asset purchase agreement with Summit. Pursuant to the terms of the asset purchase agreement, the Company purchased certain of Summit s assets which included the rights, title to and interest in Summit s preclinical drug candidate SMT C1100, thus terminating the 2008 Summit License. These assets were acquired by issuing a secured promissory note and assuming $56,000 in related liabilities. The promissory note is secured by all of the assets acquired from Summit. The value of the assumed

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liabilities was expensed in the first quarter of 2009, as the asset acquired does not have an alternative use. Under the secured promissory note, the Company is obligated to make up to $50.0 million in future development and regulatory milestone payments contingent on achieving certain development and regulatory milestones, as well as tiered royalties based on future net sales.

The Company accounts for the Summit shares, which are traded on the London Stock Exchange, as an available-for-sale investment, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary are reported in earnings in the period in which the impairment occurs.

As of December 31, 2009, the Company has recognized cumulative impairment charges of $5.5 million for the decline in the investment s value determined to be other-than-temporary. The impairment charges are comprised of $4.1 million and $1.4 million recognized in December 2008 and March 2009, respectively. The determination that the decline was other-than-temporary is, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value had been less than the value on the date of purchase, Summit s financial condition and near-term prospects, including any events which may influence its operations, and the Company s intent and ability to hold the investment for a period of time sufficient to allow for the anticipated recovery in market value.

(10) INVESTMENT IN LA JOLLA PHARMACEUTICAL COMPANY

On January 4, 2009, the Company entered into a co-exclusive worldwide (excluding Asia Pacific) licensing agreement with La Jolla Pharmaceutical Company (La Jolla) to develop and commercialize Riquent, La Jolla s investigational drug for lupus nephritis. The Company paid La Jolla $7.5 million for the license rights and an additional $7.5 million for 339,104 shares of La Jolla s Series B Preferred Stock. The initial equity investment represents the acquisition of the La Jolla Series B Preferred shares with a fair value of $6.2 million. The $1.3 million paid in excess of the fair value of the shares acquired was allocated to the license fee using the residual method and expensed in the first quarter of 2009, as the license acquired did not have an alternative future use. Research and development expense related to the Company s agreements with La Jolla in the first quarter of 2009 approximated $8.8 million, and is comprised of the $7.5 million up-front license fee and the $1.3 million premium paid in excess of the preferred stock s fair value.

On February 12, 2009, the results of the first interim efficacy analysis for the Phase 3 study of the drug were announced, and the Independent Data Monitoring Board determined that the continuation of the trial was futile. Based on the results of this interim efficacy analysis, the Company and La Jolla decided to stop the study.

On March 26, 2009, the Company terminated its licensing agreement with La Jolla, triggering the preferred stock s automatic conversion feature at a rate of one preferred share to thirty shares of common stock. Thus, as of the conversion date, the Company held approximately 10.2 million shares of common stock, or approximately 15.5% La Jolla s outstanding common stock. The Company accounted for the converted La Jolla shares, which were traded on the NASDAQ Stock Exchange, as an available-for-sale investment. The investment was classified as

available-for-sale, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary were reported in earnings in the period in which the impairment occurs.

In March 2009, the Company recognized an impairment charge of $4.5 million, for the decline in the La Jolla investment s value was determined to be other-than-temporary. The determination that the decline was

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other-than-temporary was, in part, subjective and influenced by several factors, including: the length of time and the extent to which the market value of La Jolla s common stock had been less than the value on the date of purchase, La Jolla s financial condition and near-term prospects, including any events which may influence its operations, and the Company s intent and ability to hold the investment for a period of time sufficient to allow for the anticipated recovery in market value. Based on the then current market conditions, La Jolla s current financial condition and its business prospects, the Company determined that its investment in La Jolla was other-than-temporarily impaired and adjusted the recorded amount of the investment to the stock s market price on March 31, 2009. In June 2009, the Company sold its 10.2 million shares of La Jolla common stock through a series of open market trades, ranging in gross proceeds to the Company of $0.17 to $0.22 per share. In connection with the sale of the La Jolla common stock, the Company recognized a loss of $66,000 on the sale of the equity investment during the second quarter of 2009.

(11) CONVERTIBLE DEBT

In April 2007, the Company sold approximately $324.9 million of Senior Subordinated Convertible Notes due 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately $20.36 per share, subject to adjustment in certain circumstances. There is not a call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on April 23, 2017. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the April 2007 debt, the Company paid approximately $8.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt. In 2007, the Company recognized $0.6 million of amortization expense. In both 2008 and 2009, the Company recognized amortization of expense of $0.9 million.

In March 2006, the Company sold $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. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately $16.58 per share, subject to adjustment in certain circumstances. There is not a call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on March 29, 2013. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

In connection with the placement of the March 2006 debt, the Company paid approximately $5.5 million in offering costs, which have been deferred and are included in other assets. They are being amortized as interest expense over the life of the debt, and the Company recognized $0.8 million of amortization expense in each of the years ended December 31, 2007, 2008 and 2009. During 2008, certain note holders voluntarily exchanged an insignificant number of convertible notes for shares of the Company s common stock.

Interest expense for the years ended December 31, 2007, 2008 and 2009 was $14.2 million, $16.4 million and $14.1 million, respectively. Interest expense included imputed interest related to the Company s acquisition obligation and totaled $4.5 million, $4.4 million and $2.6 million in 2007, 2008 and 2009, respectively. In the second quarter of 2009, the Company paid its acquisition obligation, resulting in the decline of imputed interest. See Note 4 for additional discussion.

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(12) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES

The Company uses hedging contracts to manage the risk of its overall exposure to fluctuations in foreign currency exchange rates. All of the Company s designated hedging instruments are considered to be cash flow hedges.

Foreign Currency Exposure

The Company uses forward foreign exchange contracts to hedge certain operational exposures resulting from changes in foreign currency exchange rates. Such exposures result from portions of its forecasted revenues being denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound.

The Company designates certain of these foreign currency forward contract hedges as hedging instruments and enters into some foreign currency forward contracts that are considered to be economic hedges which are not designated as hedging instruments. Whether designated or undesignated, these forward contracts protect against the reduction in value of forecasted foreign currency cash flows resulting from Naglazyme and Aldurazyme revenues and net asset or liability positions designated in currencies other than the U.S. dollar. The fair values of foreign currency agreements are estimated as described in Note 13, taking into consideration current interest rates and the current creditworthiness of the counterparties or the Company, as applicable. Details of the specific instruments used by the Company to hedge its exposure to foreign currency fluctuations follow below.

At December 31, 2009, the Company had 29 foreign currency forward contracts outstanding to sell a total of 37.1 million Euros with expiration dates ranging from January 29, 2010 through December 31, 2010. These hedges were entered into to protect against the fluctuations in Euro denominated Naglazyme and Aldurazyme revenues. The Company has formally designated these contracts as cash flow hedges, and they are expected to be highly effective within the meaning of ASC Subtopic 815-30, *Derivatives and Hedging- Cash Flow Hedges*, in offsetting fluctuations in revenues denominated in Euros related to changes in the foreign currency exchange rates.

The Company also enters into forward foreign currency contracts that are not designated as hedges for accounting purposes. The changes in fair value of these foreign currency hedges are included as a part of selling, general and administrative expenses in the consolidated statements of operations. At December 31, 2009, the Company had two outstanding foreign currency contracts to sell 15.2 million Euros and 2.5 million British Pounds that were not designated as hedges for accounting purposes.

The maximum length of time over which the Company is hedging its exposure to the reduction in value of forecasted foreign currency cash flows through foreign currency forward contracts is through December 2010. Over the next 12 months, the Company expects to reclassify $0.7 million from accumulated other comprehensive income to earnings as related forecasted revenue transactions occur.

Prior to the second quarter of 2008, the Company did not enter into any derivative transactions which qualified for hedge accounting. During 2009, the Company recognized foreign currency transaction loss of $65,000 from derivative transactions that qualified for hedge accounting, as compared to a gain of $1.9 million recognized in 2008.

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At December 31, 2008 and December 31, 2009, the fair value carrying amount of the Company s derivative instruments was recorded as follows (in thousands):

	Asset Derivatives December 31, 2008		Liability Derivatives December 31, 2008	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 754	Other current liabilities	$ 1,129
Total		$ 754		$ 1,129
Derivatives not designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 49	Other current liabilities	$
Total		$ 49		$
Total derivative contracts		$ 803		$ 1,129

	Asset Derivatives December 31, 2009		Liability Derivatives December 31, 2009	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 77	Other current liabilities	$ 768
Total		$ 77		$ 768
Derivatives not designated as hedging instruments				
Foreign currency forward contracts	Other current assets	$ 6	Other current liabilities	$ 27
Total		$ 6		$ 27
Total derivative contracts		$ 83		$ 795

The effect of derivative instruments on the consolidated statements of operations for the years ended December 31, 2008 and 2009 was as follows (in thousands):

	Foreign Currency Forward Contracts	
	December 31, 2008	December 31, 2009
Derivatives Designated as Hedging Instruments		
Net loss recognized in OCI (1)	$ (212)	$ (477)
Net gain (loss) reclassified from accumulated OCI into income (2)	1,908	(65)
Net gain (loss) recognized in income (3)	(329)	(76)
Derivatives Not Designated as Hedging Instruments		
Net gain (loss) recognized in income (4)	2,901	(1,144)

(1) Net change in the fair value of the effective portion classified in other comprehensive income (OCI)
(2) Effective portion classified as product revenue
(3) Ineffective portion and amount excluded from effectiveness testing classified in selling, general and administrative expense
(4) Classified in selling, general and administrative expense

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At December 31, 2008 and 2009, accumulated other comprehensive income associated with foreign currency forward contracts qualifying for hedge accounting treatment was a loss of $0.2 million and $0.7 million, respectively.

The Company is exposed to counterparty credit risk on all of its derivative financial instruments. The Company has established and maintained strict counterparty credit guidelines and enters into hedges only with financial institutions that are investment grade or better to minimize the Company s exposure to potential defaults. The Company does not require collateral to be pledged under these agreements.

(13) FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income, other equity securities and foreign currency derivatives. The tables below present the fair value of these financial assets and liabilities determined using the following inputs at December 31, 2008 and 2009 (in thousands).

	Fair Value Measurements at December 31, 2008			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market instruments and overnight deposits (1)	$ 222,900	$ 12,959	$ 209,941	$
Corporate securities (3)	55,170		55,170	
Equity securities (4)	3,965	2,332	1,633	
Government agency securities (3)	221,891		221,891	
Government-backed commercial paper (3)	24,375		24,375	
Commercial paper (3)	33,124		33,124	
Deferred compensation asset (8)	854		854	
Foreign currency derivatives (5)	803		803	
Total	$ 563,082	$ 15,291	$ 547,791	$
Liabilities:				
Deferred compensation liability (6)	$ 1,428	$ 574	$ 854	$
Foreign currency derivatives (7)	1,129		1,129	

Total	$ 2,557	$ 574	$ 1,983	$

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	Fair Value Measurements at December 31, 2009			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market instruments and overnight deposits (1)	$ 167,171	$ 18,761	$ 148,410	$
Certificates of deposit (2)	49,637		49,637	
Corporate securities (3)	161,265		161,265	
Equity securities (4)	1,753	1,361	392	
Government agency securities (3)	82,707		82,707	
Commercial paper (3)	7,993		7,993	
Deferred compensation asset (8)	1,791		1,791	
Foreign currency derivatives (5)	83		83	
Total	$ 472,400	$ 20,122	$ 452,278	$
Liabilities:				
Deferred compensation liability (6)	$ 3,505	$ 1,714	$ 1,791	$
Foreign currency derivatives (7)	795		795	
Contingent acquisition consideration (9)	21,213			21,213
Total	$ 25,513	$ 1,714	$ 2,586	$ 21,213

(1) These amounts are included in cash and cash equivalents investments in the Company s consolidated balance sheet.

(2) 62% and 38% are included in short-term and long-term investments in the Company s consolidated balance sheet, respectively.

(3) These amounts are included in short-term investments and long-term investments in the Company s consolidated balance sheet. At December 31, 2008, all balances were classified as short-term investments. At December 31, 2009, 64% of corporate securities and 58% of government agencies were included in long-term investments and the remaining balances are included in short-term investments.

(4) These amounts are included in short-term investments and long-term investments in the Company s consolidated balance sheet. At December 31, 2008 and 2009, 41% and 22%, respectively, are included in long-term investments and the remaining balances are included in short-term investments.

(5) These amounts are included in other current assets on the Company s consolidated balance sheet. Foreign currency derivatives at December 31, 2009 include forward foreign exchange contracts for the Euro. Foreign currency derivatives at December 31, 2008 include forward foreign exchange contracts for Euros and British Pounds.

(6) At December 31, 2008 and 2009, 100% and 89%, respectively, was included in other long-term liabilities and the remainder is included in accounts payable and accrued liabilities on the Company s consolidated balance sheet.

(7) These amounts are included in accounts payable and accrued liabilities on the Company s consolidated balance sheet.

(8) At December 31, 2008 and 2009 100% and 95%, respectively of this balance is included in other assets and the 5% of the December 31, 2009 balance is included in other current assets on the Company s consolidated balance sheet.

(9)

At December 31, 2009, 62% and 38% of these amounts are included in other long-term liabilities and accrued expenses, respectively. See Note 5 for additional discussion.

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(14) INCOME TAXES

Except for 2008, the Company has generated net losses since its inception in 1997. As of December 31, 2009, the Company had federal operating loss carryforwards of approximately $311.3 million and state operating loss carryforwards of approximately $134.0 million. The Company also had federal research and development and orphan drug credit carryforwards of approximately $106.2 million as of December 31, 2009, and state research credit carryovers of approximately $14.0 million. The federal net operating loss and credit carryforwards expire at various dates beginning in the year 2019 through 2029, if not utilized. The state net operating loss carryforwards will begin to expire in 2010 and will completely expire in 2029 if not utilized. Certain state research credit carryovers will begin to expire in 2019 if not utilized, with others carrying forward indefinitely. The Company also has Canadian net operating loss carryforwards of $3.4 million and research credit carryovers of $0.3 million that it currently does not expect to fully utilize. The Canadian NOLS and research credit carryovers expire from 2010 to 2027 and 2012, respectively.

The Company s net operating losses and credits could be subject to annual limitations under IRS Section 382 due to potential changes of ownership during 2009, as the Company completed its most recent Section 382 analysis as of December 31, 2008.

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

	December 31,	
	2008	2009
Net deferred tax assets:		
Net operating loss carryforwards	$ 114,536	$ 117,544
Credit and contribution carryforwards	117,254	119,207
Capitalized research expenses	3,664	2,480
Property, plant and equipment	8,041	9,278
Accrued expenses, reserves, and prepaids	7,111	7,305
Intangible assets	33,356	5,220
Deferred revenue	425	33
Stock-based compensation	6,275	12,623
Impairment on investment	1,882	2,676
Inventory	4,019	4,376
Capital loss carryforwards		1,624
Gross deferred tax assets	$ 296,563	$ 282,366

Deferred tax liability related to joint venture basis difference	(1,601)	(1,991)
Deferred tax liability related to acquisition of Huxley Pharmaceuticals, Inc.		(14,291)
Other	(222)	(464)
Valuation allowance	(294,740)	(268,080)
Net deferred tax assets (liabilities)	$	$ (2,460)

The $14.3 million deferred tax liability relates to the tax impact of future amortization or possible impairments associated with the intangible assets acquired from Huxley Pharmaceuticals, Inc., which are not deductible for tax purposes. The deferred tax liability is comprised of $11.8 million and $2.5 million related to European and U.S intangible assets, respectively. The EMEA granted Firdapse marketing approval in December

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2009, changing the useful life of the European rights from indefinite to 10 years. Upon the closing of the acquisition the Company believed it could estimate the reversal of the temporary difference related to the European asset with sufficient reliability such that the related deferred tax liability could be considered as a source of taxable income in assessing the Company s need for a valuation allowance. This was based on its approval in the EU which resulted in the European asset becoming an amortizing asset. However, the Company had sufficient uncertainty around the timing of the reversal of the US asset such that it could not be netted with any deferred tax assets.

A full valuation allowance is maintained against the Company s deferred tax assets as management believes that it is more likely than not that the deferred tax assets will not be realized, because ultimate long-term profitability of the Company is uncertain as of December 31, 2009. The net valuation allowance increased by $0.3 million in 2008 and decreased $26.7 million in 2009. The decrease in the gross amount of net deferred tax assets and net valuation allowance during 2009 is primarily attributed to the disposition of the Orapred intangible asset in 2009.

As of December 31, 2009, approximately $73.2 million of the above federal net operating loss carryforwards and $55.7 million of the above state net operating loss carryforwards arose from the exercise of employee stock options, which will be accounted for as an increase to additional paid-in-capital if and when realized.

For the years ended December 31, 2007, 2008 and 2009, the Company recognized $0.7 million, $2.6 million and $1.1 million of income tax expense, respectively, primarily related to income earned in several of the Company s international subsidiaries, California state income tax and U.S. federal Alternative Minimum Tax in 2008 only. In 2009, the Company had pre-tax book income of $3.1 million and a pre-tax book loss of $2.5 million in the U.S. and its foreign subsidiaries, respectively. The Company had no deferred income tax expense for the years ended December 31, 2007, 2008 and 2009. The reconciliations between the U.S. federal statutory tax rates to the Company s effective tax rates are as follows:

	December 31,		
	2007	2008	2009
Federal tax	35.0%	35.0%	35.0%
State tax		3.1%	8.8%
Permanent items	(55.0)%	(29.1)%	1,110.8%
General business credits	95.4%	4.4%	488.9%
Foreign income tax	(4.8)%	2.4%	223.4%
Alternative minimum tax		2.1%	(45.9)%
Valuation allowance	(75.4)%	(10.3)%	(1,634.7)%
Effective income tax rate	(4.8)%	7.6%	186.3%

	December 31,		
	2007	2008	2009
Federal income tax expense	$	$ 716	$ (362)
State income tax expense		1,055	(17)
Foreign income tax expense	729	822	1,433
Total income tax expense	$ 729	$ 2,593	$ 1,054

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The Company adopted the provisions of ASC Subtopic 740-10, *Income Taxes* on January 1, 2007. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at December 31, 2008	$
Additions based on tax positions related to the current year	2,327
Additions for tax positions of prior years	20,708
Balance at December 31, 2009	$ 23,035

The annual effective tax rate would not be affected by the amount of unrecognized tax benefits, if recognized because of a full valuation allowance.

The Company s policy for classifying interest and penalties associated with unrecognized income tax benefits is to include such items in the income tax expense. No interest or penalties have been recorded by the Company to date through December 31, 2009.

The Company or one of its subsidiaries files income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. For income tax returns filed before 2005, the Company is no longer subject to audit by the U.S. federal, state, local or non-U.S. tax authorities. However, carryforward tax attributes that were generated prior to 2005 may still be adjusted upon examination by tax authorities. Currently, the Company has no pending or open tax return audits.

Deferred taxes have not been provided on the cumulative undistributed earnings approximating $0.6 million as of December 31, 2009, of certain foreign subsidiaries as such earnings have been permanently reinvested. The Company has also elected to treat certain foreign entities as disregarded entities for U.S. tax purposes, which results in their net income or loss being recognized currently in the Company s U.S. tax return. As such, the tax benefit of net operating losses available for foreign statutory tax purposes has already been recognized for U.S. purposes.

(15) REVENUE AND CREDIT CONCENTRATIONS

The Company considers there to be revenue concentration risks for regions where net product revenue exceeds 10% of consolidated net product revenue. The concentration of the Company s revenue within the regions below may expose the Company to a material adverse effect if sales in the respective regions were to experience difficulties. The table below summarizes product revenue concentrations based on patient location for Naglazyme and Kuvan and Genzyme s location for Aldurazyme for the years ended December 31, 2007, 2008 and 2009.

	Year Ended December 31,		
	2007	2008	2009
Region:			
United States	21%	56%	53%
Europe	60%	25%	24%
Latin America	7%	10%	11%
Rest of World	12%	9%	12%
Total Net Product Revenue	100%	100%	100%

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As of December 31, 2009, accounts receivable related to net product sales of Naglazyme and Kuvan and Aldurazyme product transfer and royalty revenues. On a consolidated basis, three customers accounted for 49% of the Company s Naglazyme and Kuvan net product revenues during 2009, compared to 2008 when six customers accounted for 68% of our Naglazyme and Kuvan net product revenues. Genzyme is the Company s sole customer for Aldurazyme and is responsible for marketing and selling Aldurazyme to third parties. Prior to 2008 Aldurazyme sales were recorded through the joint venture. See Note 20 for additional discussion. Aldurazyme sales in 2008 and 2009 were $72.5 million and $70.2 million, respectively. On a consolidated basis, two customers accounted for 49% and 18% of the December 31, 2009 accounts receivable balance, respectively, compared to December 31, 2008 when two customers accounted for 17% and 50% of the accounts receivable balance, respectively. The Company does not require collateral from its customers, but performs periodic credit evaluations of its customers financial condition and requires immediate payment in certain circumstances.

(16) COLLABORATIVE AGREEMENTS

(a) Merck Serono

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

Pursuant to the agreement, Merck Serono paid BioMarin $25.0 million as consideration for executing the agreement, and is required to make additional milestone payments of up to $232.0 million based on the successful development and approval of both products in multiple indications, including $45.0 million associated with Kuvan for the treatment of PKU. The $45.0 million in Kuvan approval milestones was received in two payments of $15.0 million and $30.0 million during 2007 and 2008, respectively, when the EMEA filing was accepted and EU marketing approval was obtained. The term of the agreement is the later of 10 years after the first commercial sale of the products or the period through the expiration of all related patents within the territories. As of December 31, 2008 and 2009, accounts receivable included $0.9 million and $0.4 million, respectively, due from Merck Serono for reimbursable development costs for Kuvan.

(b) Other Agreements

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

In September 2007, the Company licensed to Asubio Pharma Co., Ltd. (a subsidiary of Daiichi Sankyo) exclusive rights to data and intellectual property contained in the Kuvan new drug application. The Company will receive a milestone payment for approval and royalties on net sales of the product.

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(17) COMMITMENTS AND CONTINGENCIES

(a) Lease Commitments

The Company leases office space and research, testing and manufacturing laboratory space in various facilities under operating agreements expiring at various dates through 2019. Certain of the leases provide for options by the Company to extend the lease for multiple five-year renewal periods and also provide for annual minimum increases in rent, usually based on a Consumer Price Index or annual minimum increases. Minimum lease payments for future years are as follows (in thousands):

2010	$ 4,283
2011	4,037
2012	3,408
2013	3,087
2014	1,356
Thereafter	3,260
Total	$ 19,431

Rent expense for the years ended December 31, 2007, 2008 and 2009 was $3.9 million, $3.6 million, and $4.3 million, respectively. Deferred rent accruals at December 31, 2009 totaled $1.3 million, of which $0.4 million was current. At December 31, 2008, deferred rent accruals totaled $1.3 million, of which $0.2 million was current.

(b) Research and Development Funding and Technology Licenses

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

The Company has also licensed technology, for which it is required to pay royalties upon future sales, subject to certain annual minimums. As of December 31, 2009, such minimum annual commitments are approximately $0.3 million.

(c) Contingencies

From time to time the Company is involved in legal actions arising in the normal course of its business. The Company is not presently subject to any material litigation nor, to management s knowledge, is any litigation threatened against the Company that collectively is expected to have a material adverse effect on the Company s cash flows, financial condition or results of operations. The Company is also subject to contingent payments totaling approximately $167.5 million upon achievement of certain regulatory and licensing milestones if they occur before certain dates in the future.

There have been several lawsuits filed in Brazil alleging that the Company s joint venture with Genzyme and/or the affiliates of the joint venture are contractually obligated to provide Aldurazyme at no cost to several patients in Brazil. The joint venture and/or its affiliates are vigorously defending against these actions. The joint venture and management of the Company are not able to predict the outcome of these cases or estimate with certainty the amount or range of any possible loss the joint venture might incur if the joint venture and/or its affiliates do not prevail in the final, non-appealable determination of these matters.

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(18) RELATED-PARTY TRANSACTIONS

The Company s former Chief Medical Officer once held an adjunct faculty position with LA Biomedical, formerly known as Harbor-UCLA Research Educational Institute, for purposes of conducting research. LA Biomedical licenses certain intellectual property and provides other research services to the Company. The Company is also obligated to pay LA Biomedical royalties on future sales of products covered by the license agreement. The Company s joint venture with Genzyme is subject to a second agreement with LA Biomedical that requires the Company s joint venture partner to pay LA Biomedical a royalty on sales of Aldurazyme through November 2019. Pursuant to the officer s agreements with LA Biomedical, which were entered into prior to his employment with the Company, the officer is entitled to certain portions of these amounts payable to LA Biomedical. The license agreements were effective before the officer was a BioMarin employee. Pursuant to these agreements, the officer was entitled to approximately $1.4 million and $1.8 million from Genzyme related to Aldurazyme during 2007 and 2008, respectively. There were no related party transactions in 2009.

(19) COMPENSATION AGREEMENTS AND PLANS

(a) Employment Agreements

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

(b) 401(k) Plan

The Company sponsors the BioMarin Retirement Savings Plan (401(k) Plan). Most employees (Participants) are eligible to participate following the start of their employment, at the beginning of each calendar month. Participants may contribute to the 401(k) Plan up to the lesser of 100% of their current compensation to or an amount up to a statutorily prescribed annual limit. The Company pays the direct expenses of the 401(k) Plan and matches 100% of each Participant s contributions, up to a maximum of the lesser of 2% of the employee s annual compensation or $4,000 per year. The Company s matching contribution vests over four years from employment commencement and was approximately $0.8 million, $1.3 million and $1.1 million for the years ended December 31, 2007, 2008 and 2009, respectively. Employer contributions not vested upon employee termination are forfeited.

(c) Deferred Compensation Plan

In December 2005, the Company adopted the BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan (the Deferred Compensation Plan). The Deferred Compensation Plan allows eligible employees, including management and certain highly-compensated employees as designated by the Plan s Administrative Committee, and members of the Board the opportunity to make voluntary deferrals of compensation to specified future dates, retirement or death. Participants are permitted to defer portions of their salary, annual cash bonus and restricted stock. The Company may not make additional direct contributions to the Deferred Compensation Plan on behalf of the participants, without further action by the Board. Deferred compensation is held in trust and generally invested to match the investment benchmarks selected by participants. The recorded cost of any investments will approximate fair value. Investments of $0.9 million and $1.8 million and the related deferred compensation liability of $1.4 million and $3.5 million were recorded as of December 31, 2008 and 2009, respectively. Restricted stock issued into the Deferred Compensation Plan is recorded and accounted for similarly to treasury stock in that the value of the employer stock id determined on the date the restricted stock vests and the shares are issued into the Deferred Compensation Plan. The restricted stock issued into the Deferred Compensation Plan is recorded in equity. As of December 31, 2008 and 2009,

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restricted stock issued into the Deferred Compensation Plan was $0.9 million and $1.7 million, respectively. The change in market value was insignificant for the year ended December 31, 2007 and amounted to a loss of approximately $0.3 million in 2008 compared to a gain of approximately $0.3 million in 2009.

(20) JOINT VENTURE

Effective January 2008, the Company and Genzyme restructured BioMarin/Genzyme LLC. Under the revised structure, the operational responsibilities for BioMarin and Genzyme did not significantly change, as Genzyme continues to globally market and sell Aldurazyme and BioMarin continues to manufacture Aldurazyme. The restructuring had two significant business purposes. First, since each party now has full control over its own operational responsibilities, without the need to obtain the approval of the other party, and the parties do not need to review and oversee the activities of the other, it reduces management s time and effort and therefore improves overall efficiencies. Second, since each party will realize 100% of the benefit of their own increased operational efficiencies, it increases the incentives to identify and implement cost saving measures. Under the previous 50/50 structure, each company shared 50% of the expense associated with the other s inefficiencies and only received 50% of the benefit of its own efficiencies. Specifically, the Company will be able to realize the full benefit of any manufacturing cost reductions and Genzyme will be able to realize the full benefit of any sales and marketing efficiencies.

On January 1, 2008, Genzyme began to record sales of Aldurazyme to third party customers and pay BioMarin a tiered payment ranging from approximately 39.5% to 50% of worldwide net product sales depending on sales volume, which is recorded by BioMarin as product revenue. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme as all of the Company s performance obligations are fulfilled at this point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue is deducted from the calculated royalty rate when the product is sold by Genzyme. Genzyme s return rights for Aldurazyme are limited to defective product. Certain research and development activities and intellectual property related to Aldurazyme continues to be managed in the joint venture with the costs shared equally by BioMarin and Genzyme. Pursuant to the terms of the joint venture restructuring, the Company received distributions of $16.7 million of cash and $26.8 million of inventory from the joint venture in the first quarter of 2008.

As a result of restructuring the joint venture, the Company made an initial transfer of inventory on-hand to Genzyme, resulting in the recognition of product transfer revenue of $14.0 million during the first quarter of 2008. A portion of that initial inventory transfer, representing $4.5 million of the related product transfer revenue, was also sold by Genzyme during the first quarter of 2008, which resulted in a royalty due to the Company totaling $14.6 million.

The Company presents the related cost of sales and its Aldurazyme-related operating expenses as operating expenses in the consolidated statements of operations. Equity in the loss of BioMarin/Genzyme LLC subsequent to the restructuring includes BioMarin s 50% share of the net income/loss of BioMarin/Genzyme LLC related to intellectual property management and ongoing research and development activities.

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The results of the joint venture s operations for the years ended December 31, 2007, 2008 and 2009, are presented in the table below (in thousands). Equity in the income (loss) of BioMarin/Genzyme LLC for the year ended December 31, 2007 represents the Company s 50% share of the joint venture s income for the period presented prior to the restructuring.

	Year ended December 31,		
	2007	2008 (unaudited)	2009 (unaudited)
Revenue	$ 123,671	$	$
Cost of goods sold	26,877		
Gross profit	96,794		
Operating expenses	36,510	4,738	5,195
Income (loss) from operations	60,284	(4,738)	(5,195)
Other income	766	198	7
Net income (loss)	$ 61,050	$ (4,540)	$ (5,188)
Equity in the income (loss) of BioMarin/Genzyme LLC	$ 30,525	$ (2,270)	$ (2,594)

At December 31, 2008 and 2009, the summarized assets and liabilities of the joint venture and the components of the Company s investment in the joint venture are as follows (in thousands):

	December 31, 2008 (unaudited)	2009 (unaudited)
Assets	$ 2,991	$ 2,088
Liabilities	(1,161)	(1,206)
Net equity	$ 1,830	$ 822
Investment in BioMarin/Genzyme LLC (50% share of net equity)	$ 915	$ 441

(21) SUBSEQUENT EVENT

On February 4, 2010, the Company announced that it entered into a stock purchase agreement with LEAD Therapeutics, Inc., or LEAD, and the stockholders of LEAD to acquire all of the outstanding shares of capital stock of LEAD. LEAD is a small private drug discovery and early stage development company with a key compound LT-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with genetically defined cancers. In connection with its acquisition of LEAD, the Company purchased all of the capital stock of LEAD on February 10, 2010 for an upfront cash payment to the stockholders of LEAD of $18.0 million, $3.0 million of which was paid in 2009, and will pay the stockholders an additional $11.0 million upon acceptance of the IND filing expected by the end of 2010 and up to $68.0 million for the achievement of other development and launch milestones for LT-673.