BIOMARIN PHARMACEUTICAL INC
Form 10-K
February 24, 2011
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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, 2010

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 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, 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: 110,723,087 shares common stock, par value $0.001, outstanding as of February 15, 2011. The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2010 was $1,026.3 million.

The documents incorporated by reference are as follows:

Portions of the Registrant s Proxy Statement for our annual meeting of stockholders to be held May 12, 2011, are incorporated by reference into Part III.

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BIOMARIN PHARMACEUTICAL INC.

2010 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 on Form 10-K. In addition to the other information in this Annual Report on 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), Aldurazyme (laronidase) and Firdapse (amifampridine phosphate).

Naglazyme received marketing approval in the United States (U.S.) in May 2005, in the European Union (EU) in January 2006 and subsequently in other countries. Kuvan was granted marketing approval in the U.S. and EU in December 2007 and December 2008, respectively. In December 2009, the European Medicines Agency (EMEA) granted marketing approval for Firdapse, which was launched in the EU in April 2010. Aldurazyme, which was developed in collaboration with Genzyme Corporation (Genzyme) was approved in 2003 for marketing in the U.S., EU and subsequently other countries. Net product revenues for 2010 for our approved products, Naglazyme, Kuvan, Firdapse and Aldurazyme were $192.7 million, $99.4 million, $6.4 million and $71.2, respectively.

We are conducting clinical trials on several investigational product candidates for the treatment of various 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 phenylketonuria or PKU, BMN-701, an enzyme replacement therapy for Pompe disease, a glycogen storage disorder, and BMN-673, an orally available poly (ADP-ribose) polymerase, or PARP inhibitor for the treatment of patients with cancer.

We are conducting preclinical development of several other enzyme product candidates for genetic and other metabolic diseases, including BMN-111, a peptide therapeutic for the treatment of achondroplasia.

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A summary of our various commercial products and major development programs, including key metrics as of December 31, 2010, is provided below:

Program	Indication	Orphan Drug Designation	Stage	2010 Total Net Product Revenues (in millions)	2010 Research & Development Expense (in millions)
Naglazyme	MPS VI (1)	Yes	Approved	$ 192.7	$ 9.7
Aldurazyme (2)	MPS I (3)	Yes	Approved	$ 71.2	$ 0.7
Kuvan	PKU (4)	Yes	Approved	$ 99.4	$ 12.8
Firdapse (5)	LEMS (6)	Yes	Approved in the EU only	$ 6.4	$ 8.8
GALNS for MPS IV A	MPS IVA	Yes	Clinical Phase 3	N/A	$ 28.1
PEG-PAL	PKU	Yes	Clinical Phase 2	N/A	$ 16.4
BMN-701 for Pompe disease	POMPE (7)	Yes	Clinical Phase 1/2	N/A	$ 2.5
BMN-673, PARP inhibitor for the treatment of patients with cancer	Not yet determined	Not yet determined	Clinical Phase 1/2	N/A	$ 8.3

(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 agreement with Genzyme Corporation. See *Commercial Products Aldurazyme* below for further discussion.
(3) Mucopolysaccharidosis I, or MPS I
(4) Phenylketonuria, or PKU
(5) Marketing approval from the EMEA for Firdapse was granted in December 2009. We launched Firdapse in the EU in April 2010.
(6) Lambert Eaton Myasthenic Syndrome, or LEMS
(7) Pompe disease, a glycogen storage disorder

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 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 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. We market Naglazyme in the U.S., EU, Canada, Latin America, and Turkey using our own sales force and commercial organization. Additionally, we use local distributors in several other regions to help us pursue registration and/or market Naglazyme on a named patient basis. Naglazyme net product sales for 2010 totaled $192.7 million, as compared to $168.7 million for 2009. Naglazyme net product sales for 2008 were $132.7 million.

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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.

Kuvan was granted marketing approval for the treatment of PKU in the U.S. in December 2007. We market Kuvan in the U.S. and Canada 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. We expect that our patents will provide market exclusivity beyond the expiration of orphan status. Kuvan net product sales for 2010 were $99.4, as compared to $76.8 million for 2009. Kuvan net product sales for the 2008 were $46.7 million.

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. Merck Serono launched Kuvan in the EU in the second quarter of 2009 and they are launching in other countries. Under the agreement with Merck Serono, we are entitled to receive royalties, on a country-by-country basis, until the later of the expiration of patent right licensed to Merck or ten years after the first commercial sale of the licensed product in such country. Over the next several years, we expect a royalty of approximately 4% on net sales of Kuvan by Merck Serono. 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 2010, we earned $0.9 million in net royalties on net sales of $23.7 million of Kuvan by Merck Serono, compared to 2009 when we earned $0.3 million in net royalties on net sales of $6.9 million. We recorded collaborative agreement revenue associated with Kuvan in the amounts of $0.7 million in 2010, $2.4 million in 2009 and $38.9 million in 2008.

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 is a progressive and debilitating life-threatening genetic disease, for which no other drug treatment currently exists, that is caused by the deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of GAGs. Patients with MPS I typically become progressively worse and experience multiple severe and debilitating symptoms resulting from the build-up of carbohydrate residues in all tissues in the body. These symptoms include: inhibited growth, delayed and regressed mental development (in the severe form of the disease), 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.

We developed Aldurazyme through a collaboration with Genzyme Corporation. Under our collaboration agreement, we are responsible for manufacturing Aldurazyme and supplying it to Genzyme. Genzyme records sales of Aldurazyme and is required to pay us, on a quarterly basis, a 39.5% to 50% royalty on worldwide net

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product sales. 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. Additionally, Genzyme and we are members of a 50/50 limited liability company that: (1) holds 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) engages in research and development activities that are mutually selected and funded by Genzyme and us.

Aldurazyme net product revenues totaled $71.2 million for 2010 as compared to $70.2 million for 2009 and $72.5 million for 2008. The net product revenues for 2010, 2009 and 2008 include $68.0 million, $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 $166.8 million for 2010, $155.1 million for 2009 and $151.3 million for 2008. Incremental Aldurazyme net product transfer revenue of $3.2 million, $8.4 million and $12.4 million for 2010, 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

In conjunction with our acquisition of Huxley Pharmaceuticals, Inc. (Huxley) we acquired the rights to Firdapse in October 2009, a proprietary form of 3,4-diaminopyridine (amifampridine phosphate), or 3,4-DAP for the treatment of LEMS. Firdapse was originally developed by AGEPS, the pharmaceutical unit of the Paris Public Hospital Authority, or AP-HP, and sublicensed to Huxley from EUSA Pharma in April 2009. Firdapse was granted marketing approval in the EU in December 2009. In addition, Firdapse has been granted orphan drug status in the EU, which confers ten years of market exclusivity in the EU. We launched Firdapse on a country by country basis in Europe beginning in April 2010. Firdapse net product revenues in 2010 were $6.4 million. We also continue to develop Firdapse for the possible treatment of LEMS in the U.S. and expect to initiate a Phase 3 clinical trial in the second quarter of 2011. If the clinical trial is successful, we expect to submit an NDA to the FDA in the first half of 2012.

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 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 developing GALNS, an enzyme replacement therapy for the treatment of MPS IV A, a lysosomal storage disorder. In November 2008, we announced the initiation of a clinical assessment program for patients

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with MPS IV A. We initiated a Phase 1/2 clinical trial of GALNS in the first half of 2009. The objectives of the Phase 1/2 study were to evaluate safety, pharmacokinetics, and pharmacodynamics and to identify the optimal dose of GALNS for future studies. The results reported in April 2010, showed clinically meaningful improvements in two measures of endurance (6-minute walk distance and 3-minute stair climb) were achieved at both 24 weeks and 36 weeks as compared to baseline. Clinically meaningful improvements in two measures of pulmonary function (forced vital capacity and maximum voluntary ventilation) were achieved at 36 weeks as compared to baseline and keratin sulfate levels decreased shortly after the initiation of treatment and fell further as the study progressed. In December 2010, we received a notice of acceptance for a Phase 3 clinical trial for GALNS from the MHRA in the U.K. In February 2011, we announced the initiation of a pivotal Phase 3 clinical trial for GALNS for the treatment of MPS IV A. This Phase 3 trial is a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of GALNS in patients with MPS IV A. The trial will be conducted at approximately 40 centers worldwide including Brazil, Japan, Taiwan, most Western European countries, Canada and the U.S. We expect to enroll approximately 160 patients in this trial. This trial will explore doses of two milligrams per kilogram per week and two milligrams per kilogram every other week for a treatment period of 24 weeks.

PEG-PAL is an investigational enzyme substitution therapy that we are developing as a subcutaneous injection and is intended for those patients with PKU who 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 June 2009, we announced results from a Phase 1 open-label, single-dose, dose-escalation clinical trial of PEG-PAL for PKU. Significant reductions in blood Phe levels were observed in all patients in the fifth dosing cohort of the Phase 1 trial. In addition, there are 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. Preliminary results from this clinical trial were presented in August 2010 and showed that of the seven patients who received at least one milligram per kilogram per week of PEG-PAL for at least four weeks, six patients have achieved Phe levels below 600 micromoles per liter. Mild to moderate self limiting injection site reactions are the most commonly reported toxicity. Final results are expected in the second or third quarter of 2011 and we expect to initiate a Phase 3 clinical trial of PEG-PAL in the first quarter of 2012.

BMN-673 is a PARP inhibitor that we are investigating for the treatment of cancer. BMN-673 is a poly-ADP ribose polymerase (PARP) inhibitor, a class of molecules that has shown clinical activity against cancers involving defects in DNA repair. In December 2010, we obtained approval of both an investigational new drug (IND) application from the FDA and a clinical trial application from MHRA in the U.K. for BMN-673. In January 2011, we announced the initiation of a Phase 1/2 clinical trial for BMN-673 for the treatment of patients with cancer in the U.S. and expect to expand the study to the U.K. in the second or third quarter of 2011. The clinical trial is an open-label study of once daily, orally administered BMN-673 in approximately 70 patients ages 18 and older with advanced or recurrent solid tumors. The primary objective of the study is to establish the maximum tolerated dose of daily oral BMN-673. The secondary objective of the study is to establish the safety, pharmacokinetic profile and recommended Phase 2 dose.

BMN-701 is a novel fusion of insulin-like growth factor 2 and alpha glucosidase (IGF2-GAA) in development for Pompe disease. We acquired the BMN-701 program in August 2010 in connection with the acquisition of ZyStor Therapeutics, Inc. (ZyStor) In January 2011, we announced the initiation of a Phase 1/2 clinical trial for BMN-701. This clinical trial is an open-label study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamic and clinical activity of BMN-701 administered as an intravenous infusion every two weeks at doses of 20 milligrams per kilogram. We expect to enroll approximately 30 patients between the ages of 13 and 65 years old with late-onset Pompe disease for a treatment period of 24 weeks. The primary objectives of this study are to evaluate the safety and tolerability of BMN-701 as well as determine the antibody

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response to BMN-701. The secondary objectives of the study are to determine the single and multi-dose pharmacokinetics of BMN-701 and determine mobility and functional exercise capacity in patients receiving BMN-701. Pompe disease is a lysosomal storage disorder caused by a deficiency in GAA, which prevents cells from adequately degrading glycogen. This results in the storage of glycogen in lysosomes, particularly those in muscle cells, thereby damaging those cells and causing progressive muscle weakness which in turn can result in death due to pulmonary or cardiac insufficiency.

Manufacturing

We manufacture Naglazyme, Aldurazyme, GALNS and PEG-PAL, which are all 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 as well as the clinical requirements and initial launch of GALNS and PEG-PAL, if approved.

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, BMN-701 and BMN-673 are each 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, Canada, Brazil, other Latin American countries and Turkey. For other selected markets, we have signed

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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 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, Kuvan and Firdapse 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 stock significant quantities of Naglazyme. During 2010, 46% of our net Naglazyme, Kuvan and Firdapse 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, Kuvan and Firdapse is driven primarily by patient therapy requirements and we are not dependent upon any individual distributor with respect to Naglazyme, Kuvan or Firdapse sales. Due to the pricing of Naglazyme, Kuvan and Firdapse and the limited number of patients, the specialty pharmacies and wholesalers generally carry a very limited inventory, resulting in sales of Naglazyme, Kuvan and Firdapse being closely tied to end-user demand. However, in certain countries particularly in Latin America, governments place large periodic orders for Naglazyme. The timing of these orders can create significant quarter to quarter variation in our revenue.

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 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.

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 versus 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.

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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 base, through various compounding pharmacies, as a special or magistral formulation, or through investigator sponsored studies. Firdapse is the only approved version of 3,4 DAP. One other aminopyridine, 4AP, has been approved in the U.S. 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.

BMN-673

There are seven other PARP inhibitors ahead of BMN-673 in clinical development for the treatment of various cancers. None of these PARP inhibitors, however, has yet been approved by the FDA or any other regulatory agency.

BMN-701

There is one approved enzyme replacement therapy for Pompe disease and at least one more in preclinical studies. Gene therapy is also being tested in clinical trials and it has been announced that a small molecule chaperone will reenter clinical trials as a combination therapy with enzyme replacement therapy.

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 169, including approximately 51 patents issued by the U.S. Patent and Trademark Office, USPTO. Furthermore, our portfolio of pending patent applications totals approximately 390 applications, including approximately 67 pending U.S. applications.

With respect to Naglazyme, we have eight issued patents, including three U.S. patents. Claims cover our ultrapure *N*-acetylgalactosamine-4-sulfatase compositions of Naglazyme, methods of treating deficiencies of *N* -acetylgalactosamine-4-sulfatase, including MPS VI, methods of producing and purifying such ultrapure *N* -acetylgalactosamine-4-sulfatase compositions, and methods of detecting lysosomal enzyme-specific antibodies. These patents will expire between 2022 and 2028.

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 rights to eleven issued patents including six 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, crystalline forms of BH4, and methods of producing BH4. These patents will expire in 2024.

We have rights to 31 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. These patents will expire in 2019 and 2020.

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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.

We only have limited patent protection in the E.U. for Firdapse for the treatment of LEMS and we have no issued patients in the U.S. for Firdapse for the treatment of LEMS.

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

The FDC Act and other federal and state statutes and regulations govern, among other things, the testing, research, development, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, import and export 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

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled human 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

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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 new drug applications, or NDAs, or biological product licenses, or BLAs, for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and 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. After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical and other testing, a compilation of data relating to the product s pharmacology, chemistry, manufacture and controls, proposed labeling and a payment of a user fee, among other things.

The FDA has 60 days from its receipt of an NDA or BLA 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. The FDA may request additional information rather than accepting an NDA or BLA for filing. 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 or BLAs. Most such applications for non-priority drug products are reviewed within ten months. The goal for initial review of most applications for priority review of drugs, that is, drugs that the FDA determines represent a significant improvement over existing therapy, is six 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 products or products that 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 or BLA, 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 or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA, including the manufacturing procedures and 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, 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.

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An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA 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

Upon approval of a drug through an NDA, applicants are required to submit to the FDA each patent that covers the applicant s product or FDA approved method of using this product. Those patents are 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. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strength(s), route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

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

If the ANDA applicant has submitted 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 condition of 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. Both of the five-year and three-year exclusivity periods, as well as any unexpired patents listed in the Orange Book for the listed drug, can be extended by six months if the FDA grants the NDA sponsor a period of pediatric exclusivity based on studies submitted by the sponsor in response to a written request.

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Section 505(b)(2) New Drug Applications

Most drug products (other than biological 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 labeled 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.

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 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, nor does it provide 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.

Pediatric Information

Under the Pediatric Research Equity Act of 2007, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) 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

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waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. The Best Pharmaceuticals For Children Act, or BPCA, provides sponsors with an additional 6-month period of market exclusivity on all forms of the drug containing the active moiety, if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA. In order to receive the BPCA exclusivity, the drug must have other existing patent or exclusivity protection in effect.

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 or BLA 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 or BLA 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 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.

Post-Approval Regulatory Requirements

Following FDA approval, a product is subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of approved products, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet.

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Approved products 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, may require a submission to and approval by FDA before the change can be implemented. An NDA or BLA 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 or BLA supplements as it does in reviewing NDAs and BLAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. 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 the manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug and biological product manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

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.

Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program.

The PPACA created a regulatory pathway for the abbreviated approval for biological products that are demonstrated to be biosimilar or interchangeable with an FDA-approved biological product. In order to meet the standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Such biosimilars would reference biological products approved in the U.S. The law establishes a period of 12 years of data exclusivity for reference products, which protects the data in the original BLA by prohibiting sponsors of biosimilars from gaining FDA approval based in part on reference to data in the original BLA.

The PPACA also imposes a new fee on certain manufacturers and importers of branded prescription drugs (excluding orphan drugs). The annual fee will be apportioned among the participating companies based on each company s sales of qualifying products to, and used by, certain U.S. government programs during the preceding year.

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In addition, beginning in 2013, drug manufacturers will be required to report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties. Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims laws.

Other Regulatory Requirements

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in these states. Other states prohibit providing various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

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.

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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.

Anti-Corruption Legislation

The U.S. Foreign Corrupt Practices Act (FCPA), 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. Similar laws exist in other countries, such as the United Kingdom that restrict improper payments to public and private parties. Many countries have laws prohibiting these types of payments within the respective country. Historically, pharmaceutical companies have been the target of FCPA and other anti-corruption investigations and penalties.

Employees

As of January 21, 2011, we had 871 full-time employees, 399 of whom are in operations, 222 of whom are in research and development, 153 of whom are in sales and marketing and 97 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 2008, 2009 and 2010, see Item 7, *Management Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expense* .

Geographic Area Financial Information

Our chief operating decision maker (*i.e.*, our 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 maker, 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, Kuvan and Firdapse, and are based on Genzyme s U.S. location for Aldurazyme. The following table outlines revenues by geographic area (in thousands):

	Year Ended December 31,		
	2010	2009	2008
Net product revenues:			
United States	$ 196,979	$ 168,373	$ 140,418
Europe	90,321	76,475	63,333
Latin America	41,581	35,528	25,250
Rest of the World	40,820	35,345	22,850
Total net product revenues	$ 369,701	$ 315,721	$ 251,851

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Total revenue generated outside the U.S. was $172.7 million, $150.7 million and $147.0 million, in the years ended December 31, 2010, 2009 and 2008, respectively.

The following table outlines long-lived assets by geographic area (in thousands):

	Year Ended December 31,	
	2010	2009
Long-lived assets:		
United States	$ 597,278	$ 246,160
International	32,914	33,427
Total long-lived assets	$ 630,192	$ 279,587

The increase in long-lived assets is primarily comprised an increase in the long-term deferred tax asset of $236.0 million resulting from the release of our income tax valuation allowance in the third quarter of 2010, intangible assets and goodwill of $62.7 million and $29.6 million, respectively, acquired from LEAD and ZyStor and purchases of property, plant and equipment.

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.

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 and maintain regulatory approval to market and sell our drug products in the U.S. and in jurisdictions outside of the U.S. 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 government regulation by international regulatory authorities. 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 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.

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From time to time during the regulatory approval process for our products and our product candidates, we engage in discussions with the FDA and comparable international 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 other non-U.S. 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, which can impact, among other things product labeling, manufacturing practices, adverse event reporting, storage, distribution, advertising and promotion, and record keeping. 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, and enforcement actions, including injunctions and civil or criminal prosecution. The FDA and comparable international 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 FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such 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 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.

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

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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.

We may face competition from biological products approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, created a regulatory pathway for the abbreviated approval for biological products that are demonstrated to be biosimilar or interchangeable with an FDA-approved biological product. In order to meet the standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Such biosimilars would reference biological products approved in the U.S. The law establishes a period of 12 years of data exclusivity for reference products, which protects the data in the original BLA by prohibiting sponsors of biosimilars from gaining FDA approval based in part on reference to data in the original BLA. Our products approved under BLAs, as well as products in development that may be approved under BLAs, could be reference products for such abbreviated BLAs.

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. We also rely on independent third party contract research organizations (CROs), to perform [most] of our clinical studies and many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our

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clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third party CROs. If any of our CROs processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could adversely be impacted.

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 our 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 and 2010, we operated at a slight net loss in 2009. Based upon our current plan for investments in research and development for existing and new programs, we expect to operate at a net loss for 2011 and may operate at an annual net loss beyond 2011. 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, our pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA, the State of California and international 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 European Commission (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 and may be unable to initially or continue to pass a federal or international regulatory inspection.

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

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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 and success of our preclinical studies and clinical trials (including studies and the manufacture of materials);
- the timing, number, size and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems, and to build or acquire manufacturing capabilities;
- the progress of research programs carried out by us;
- our possible achievement of milestones identified in our stock purchase agreements with the former stockholders of Huxley, LEAD Therapeutics, Inc. (LEAD) and ZyStor that trigger related milestone payments;
- 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, 2010 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.

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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. Problems may arise during manufacturing for a variety of reasons, including human error, mechanical breakdowns, problems with raw materials, 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. If the failure rate increased substantially, we could experience increased costs, lost revenue, damage to customer relations, time and expense investigating the cause and depending upon the cause, similar losses with respect to other lots or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

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 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

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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.

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 continue to market worldwide to achieve significant market penetration of the product. In addition, because the number of potential patients in the disease populations are small, it is not only important to find patients who begin therapy to achieve significant market penetration of the product, but we also need to be able to maintain these patients on therapy for an extended period of time. 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.

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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.

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, our revenue would be adversely affected, and 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.

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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 international 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.

Government health care reform could increase our costs, which would adversely affect our revenue and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program.

Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, the Medicaid rebate rate was increased and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations. The PPACA also expands the 340B drug discount program (excluding orphan drugs), including the creation of new penalties for non-compliance and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or donut hole. The law also revised the definition of average manufacturer price for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states. Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially have an impact on our business over time.

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We face credit risks from customers that may adversely affect our results of operations.

Our product sales to government-owned or supported customers in various countries outside of the U.S. are subject to significant payment delays due to government funding and reimbursement practices. This has resulted and may continue to result in an increase in days sales outstanding due to the average length of time that we have accounts receivable outstanding. If significant changes were to occur in the reimbursement practices of these governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected.

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. However, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability, although we seek to comply with these safe harbors. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

Many states have adopted laws similar to the federal antikickback statute, some of which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. They also may apply to the 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.

Federal and state false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. 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. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

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 some 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

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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 and all of the sales of Firdapse are generated from countries other than the United States. Additionally, we have operations in several European countries, Brazil, other Latin America countries, Turkey and Asia. We expect that we will continue to expand our international operations in the future. International operations inherently subject us to a number of risks and uncertainties, including:

- changes in international regulatory and compliance requirements that could restrict BioMarin s ability to manufacture, market and sell its products;
- political and economic instability;
- diminished protection of intellectual property in some countries outside of the United States;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing international operations;
- differing labor regulations and business practices;
- potentially negative consequences from changes in or interpretations of tax laws;
- changes in international medical reimbursement policies and programs;
- financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors and service providers activities that may fall within the purview of the Foreign Corrupt Practice Act.

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 and maintaining 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

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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-DAP 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.

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 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, as with patent litigation, is expensive and time consuming, requires

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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 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 and cannot be re-filed. A corresponding Canadian 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 prevented from continuing to commercialize 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, as such term is defined in the MMS agreement, or has declared bankruptcy and also is in breach of the MMS. Although we are 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 BioMarin/Genzyme LLC (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 buyout 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.

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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 worldwide 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. If this happened, not only would our product revenues decrease, but our share price would also decline.

The impact of the pending transaction between Genzyme and Sanofi-Aventis on our current relationship with Genzyme regarding Aldurazyme is uncertain and could result in a dispute between the parties, reduced sales of Aldurazyme and reduced revenue and profit for BioMarin.

On February 17, 2011, we sent a communication to Sanofi-Aventis (Sanofi) to initiate discussions about potentially restructuring our relationship related to Aldurazyme. Sanofi has responded that Sanofi and Genzyme are of the view that since Genzyme will continue to exist after the transaction as a wholly-owned subsidiary of Sanofi, the transaction does not give rise to a right of BioMarin to terminate the MMS Agreement and initiate the buyout process contemplated by the MMS Agreement, and that Genzyme plans to continue to operate under the terms of the MMS Agreement.

We are evaluating our options with respect to our relationship with Genzyme related to Aldurazyme, including whether or not we will seek to pursue termination rights under the MMS Agreement or otherwise further pursue discussions with Sanofi and Genzyme in the near or longer term. Particularly since Sanofi has communicated to us that it and Genzyme do not believe that we have the right to terminate the MMS Agreement in connection with the transaction between Genzyme and Sanofi, the outcome of any efforts we may undertake to pursue a termination of the MMS Agreement and initiate a buyout process, or otherwise pursue a modification of the MMS Agreement, is uncertain, and it is possible that the parties will continue to operate under the terms of the MMS Agreement through and following the completion of the acquisition of Genzyme by Sanofi.

If we choose to seek to enforce the termination rights contemplated by the MMS Agreement, we expect that Sanofi and Genzyme would formally assert that the acquisition of Genzyme does not trigger BioMarin s right to terminate the MMS Agreement. The outcome of any dispute resolution procedures related to this issue is highly uncertain and could take an extended period of time. This would present substantial operational challenges in managing the Aldurazyme business while the process is ongoing, and could reduce the sales of Aldurazyme, the value of the Aldurazyme business, our revenues and our profitability. Further, the dispute resolution process could require substantial management attention and could result in substantial legal expenses.

If the parties pursue the termination rights and buyout process contemplated by the MMS Agreement, the process dictated by the MMS Agreement limits the ability of the parties to negotiate a mutually acceptable solution by forcing a specific purchase offer to be made unilaterally, which could result in a transaction structure and price that is less advantageous than the parties could structure by a mutual negotiation. Further, the termination contemplated by the MMS Agreement would be effective immediately as of the closing of an applicable

transaction, which would leave the parties with a substantial period of time before the process determines which party would retain control of the product. This delay could result in operational challenges,

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such as lack of certainty regarding obligations to market, sell and manufacture Aldurazyme, which could reduce product sales and the value of the Aldurazyme business. Further, Sanofi and Genzyme would have the right to purchase our interest in Aldurazyme on the terms that we offer to purchase their interest. If Sanofi and Genzyme choose to exercise this right, although we would receive the compensation specified in the offer, our revenue and profitability associated with Aldurazyme sales would be reduced. Additionally, although we will continue to supply Aldurazyme during a specified transition period, after that time we could have excess capacity in our manufacturing facility, which would adversely affect our financial performance.

We cannot predict the outcome of the pending transaction between Genzyme and Sanofi on our current relationship with Genzyme regarding Aldurazyme or the operation of the Aldurazyme business, and it is possible that the transaction will have an adverse effect on our financial performance.

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.

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

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

If 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 BMN-701 and BMN-673 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

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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.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

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

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

Our future growth and success will depend in large part of our continued ability to attract, 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 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, and there is a limited pool of qualified potential employees to recruit. 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. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.

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 development and marketing of these products, if approved, we will need to significantly expand our operations.

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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, BMN-701 or BMN-673 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.

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

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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 non U.S. 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 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 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

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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	259,000	Corporate headquarters, office, laboratory and warehouse	2011-2020
Galli Drive facility, Novato, California	91,500	Clinical and commercial manufacturing and laboratory	NA: owned property
Bel Marin Keys facility, Novato, California	84,000	Technical operations, finance, administration, and laboratory	NA: owned property

Our administrative office space and plans to develop additional space are expected to be adequate for the foreseeable future. In addition to the above, we also maintain small offices in Brisbane, California, London, England, Sao Paulo, Brazil, Istanbul, Turkey, Hong Kong, Shanghai, China and Dublin, Ireland. 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. (Removed and Reserved)

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Part II

Item 5. Market for Registrant s 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**
2010	First Quarter	$ 23.81	$ 18.95
2010	Second Quarter	$ 24.71	$ 18.33
2010	Third Quarter	$ 23.09	$ 18.24
2010	Fourth Quarter	$ 28.25	$ 21.82
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 15, 2011, the last reported sale price on the Nasdaq Global Select Market for our common stock was $26.94. We have never paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the year ended December 31, 2010.

Holders

As of February 15, 2011, there were 65 holders of record of 110,723,087 outstanding shares of our common stock. Additionally, on such date, options to acquire 14.8 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 we make under the Securities Act of 1933, as amended, 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, 2005 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.

* $100 invested on 12/31/05 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10
BioMarin Pharmaceutical Inc.	100.00	152.04	328.39	165.12	174.49	249.81
NASDAQ Composite	100.00	111.74	124.67	73.77	107.12	125.93
NASDAQ Biotechnology	100.00	99.71	103.09	96.34	106.49	114.80

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Item 6. Selected Consolidated Financial Data

The information set forth below for the five years ended December 31, 2010 is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations* and the consolidated financial statements and related notes thereto included in Item 8 of this Annual Report on Form 10-K to fully understand factors that may affect the comparability of the information presented below:

	Years ended December 31, (In thousands of U.S. dollars, except for per share data)				
	2010	2009	2008	2007	2006
Consolidated statements of operations data:					
REVENUES:					
Net product revenues	$ 369,701	$ 315,721	$ 251,851	$ 86,802	$ 49,606
Collaborative agreement revenues	682	2,379	38,907	28,264	18,740
Royalty and license revenues	5,884	6,556	5,735	6,515	15,863
Total revenues	376,267	324,656	296,493	121,581	84,209
OPERATING EXPENSES:					
Cost of sales (excludes amortization of developed product technology)	70,285	65,909	52,509	18,359	8,740
Research and development	147,309	115,116	93,291	78,600	66,735
Selling, general and administrative	151,723	124,290	106,566	77,539	48,507
Intangible asset amortization and contingent consideration	6,406	2,914	4,371	4,371	3,651
Total operating expenses	375,723	308,229	256,737	178,869	127,633
INCOME (LOSS) FROM OPERATIONS	544	16,427	39,756	(57,288)	(43,424)
Equity in the income (loss) of BioMarin/Genzyme LLC	(2,991)	(2,594)	(2,270)	30,525	19,274
Interest income	4,112	5,086	16,388	25,932	12,417
Interest expense	(10,329)	(14,090)	(16,394)	(14,243)	(13,411)
Debt conversion expense	(13,728)	0	0	0	(3,315)
Impairment loss on equity investments	0	(5,848)	(4,056)	0	0
Net gain from sale of investments	902	1,585	0	0	0
INCOME (LOSS) BEFORE INCOME TAXES	(21,490)	566	33,424	(15,074)	(28,459)
Provision for (benefit from) income taxes	(227,309)	1,054	2,593	729	74
NET INCOME (LOSS)	$ 205,819	$ (488)	$ 30,831	$ (15,803)	$ (28,533)
NET INCOME (LOSS) PER SHARE, BASIC	$ 2.00	$ (0.00)	$ 0.31	$ (0.16)	$ (0.34)
NET INCOME (LOSS) PER SHARE, DILUTED	$ 1.73	$ (0.00)	$ 0.29	$ (0.16)	$ (0.34)
Weighted average common shares outstanding, basic	103,093	100,271	98,975	95,878	84,582
Weighted average common shares outstanding, diluted	125,674	100,271	103,572	95,878	84,582

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	December 31, (in thousands)				
	2010	2009	2008	2007	2006
Consolidated balance sheet data:					
Cash, cash equivalents and investments	$ 402,283	$ 470,526	$ 561,425	$ 585,594	$ 288,847
Total current assets	504,260	467,727	737,696	644,297	334,224
Total assets	1,262,623	917,163	906,695	815,279	463,436
Long-term liabilities, net of current portion	461,522	516,824	499,939	566,010	299,589
Total stockholders equity	717,257	322,185	276,675	187,726	117,802

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.

	Three Months Ended (In thousands, except per share data, unaudited)			
	March 31,	June 30,	September 30,	December 31,
2010:				
Total revenue	$ 84,953	$ 91,950	$ 97,750	$ 101,614
Net income (loss)	1,151	(477)	217,334	(12,189)
Net income (loss) per share, basic	0.01	(0.00)	2.13	(0.11)
Net income (loss) per share, diluted	0.01	(0.01)	1.68	(0.11)
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

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and 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.

Key components of our results of operations include the following (in millions):

	Years Ended December 31,		
	2010	2009	2008
Total net product revenues	$ 369.7	$ 315.7	$ 251.9
Collaborative agreement revenues	0.7	2.4	38.9
Cost of sales	70.3	65.9	52.5
Research and development expense	147.3	115.1	93.3
Selling, general and administrative expense	151.7	124.3	106.6
Provision for (benefit from) income taxes	(227.3)	1.1	2.6
Net income (loss)	205.8	(0.5)	30.8
Stock-based compensation expense	37.5	34.5	25.3

See *Results of Operations* below for a discussion of the detailed components and analysis of the amounts above.

Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme, Kuvan, Firdapse and Aldurazyme.

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 2010 were $192.7 million, compared to $168.7 million and $132.7 million in 2009 and 2008, respectively.

Kuvan was granted marketing approval in the U.S. and EU in December 2007 and December 2008, respectively. Kuvan net product revenues for 2010 totaled $99.4 million, compared to $76.8 million and $46.7 million in 2009 and 2008, respectively.

In December 2009, the EMEA granted marketing approval for Firdapse. We launched this product on a country by country basis in the EU beginning in April 2010. Firdapse net product revenues in 2010 were $6.4 million. We also continue to develop Firdapse for the possible treatment of LEMS in the U.S. and expect to initiate a Phase 3 clinical trial in the second quarter of 2011.

Aldurazyme, which was developed in collaboration with Genzyme, was approved in 2003 for marketing in the U.S., EU and subsequently other countries. Aldurazyme net product revenues for 2010 were $71.2 million, compared to $70.2 million and $72.5 million in 2009 and 2008, respectively.

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 MPS IV A;

PEG-PAL, an enzyme substitution therapy for the treatment of phenylketonuria or PKU;

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BMN-701, an enzyme replacement therapy for Pompe disease, a glycogen storage disorder; and

BMN-673, an orally available PARP inhibitor for the treatment of patients with cancer.

We are conducting preclinical development of several other enzyme product candidates for genetic and other metabolic diseases, including BMN-111, a peptide therapeutic for the treatment of achondroplasia.

Cost of sales include raw materials, personnel and facility and distribution costs associated with manufacturing Naglazyme and Aldurazyme at our production facility in Novato, California. Cost of sales also includes third-party manufacturing costs for the production of Kuvan and Firdapse and third-party production costs related to vialing and packaging services for all products.

Research and development includes costs associated with the research and development of product candidates and post marketing commitments related to approved products. These costs primarily include preclinical and clinical studies, personnel and raw materials costs associated with manufacturing product candidates, quality control and assurance and regulatory costs.

Selling, general and administrative expense primarily includes expenses associate with the commercialization of approved products and general and administrative costs to support our operations. These expenses include: product marketing and sales operations personnel; corporate facility operating expenses and depreciation; and core corporate support functions including human resources, finance and legal, and other external corporate costs such as insurance, audit and legal fees.

Our cash, cash equivalents, short-term investments and long-term investments totaled $402.3 million as of December 31, 2010, compared to $470.5 million as of December 31, 2009. 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 2011, 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, we may in the future choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities. See *Financial Position, 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. 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 business combinations, contingent acquisition consideration payable, income taxes, long-lived assets, revenue recognition and inventory 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 policies have not differed materially from actual results.

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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 the acquisition date with respect to intangible assets and in-process research and development (IPR&D). In connection with the purchase price allocations for acquisitions, we estimate the fair value of contingent consideration payments utilizing a probability-based income approach inclusive of an estimated discount rate.

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 and any contingent consideration 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.

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

Valuation of Contingent Acquisition Consideration Payable

Each period we reassess the fair value of the contingent acquisition consideration payable associated with certain acquisitions and record increases in the fair value as contingent consideration expense and record decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent acquisition consideration payable can result from changes in assumed probability adjustments with respect to regulatory approval, changes in the assumed timing of when milestones will be achieved and changes in assumed discount periods and rates. Significant judgment is employed in determining the appropriateness of these assumptions each period. Accordingly, future business and economic conditions, as well as changes in any of the assumptions described in the accounting for business combinations above can materially impact the amount of contingent consideration expense that we record in any given period.

Income Taxes

Our consolidated balance sheets reflect net deferred tax assets that primarily represent the tax benefit of net operating loss carryforwards and credits and timing differences between book and tax recognition of certain revenue and expense items, net of a valuation allowance. When it is more likely than not that all or some portion of deferred tax assets may not be realized, we establish a valuation allowance for the amount that may not be realized. Each quarter, we evaluate the need to retain all or a portion of the valuation allowance on our net deferred tax assets. Our evaluation considers historical earnings, estimated future taxable income and ongoing prudent and feasible tax planning strategies. Adjustments to the valuation allowance increase or decrease net income/(loss) in the period such adjustments are made. If our estimates require adjustments,

it could have a significant impact on our consolidated financial statements.

We continually review the adequacy and necessity of the valuation allowance. If it is more likely than not that we would not realize the deferred tax benefits, then all or a portion of the valuation allowance may need to be re-established. Changes in tax laws and rates could also affect recorded deferred tax assets in the future. Management is not aware of any such changes that would have a material effect on our consolidated financial statements.

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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, indefinite-lived intangible assets 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. 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.

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.

We have recorded intangible assets, primarily related to IPR&D, and goodwill as part of our recognition and measurement of assets acquired and liabilities assumed in conjunction with our business combinations. Goodwill and intangible assets determined to be indefinite-lived assets are not amortized, but are required to be reviewed annually for impairment or more frequently if events and circumstances indicate that the carrying value may not be recoverable. We perform our annual impairment test of indefinite-lived intangible assets in the fourth quarter of each fiscal year and in between annual tests if we become aware of any events or changes in circumstances that would indicate a reduction in the fair value of the assets below their carrying values. As of December 31, 2010, we had $70.4 million of indefinite-lived assets related to IPR&D projects that we acquired from ZyStor, LEAD, and Huxley. We assess recoverability by determining whether the carrying value of IPR&D assets will be recovered through the undiscounted expected future cash flows. If the future discounted 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 the IPR&D assets.

At December 31, 2010, the net book value of our intangible assets whose lives are considered finite in nature was $33.3 million. These intangible assets are related to marketing rights in the U.S. and EU for Kuvan and EU for Firdapse which are being amortized over their estimated useful lives using the straight-line method. We review these intangible assets for impairment when facts or circumstances indicate a reduction in the fair value below their carrying amount.

As of December 31, 2010, we had goodwill of $53.4 million resulting from our business combinations. 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

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only one reporting unit as per Financial Accounting Standards Board, or FASB Accounting Standards Codification, or ASC Topic 350-20, *Intangibles Goodwill and Other*. We perform our annual impairment review of goodwill during the fourth quarter and whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. If it is determined that the full carrying amount of an asset is not recoverable an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. We performed our annual impairment test in the fourth quarter of 2010 and determined no impairment of goodwill existed as of December 31, 2010.

Revenue Recognition

We recognize revenue in accordance with FASB ASC Subtopics ASC 605-15, *Revenue Recognition Products* and ASC 605-25, *Revenue Recognition Multiple-Element Arrangements.* Our revenues consist of net product revenues from commercial products, revenues from 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 and Firdapse sales in foreign jurisdictions, are presented on a net basis in our consolidated 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 the consolidated statements of operations. We recognize a portion of this amount as product transfer revenue when product is released to Genzyme because all of our 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 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. We record 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, 2010 and 2009, accounts receivable included $23.1 million and $20.3 million, respectively, of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

We sell Naglazyme worldwide, Kuvan in the U.S. and Canada and Firdapse in the EU. 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 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 and approximates 4%. Outside the U.S., Naglazyme and Firdapse are 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

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customers limited return rights and our experience with returns. Because of the pricing of Naglazyme, Kuvan and Firdapse, the limited number of patients and the customers limited return rights, most Naglazyme, Kuvan and Firdapse customers and retailers carry a limited inventory. However, 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 to estimate returns for Aldurazyme, Naglazyme and Kuvan. Genzyme s contractual return rights for Aldurazyme are limited to defective product. Our products are comparable in nature and sold to similar customers with limited return rights; therefore we rely on historical return rates for Aldurazyme, Naglazyme and Kuvan to estimate returns for Firdapse, which has a limited history of product returns. 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, Kuvan and Firdapse to derive net sales are described in the table below.

Revenue Dilution Item	Percentage of Gross Sales	Description
Rebates	1.0-5.5%	Rebates payable to state Medicaid, other government programs and certain managed care providers
Distributor Fees	0.3-2.9%	Fees paid to authorized distributors
Cash Discounts	0.5-1.9%	Discounts offered to customers for prompt payment of accounts receivable
Total	1.8-10.3%	

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, 2010, we have experienced no significant bad debts and our allowance for doubtful accounts was insignificant.

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 and license revenues 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.

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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. During 2010 we completed a significant expansion of our Novato, California manufacturing facility and commenced process qualification production activities related to FDA approval for Naglazyme production in the expanded facility. The value of the qualification lots was $14.8 million as of December 31, 2010, which was capitalized as inventory because the product is expected to be sold commercially. While we believe it is unlikely that the expanded facility will not be approved for Naglazyme production, should that occur, the value of the inventory will be expensed at that time.

Recent Accounting Pronouncements

See Note 3 of our accompanying consolidated financial statements for a full description of recent accounting pronouncements and our expectation of their impact on our consolidated results of operations and financial condition.

Results of Operations

Net Income (Loss)

Net income for the year ended December 31, 2010 was $205.8 million, compared to net loss of $0.5 million for the year ended December 31, 2009, representing a change of $206.3 million. The change in net income was primarily a result of the following (in millions):

Net loss for the year ended December 31, 2009	$ (0.5)
Benefit from reversal of deferred tax asset valuation allowance	230.6
Increased gross profit from product sales	49.6
Decreased impairment loss on equity investments	5.8
Increased research and development expense	(32.2)

Increased selling, general and administrative expense	(27.4)
Debt conversion expense	(13.7)
Increased intangible asset amortization and contingent consideration expense	(3.5)
Other individually insignificant fluctuations	(2.9)
Net income for the year ended December 31, 2010	$ 205.8

In the third quarter of 2010, we determined that it is more likely than not that the majority of our deferred tax assets, including non operating loss carryforwards and tax credits, will be realized, resulting in the reversal of the valuation allowance and an income tax benefit of $223.1 million for the quarter. The increase in gross profit

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from product sales in 2010 as compared to 2009 is primarily a result of additional Naglazyme patients initiating therapy, additional Kuvan patients initiating therapy in the U.S., and the commercial launch of Firdapse in April 2010. The increase in research and development expense is primarily attributed to increased development expenses for our GALNS, PEG-PAL, Firdapse, BMN-701 and BMN-673 programs. The increase in selling, general and administrative expense is primarily due to increased facility and employee related costs, continued international expansion of Naglazyme and the commercialization of Firdapse in Europe. The debt conversion expense was related to the early conversion of a portion of our convertible debt in November 2010. The increase in intangible asset amortization and contingent consideration is attributed to the amortization of the Firdapse EU marketing rights and the change in the fair values of contingent acquisition consideration payable to the former stockholders of Huxley, LEAD and ZyStor. See below for additional information related to the primary net income/(loss) fluctuations presented above, including details of our operating expense fluctuations.

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 in net income 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 gross profit from product sales	50.7
Gain on the sale of equity investments	1.6
Decreased interest expense	2.3
Other individually insignificant fluctuations	1.4
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 gross profit from product sales in 2009 as compared to 2008 is primarily a result of additional Naglazyme patients initiating therapy outside the U.S. and additional Kuvan 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.

Net Product Revenues, Cost of Sales and Gross Profit

Net product revenues were as follows (in millions):

	Years Ended December 31,				
	2010	**2009**	**2008**	**2010 v. 2009**	**2009 v. 2008**
Naglazyme	$ 192.7	$ 168.7	$ 132.7	$ 24.0	$ 36.0
Kuvan	99.4	76.8	46.7	22.6	30.1
Aldurazyme	71.2	70.2	72.5	1.0	(2.3)

Firdapse	6.4	0	0	6.4	0
Total Net Product Revenues	$ 369.7	$ 315.7	$ 251.9	$ 54.0	$ 63.8

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Net revenues and related gross profit attributed to our relationship with Genzyme were as follows (in millions):

	Years Ended December 31,				
	2010	2009	2008	2010 v. 2009	2009 v. 2008
Aldurazyme revenue reported by Genzyme	$ 166.8	$ 155.1	$ 151.3	$ 11.7	$ 3.8
Royalties due from Genzyme	$ 68.0	$ 61.8	$ 60.1	$ 6.2	$ 1.7
Incremental (previously recognized) Aldurazyme product transfer revenue	3.2	8.4	12.4	(5.2)	(4.0)
Total Aldurazyme net product revenues	$ 71.2	$ 70.2	$ 72.5	$ 1.0	$ (2.3)
Gross profit	$ 53.4	$ 51.9	$ 52.2	$ 1.5	$ (0.3)

2010 compared to 2009

Net product revenues for Naglazyme in 2010 totaled $192.7 million, of which $163.4 million was earned from customers based outside the U.S. The impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was unfavorable by $1.7 million for 2010. Gross profit from Naglazyme sales in 2010 was $158.3 million representing gross margins of 82%. Gross profits from Naglazyme sales in 2009 were $134.0 million representing gross margins of approximately 79%. The slight increase in gross margins during 2010 as compared to 2009 is primarily due to the impact of improved manufacturing yields.

Net product revenue for Kuvan during 2010 was $99.4 million, compared to $76.8 million in 2009. Gross profit from Kuvan in 2010 was approximately $82.7 million, representing gross margins of approximately 83%, compared to 2009 when gross profit totaled $63.9 million, representing gross margins of approximately 83%. Cost of goods sold for all periods reflect royalties paid to third parties of 11%. During 2010, we earned $0.9 million in royalties from Merck Serono on net sales of $23.7 million. Royalties earned from Merck Serono during 2009 were $0.3 million on net sales of $6.9 million.

We launched Firdapse in Europe on a country by country basis in April 2010. Net product revenue for Firdapse during 2010 was $6.4 million. Gross profit from Firdapse was $5.0 million representing gross margins of 79%.

In 2010, Aldurazyme gross margins were 75%, compared to 74% in 2009. 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. 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 2010 was $70.3 million, compared to $65.9 million in 2009. The increase in cost of sales in 2010 compared to 2009 is primarily attributed to the increase in Kuvan product sales and Firdapse product sales which commenced in April 2010.

2009 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

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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.

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.

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.

Collaborative Agreement Revenues

Collaborative agreement revenues were as follows (in millions):

	Years Ended December 31,		
	2010	**2009**	**2008**
Amortization of the $25.0 million up-front license payment from Merck Serono	$ 0	$ 0	$ 5.2
Reimbursable Kuvan development costs	0.7	2.4	3.7
Kuvan EMEA approval milestone from Merck Serono	0	0	30.0
Total	$ 0.7	$ 2.4	$ 38.9

Our performance obligations related to the initial $25.0 million up-front license payment from Merck Serono were completed in December 2008. Therefore, periods subsequent to December 31, 2008 do not include amortization amounts related to this payment. Contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. 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 right to co-develop it. The related costs are included in research and development expenses.

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Royalty and License Revenues

Royalty and license revenues were as follows (in millions):

	Years Ended December 31,		
	2010	2009	2008
Orapred product royalties	$ 4.7	$ 5.6	$ 3.8
6R-BH4 royalty revenues	1.2	1.0	1.9
Total	$ 5.9	$ 6.6	$ 5.7

Royalty and license revenues include Orapred product royalties, a product we acquired in 2004 and sublicensed in 2006, and 6R-BH4 royalty revenues for product sold in Japan. Additionally in 2008, 6R-BH4 royalty revenues include 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. 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.

We receive a royalty of 10% to 30% on net sales of Orapred from Shionogi Inc. and a 15% royalty on net sales of 6R-BH4 from Daiichi Sankyo Co., LTD.

Research and Development

Research and development increased by $32.2 million to $147.3 million for the year ended December 31, 2010, from $115.1 million for the year ended December 31, 2009. The change in research and development was primarily a result of the following (in millions):

Research and development for the year ended December 31, 2009	$ 115.1
Increased GALNS for MPS IV A development expense	10.5
Increased BMN-673 development expenses	8.3
Increased development expenses related to commercial products	8.9
Increased PEG-PAL development expenses	5.3
Increased research and development expenses on early development stage programs	5.8
Increased BMN-701 development expenses	2.5
Absence of license payment related to collaboration with La Jolla Pharmaceutical Company	(8.8)
Decreased 6R-BH4 development expenses for indications other than PKU	(4.2)
Decreased prodrug development expense	(2.6)
Increased stock-based compensation expense	1.9
Increase in non-allocated research and development expenses and other net changes	4.6
Research and development for the year ended December 31, 2010	$ 147.3

The increase in GALNS and PEG-PAL development expense is attributed to increased clinical trial activities related to the product candidates. The increase in BMN-673 development expense relates to pre-clinical activities related to the product candidate acquired from LEAD during the first quarter of 2010. The increase in research and development expenses related to commercial products is primarily attributed to long-term Kuvan and Firdapse clinical activities related to post-approval regulatory commitments in the U.S. and EU, respectively. The increase in BMN-701 development expense relates to pre-clinical activities related to the product candidate acquired from ZyStor during the third quarter of 2010. During the first quarter of 2009, we paid La Jolla an up-front license fee for the rights to develop and commercialize La Jolla s investigational drug, Riquent. We

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terminated the license agreement with La Jolla in 2009 and there will not be any additional development expense for Riquent. The decrease in 6R-BH4 development expense expenses for indications other than PKU is primarily due to a decline in clinical studies in 2010 compared to 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 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 regulatory commitments related to our products and spending on our GALNS, PEG-PAL, Firdapse, BMN-673 and BMN-701 programs and our other product candidates.

Research and development 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 for the year ended 2009 was primarily a result of the following (in millions):

Research and development for year ended December 31, 2008	$ 93.3
License payment related to collaboration with La Jolla Pharmaceutical Company	8.8
Increased GALNS for MPS IV 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 development expenses related to commercial products	1.0
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 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.

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Selling, General and Administrative

Selling, general and administrative increased by $27.4 million to $151.7 million for the year ended December 31, 2010, from $124.3 million for the year ended December 31, 2009. The change in selling, general and administrative expenses was primarily a result of the following (in millions):

Selling, general and administrative for year ended December 31, 2009	$ 124.3
Increased Naglazyme sales and marketing expenses	6.2
Firdapse commercial expenses	5.5
Increased consulting expenses	3.0
Increased information technology expense	1.5
Increased legal and accounting expenses	1.1
Transaction costs related to the acquisition of ZyStor in the third quarter of 2010	1.8
Increased depreciation expense	1.5
Increased stock-based compensation expense	0.8
Decreased Kuvan commercialization expenses	(1.7)
Increased foreign exchange losses on un-hedged transactions	(0.3)
Net increase in corporate overhead and other administrative expenses	8.0
Selling, general and administrative for the year ended December 31, 2010	$ 151.7

The increase in Naglazyme sales and marketing expenses in 2010 is attributed to continued expansion of our international activities. We continue to incur spending related to the European commercialization of Firdapse, which launched in April 2010. Transactions costs related to the ZyStor acquisition consisted of legal and investment banker fees and transaction bonuses paid to former ZyStor employees and directors. The increase in corporate overhead and other administrative costs during the 2010 is primarily comprised of increased employee related costs, legal costs and facility costs. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme, the European commercialization activities for Firdapse and the U.S. commercialization activities for Kuvan.

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 increase in selling, general and administrative expenses was primarily a result of the following (in millions):

Selling, general and administrative 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 for the year ended December 31, 2009	$ 124.3

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 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 was primarily comprised of increased employee related costs.

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Intangible Asset Amortization and Contingent Consideration

Intangible asset amortization and contingent consideration was comprised of the following (in millions):

	Years Ended December 31,		
	2010	2009	2008
Amortization of Orapred intangible assets	$ 0	$ 2.9	$ 4.4
Amortization of Firdapse European marketing rights	2.4	0	0
Change in the fair value of the contingent acquisition consideration payable to the former ZyStor stockholders	(0.5)	0	0
Change in the fair value of the contingent acquisition consideration payable to the former LEAD stockholders	3.3	0	0
Change in the fair value of the contingent acquisition consideration payable to the former Huxley stockholders	1.2	0	0
Total	$ 6.4	$ 2.9	$ 4.4

Intangible asset amortization and contingent consideration during 2010 was comprised of the change in fair value of the contingent acquisition consideration payable to the former stockholders of ZyStor, LEAD and Huxley (See Notes 5, 6 and 7 of the accompanying consolidated financial statements for additional discussion) and the amortization of the European marketing rights for Firdapse. Amortization of intangible assets for 2009 and 2008 included seven and twelve months, respectively, of amortization expense related to the intangible assets acquired in the Ascent Pediatrics transaction in May 2004, including the Orapred developed and core technology.

Equity in the 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. BioMarin/Genzyme LLC s operations consist primarily of certain research and development activities and the intellectual property which are managed by the joint venture with costs shared equally by BioMarin and Genzyme.

Equity in the loss of the joint venture totaled $3.0 million for 2010, compared to $2.6 million and $2.3 million for 2009 and 2008, respectively.

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 $4.1 million in 2010, compared to $5.1 million and $16.4 million in 2009 and 2008, respectively. The reduced interest income during 2010 and 2009 was due to lower market interest rates and decreased levels of cash and investments. We expect that interest income will decline during 2011 as compared to 2010 due to lower cash and investment balances and reduced interest yields.

Interest Expense and Debt Conversion Expense

We incur interest expense on our convertible debt. Interest expense in 2010 was $10.3 million, compared to $14.1 million and $16.4 million in 2009 and 2008, respectively. Interest expense in 2009 and 2008 included imputed interest of $2.6 million and $4.4 million, respectively, related to the discounted acquisition obligation for the Ascent Pediatrics transaction. Imputed interest has not been incurred in periods subsequent to September 2009 as the discounted acquisition obligation was paid in full in June 2009.

In November 2010, we entered into separate agreements with nine of our existing holders of our 2.5% convertible senior subordinated notes due in 2013 (Notes) pursuant to which such holders converted $119.6 million in aggregate principal amount of the Notes to 7,213,379 shares of our common stock. In addition to

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issuing the requisite number of shares of our common stock pursuant to the Notes, we paid the holders future interest of approximately $7.2 million along with an aggregate of approximately $6.5 million related to varying cash premiums for agreeing to convert the Notes, which was recognized as debt conversion expense on our consolidated statement of operations for the year ended December 31, 2010. As a result, we expect interest expense to decrease in future periods.

Income Taxes

During 2010, we determined that it is more likely than not that the majority of our deferred tax assets, including net operating losses and tax credit carryforwards, will be realized. In making this determination, we analyzed our recent history of earnings, forecasts of future earnings and cumulative U.S. earnings for the last twelve quarters. The partial reversal of the valuation allowance in the U.S. resulted in an income tax benefit of $230.6 million on the consolidated statement of operations during 2010 and an increase in the current and non-current deferred tax assets on the consolidated balance sheet as of December 31, 2010. Our effective tax rate for 2010 was 19.8%, excluding the discrete adjustment to the valuation allowance of $223.1 million in the third quarter of 2010, consisting primarily of foreign, federal alternative minimum tax and state income taxes.

Financial Position, Liquidity and Capital Resources

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 2011, 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, we may in the future choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

Our financial condition as of December 31 for each of the years indicated was as follows (in millions):

	2010	2009	2010 v. 2009	2008	2009 v. 2008
Cash and cash equivalents	$ 88.1	$ 167.2	$ (79.1)	$ 222.9	$ (55.7)
Short-term investments	186.0	133.5	52.5	336.9	(203.4)
Long-term investments	128.2	169.8	(41.6)	1.6	168.2
Cash, cash equivalents and investments	$ 402.3	$ 470.5	$ (68.2)	$ 561.4	$ (90.9)
Current assets	$ 504.3	$ 467.7	$ 36.6	$ 737.7	$ (270.0)
Current liabilities	83.8	78.2	(5.6)	130.1	51.9
Working capital	$ 420.5	$ 389.5	$ 31.0	$ 607.6	$ (218.1)
Convertible debt	$ 377.5	$ 497.1	$ (119.6)	$ 497.1	$ 0

Our cash flows for each of the years ended December 31 is summarized as follows (in millions):

	2010	2009	2010 v 2009	2008	2009 v 2008
Cash and cash equivalents at the beginning of the year	$ 167.2	$ 222.9	$ (55.7)	$ 228.3	$ (5.4)
Net cash provided by (used in) operating activities	18.7	87.7	(69.0)	(9.2)	96.9
Net cash (used in) investing activities	(101.3)	(79.7)	(21.6)	(19.0)	(60.7)
Net cash provided by (used in) financing activities	3.5	(63.8)	67.3	22.8	(86.6)
Cash and cash equivalents at the end of the year	$ 88.1	$ 167.1	$ (79.0)	$ 222.9	$ (55.8)
Short-term and long-term investment	314.2	303.4	10.8	338.5	(35.1)
Cash, cash equivalents and investments	$ 402.3	$ 470.5	$ (68.2)	$ 561.4	$ (90.9)

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Net cash provided by operating activities was $18.7 million for the year ended December 31, 2010, compared to net cash provided of $87.7 million in 2009 and net cash used in operating activities of $9.2 million in 2008. Net cash provided by (used in) operating activities includes net income (loss) adjusted for non-cash items and changes in our working capital balances. The decrease in net cash provided by operating activities for the year ended December 31, 2010, compared to 2009 was primarily due to $24.3 million higher net loss, after adjusting for the non-cash deferred income tax benefit of $230.6 million related to the Company s reversal of a substantial portion of its deferred tax asset allowance, $34.2 decrease in other current assets resulting primarily from the $30.0 million milestone payment received in 2009 for the EMEA approval of Kuvan, and $25.5 million increase in inventory primarily related to the build-up of Naglazyme inventories concurrent with the validation process of our expanded production facility and planned inventory build. The increase in net cash provided by operating activities in 2009 compared to 2008 was due to $78.6 million from increased other current assets related the receipt of a $30.0 million receivable from Merck-Serono accrued in the prior year and a reduction in the Company s restricted cash balances, and $18.1 million increased accounts receivable resulting from higher sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues.

Net cash used in investing activities was $101.3 million for the year ended December 31, 2010, compared to net cash used of $79.7 million and $19.0 million in 2009 and 2008, respectively. Our investing activities have consisted primarily of purchases and sales and maturities of investments, capital expenditures, and cash paid for net assets acquired in business combinations. The increase in net cash used in investing activities for the year ended December 31, 2010 compared to 2009 was primarily due to $51.3 million net purchases of investment securities, $15.4 million related to business combinations in 2010 for LEAD and ZyStor, partially offset by $40.3 million lower capital expenditures as compared to 2009. The increase in net cash used in investing activities for 2009 compared to 2008 was due to $33.4 million in capital expenditures related to the Company s expansion of the Novato, California facilities, $17.5 million related to the Company s Huxley acquisition, and $16.7 million related to the distribution from BioMarin/Genzyme LLC received in 2008.

Net cash provided by financing activities was $3.5 million for the year ended December 31, 2010, compared to net cash used in financing activities of $63.8 million in 2009 and net cash provided by financing activities of $22.8 million in 2008. Our financing activities primarily include contingent acquisition obligations, payments related to our convertible debt obligations and proceeds from the Employee Stock Purchase Plan (ESPP) and stock option exercises. The increase in our net cash provided by financing activities for the year ended December 31, 2010 compared to 2009 was primarily due to the absence of the $73.6 million Orapred acquisition payment made in 2009, $22.2 million increased proceeds from ESPP and stock option exercises, partially offset by $14.9 million increased contingent acquisition payments and $14.1 million payment on our debt conversion.

On October 23, 2009, we acquired Huxley, which has rights to Firdapse for a total purchase price of $37.2 million, of which $15.0 million was paid in cash and $22.2 million is contingent acquisition consideration payable, of which $1.0 million was paid in the fourth quarter of 2009 and $6.5 million was paid in April 2010. In connection with the acquisition, we agreed to pay the Huxley stockholders additional consideration in future periods of up to $41.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and U.S. development milestones are met.

On February 10, 2010, we acquired LEAD, which has the key compound, LT-673 (now referred to as BMN-673), for a total purchase price of $39.1 million, of which $18.6 million was paid in cash and $20.5 million is contingent acquisition consideration payable. We paid $3.0 million of the $18.6 million in cash during December 2009. In connection with the acquisition, we agreed to pay the LEAD stockholders additional consideration in future periods of up to $68.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met. In December 2010, the MRHA issued a notice of acceptance for BMN-673 triggering the payment of an $11.0 million regulatory milestone to the former LEAD stockholders.

On August 17, 2010, we acquired ZyStor, which had the compound now referred to as BMN-701, for a total purchase price of $35.9 million, of which $20.3 million was paid in cash, $2.0 million was held back and $15.6

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million is contingent acquisition consideration payable. The purpose of the holdback of the purchase price is to satisfy any obligations of the former ZyStor stockholders to pay any indemnification claims to BioMarin and is expected to be released in August 2011. In connection with the acquisition, we agreed to pay ZyStor stockholders additional consideration in future periods of up to $93.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met.

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.

Funding Commitments

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 years ended December 31, 2010, 2009 and 2008 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

	Years Ended December 31,			Since Program Inception
	2010	2009	2008	
Naglazyme	$ 9.7	$ 9.8	$ 9.6	$ 142.1
Kuvan	12.8	11.5	10.8	114.1
Firdapse	8.8	0.5	0	9.3
GALNS for MPS IV A	28.1	17.7	12.6	62.2
BMN-673	8.3	0	0	8.3
BMN-701	2.5	0	0	2.5
PEG-PAL	16.4	11.2	11.0	58.8
Not allocated to specific major current projects	60.7	64.4	49.3	357.9
Totals	$ 147.3	$ 115.1	$ 93.3	$ 755.2

We cannot estimate with certainty the cost to complete any of our product development programs. Additionally, except as disclosed under *Overview* above, we cannot precisely 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* included in this Annual Report on Form 10-K for a discussion of the reasons 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;

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If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected; and

If we do not achieve our projected development goals in the 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 consequently we may be unable to achieve our long-term goals. This may increase our capital requirements, including: costs associated with the commercialization of our products; additional clinical trials; investments in 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 consolidated financial position or results of operations.

Borrowings and Contractual Obligations

In April 2007, we sold approximately $324.9 million of senior subordinated convertible notes due April 2017 (the 2017 Notes). 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. Our debt does not contain a call provision 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 2013 Notes). 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

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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. In November 2010, we entered into separate agreements with nine of our existing holders of our 2013 Notes pursuant to which such holders converted $119.6 million in aggregate principal amount of the 2013 Notes to 7,213,379 shares of our common stock. In addition to issuing the requisite number of shares of our common stock pursuant to the 2013 Notes, we paid the holders future interest of approximately $7.2 million along with an aggregate of approximately $6.5 million related to varying cash premiums for agreeing to convert the 2013 Notes, which was recognized as debt conversion expense on our consolidated statement of operations for the year ended December 31, 2010. Our $377.5 million of convertible debt as of December 31, 2010 will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

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, 2010 is presented in the table below (in millions).

	Payments Due by Period					
	2011	2012	2013 -2014	2015-2016	2017 and Thereafter	Total
Convertible debt and related interest	$ 7.4	$ 7.4	$ 65.2	$ 12.2	$ 326.8	$ 419.0
Operating leases	4.5	4.0	5.3	3.0	3.7	20.5
Research and development and purchase commitments	6.8	3.5	11.3	0	0	21.6
Total	$ 18.7	$ 14.9	$ 81.8	$ 15.2	$ 330.5	$ 461.1