



# RACING AGAINST TIME

BioMarin Pharmaceutical Inc. | 2009 Annual Report

BOMARIN®

*"OUR GREATEST HOPE IS THAT A DRUG WILL BE AVAILABLE  
IN TIME TO HELP OUR SWEET GIRL."*



"Every minute of every day counts for us. Because every day that goes by without a treatment, we know that MPS IVA is taking its toll on our daughter's body. We are literally in a race against time to get ahead of the damage caused by this disease, and as parents, we cannot watch this happen without a fight," said Stephanie, Annabelle's mother.

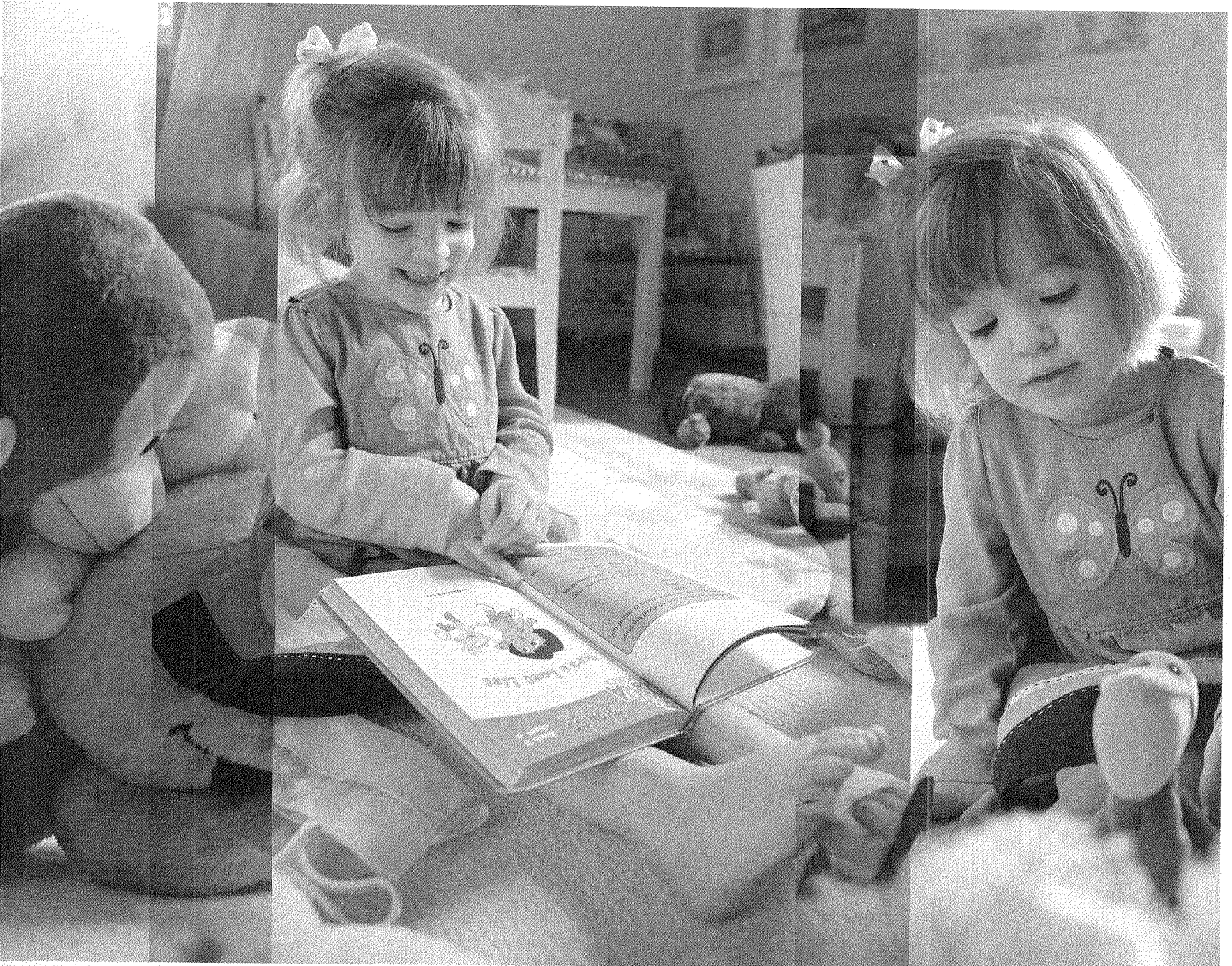
Stephanie and her husband Austin have spent the past three years in a desperate chase to find a treatment to save their daughter's life and alleviate the crippling effects of MPS IVA. This rare genetic disorder, also known as Morquio A Syndrome, causes skeletal dysplasia, spinal malformation, heart and respiratory failure and other severe organ damage. Since her diagnosis at 6 months, Annabelle has

braved countless doctors' visits, invasive surgery and a lifetime of pain. Others like her have been fighting the disease for years.

These patients receive constant medical attention and remedial care for their symptoms, but still await a treatment that will address the underlying cause and effects of their disease. BioMarin has developed a potential new

therapy for MPS IVA which is currently in human clinical trials to test its safety and efficacy. Thus far, preliminary data suggest improvements in endurance and pulmonary function. In clinical studies for the company's similar FDA-approved drugs for MPS I and MPS VI the company observed similar measures of efficacy.

"Our greatest hope is that a drug will be available in time to help our sweet girl."



BARBARA K. BURTON, M.D.

PROFESSOR OF PEDIATRICS : NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

DIRECTOR, PKU AND METABOLIC DISEASE CLINIC : CHILDREN'S MEMORIAL HOSPITAL CHICAGO, IL

*"WHILE EXTRAORDINARY PROGRESS HAS BEEN MADE IN RECENT YEARS,  
IT IS CRUCIAL THAT WE WORK TOGETHER TO FURTHER ENABLE DRUG  
DEVELOPMENT FOR RARE DISORDERS."*



"Too often by the time patients make it to my clinic, irreversible damage has already occurred. Then, once an accurate diagnosis is established, patients and their families are faced with the depressing reality that there may be no drugs available to treat their diseases. So it's our responsibility to always try to help patients in some way now."

Geneticist Dr. Barbara Burton has treated patients with rare disorders for 33 years. Daily, she and her team of genetic

counselors, nurses, nutritionists, and research and education coordinators provide supportive medical care to help address patients' most immediate needs. These may include pain relief, finding ways to increase mobility, or addressing their sense of isolation by connecting them with other patients. Specific needs of patients with rare genetic disorders are complex and vary considerably.

"While extraordinary progress has been made in recent years to improve the quality of patients' lives, it is crucial that we—clinicians, researchers, patient advocacy groups and pharmaceutical companies—work together to further enable drug development for rare disorders. We must continue to provide hope for patients and make sure they are reaching their full potential."





"We have a patient-driven mission at NORD. Our goal is to work with government partners such as the NIH (National Institutes of Health) and FDA, along with patient organizations, academic institutions and biopharmaceutical companies like BioMarin to speed up the process of developing safe and effective treatments for people with rare diseases," said Peter L. Saltonstall, NORD President and CEO (pictured below; right).

A rare "orphan" disease is one that affects fewer than 200,000 Americans. According to the NIH there are 7,000 of these diseases that affect an estimated 30 million people in the United States alone. Approximately 360 orphan drugs and biologics have been approved by the FDA. While estimates indicate that 15 million Americans now benefit from these products, millions more remain untreated.

"We sometimes think of NORD as the hub of a wheel because we have the singular ability to bring people and organizations together in ways that will ultimately benefit patients," added Diane Dorman, NORD's Vice President of Public Policy (pictured below; left).

NORD, a U.S. based patient advocacy organization, is responsible for spearheading orphan drug legislation, specifically the Orphan Drug Act of

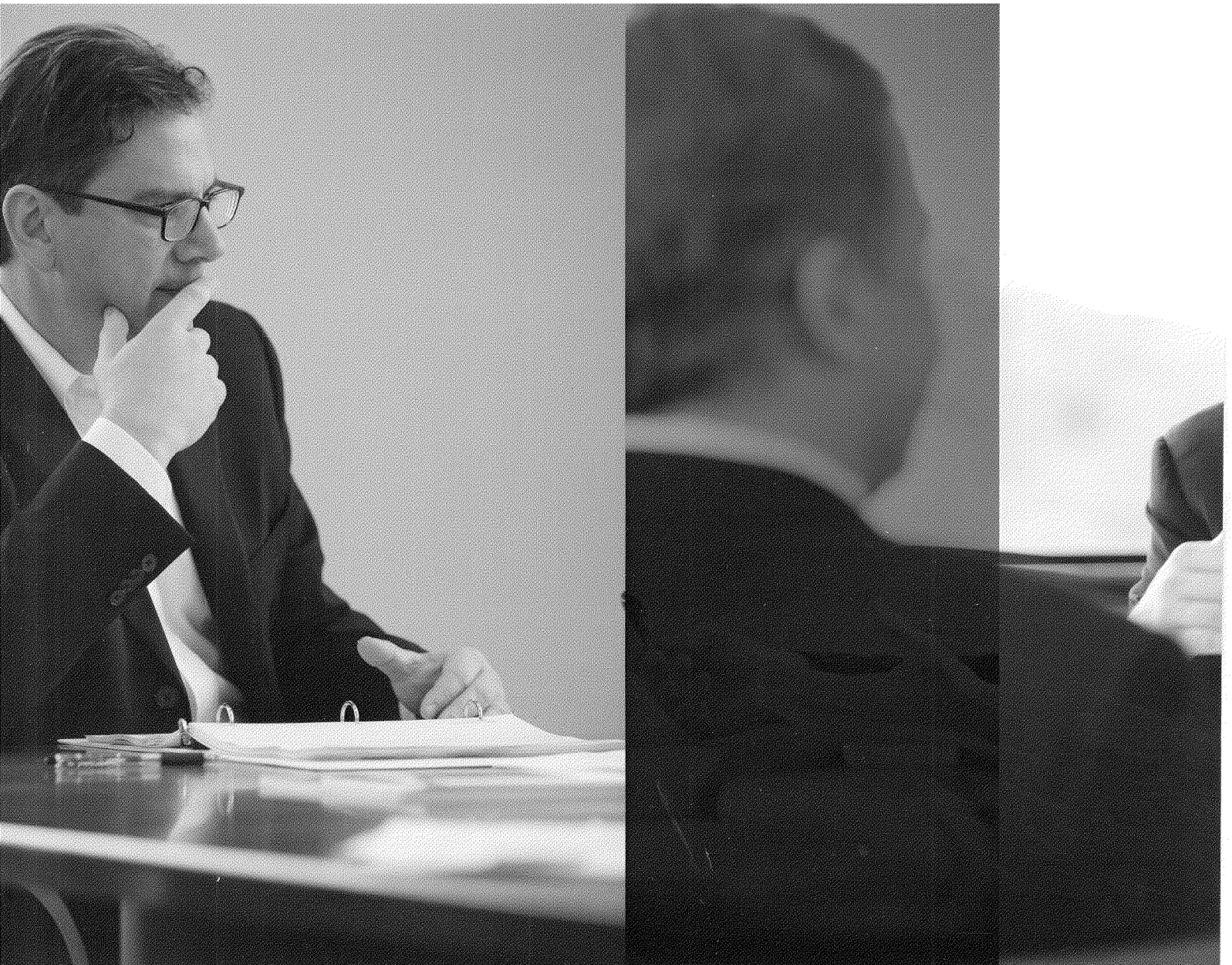
*"OUR GOAL AT  
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1983, to create financial incentives for companies to develop treatments for rare diseases. Today, the group continues its long legacy of serving the needs of patients with rare diseases. Similar sister organizations such as EURORDIS, the European Rare Disease Organization, are also active internationally.



*"BIOMARIN IS POISED TO CONTINUE TO MAKE SIGNIFICANT CONTRIBUTIONS TO MEDICINE AND TO THE LIVES OF PATIENTS WITH SERIOUS, UNMET MEDICAL CONDITIONS."*





"I am really proud to work at BioMarin. This company has already helped patients with rare diseases enjoy better lives. And we have a pipeline that is both broad and deep. In the relatively near term, we will be evaluating products in studies designed to support new product approvals, products in mid-stage clinical testing to prove important clinical hypotheses, and new products about to enter the first phase of

clinical testing. The team that has already accomplished a lot on behalf of patients is growing, both in number and impact. Their leadership will inspire new generations of product development and approval activities. BioMarin has been, is and will continue to be a world class scientific organization. We ask challenging questions about why patients suffer, about how to alleviate that suffering and how to turn ideas into new medicines quickly."

"With explosions in our understanding of the genetic basis of disease, BioMarin is poised to continue to make significant contributions to medicine and to the lives of patients with serious, unmet medical conditions. My heartfelt thanks go to our investigators, patients, families and caregivers, as well as the employees of BioMarin who work tirelessly to help alleviate suffering."



*FOLLOWING THE RECENT COMPLETION OF A NEW EXPANSION PROJECT, BIOMARIN WILL MORE THAN DOUBLE ITS CLINICAL AND COMMERCIAL MANUFACTURING CAPACITY THROUGHOUT THE NEXT FIVE YEARS.*



BioMarin is investing in valuable infrastructure to keep pace with international demand for drugs to treat rare genetic diseases. Currently, the company produces two products, Naglazyme® and Aldurazyme®, at its manufacturing facilities in Novato, California. Following the recent completion of a new expansion project, the company will more than double its clinical and com-

mercial manufacturing capacity. Kuvan® is produced off site at contract manufacturing facilities in Switzerland. Firdapse™ is produced at contract manufacturing facilities in France.

The addition of this new facility will provide a total of 70,000 square feet of manufacturing space at BioMarin, Novato. Commissioned in 2010, it is

slated for FDA approval in early 2011. The new flexible design will accommodate a wide range of production systems to support future clinical and commercial manufacturing needs for Aldurazyme and Naglazyme and, if approved, GALNS and PEG-PAL.



*"AFTER SPENDING YEARS WORKING ON A DRUG, IT IS AMAZING TO FINALLY WITNESS THE FIRST INJECTION AND SEE A PATIENT'S SUBSEQUENT IMPROVEMENTS IN HEALTH."*



"I've spent my entire career looking for cures for rare genetic diseases. It's been a very personal quest for me because I've experienced firsthand what it's like to live with the uncertainty of tomorrow. My young niece, Anne-Claire, has a lysosomal storage disease. Every passing day brings uncertainty: what symptoms will appear next week, and next month? How much more damage will be

irreversible? These diseases are debilitating and often progress quickly. There's simply no time to spare when you are racing to save lives," said Dr. Michael Vellard (pictured below).

Dr. Vellard and his team of researchers at BioMarin have developed a promising new compound for the treatment of MPS IVA (Morquio A Syndrome) which is now under evaluation in human clinical trials.

"Developing biologics is a painstaking and exacting science, but we have to work quickly and efficiently, being mindful of the costs. From a research perspective, it is often frustrating for us to see that while we may have developed a viable treatment for an unmet medical need, this is only the first step in a lengthy process to bring the drug directly to patients."

"We have a pioneer spirit at BioMarin and share a keen sense of urgency to help sick patients. This continually challenges and inspires us. After spending years working on the development of a drug, it is amazing to finally witness the first injection, and see a patient's subsequent improvements in health."



*"IT TAKES A LOT OF TEAMWORK TO MEET AGGRESSIVE TIMELINES...  
WE'RE WORKING ON ENORMOUSLY IMPORTANT THERAPIES TO HELP  
PATIENTS WHO HAVE NO OTHER HOPE."*



"We put a lot of pressure on ourselves to develop drugs quickly. It takes a lot of teamwork to meet aggressive timelines, rigorous product specifications and surmount what seems like endless regulatory hurdles. We're working on enormously important therapies to help patients who have no other hope. The clock is ticking fast and we have to work together to meet our goals and overcome every single challenge," said Dr. Mubarak Muthalif, BioMarin's Associate Director of Product Development (pictured below; seated).

Biopharmaceutical product development requires visionary leadership and the close collaboration of multiple cross-functional experts. At BioMarin, program development teams work together to advance individual product candidates from research, into the clinic and on to regulatory approval and commercialization. We strive to do it in record time.

The team pictured here is in charge of the navigation and execution of the company's second PKU program, PEG-PAL, a product candidate that is

designed to offer additional benefits to patients with the disorder. Another important project also in development is a real-time portable blood Phe monitor which will allow patients and physicians to better manage the disease.

Pictured here are several members of BioMarin's PEG-PAL core team including (left to right); Paul Fitzpatrick, Ph.D.; Mubarak Muthalif, Ph.D.; Jeri Beltman, Ph.D.; Saba Sile, M.D.; and Mari Maurer.



*"WE HAVE BEEN VERY SUCCESSFUL IN DEFENDING THE USE OF NOVEL EFFICACY ASSESSMENTS AND STATISTICAL METHODS FOR USE IN OUR PIVOTAL STUDIES THAT HAVE ENABLED RAPID DEVELOPMENT TIMES."*





"Seeing the profound rates of morbidity and debilitating symptoms of rare diseases, it is abundantly clear that time is of the essence for patients and their families. We have worked closely with regulatory agencies to streamline processes in order to provide therapies to improve patient outcomes."

"Because we are often in the position of developing the very first treatment for an orphan disease, there is no clear regulatory approval pathway in place. We work very hard to ensure that the regulatory agencies understand the diseases and the impact that our drug has upon patients' lives. We have been very successful in defending the use of novel efficacy assessments and statistical methods for use in our pivotal studies that have enabled rapid development times."

"We operate under very tight timelines, and quite frankly, there's no trick to it. There are periods of time when extraordinary effort is required to meet our deadlines and it helps to know the sacrifices we make during these crunch periods are supporting an important cause."

"We thrive on meeting rigorous demands. Filing the 37-volume IND for Kuvan in 2008, for example, was an exhilarating

milestone, especially when most INDs are just three volumes in size. And over the past four years, we've obtained marketing approvals for Naglazyme in more than 50 countries across Europe, Asia, and North and South America. But what's most amazing is to witness the unbelievable real-life stories of patients who experience firsthand the benefits of our therapies."



"Advancements in the treatment of PKU have made a huge impact in my life in an incredibly short period of time. I've had PKU all my life—28 years—and the advances made just within the last five years blow the previous 23 years out of the water!"

Julie has a rare genetic disorder, PKU (phenylketonuria), and has been on treatment with Kuvan® (sapropterin dihydrochloride)

Tablets since 2005 when she enrolled in BioMarin's Phase I clinical trials. "Initially, I enrolled in the Kuvan clinical study to help younger people with PKU to have more options," she said. "I sort of felt it was too late for me. I was 23 then and believed I had pretty good control of my diet and couldn't do much more than that. But almost immediately I became one of the highest responders in

my clinic! Now, five years later, I feel a major improvement, especially when I train for runs and triathlons, and my Phe levels remain well within the normal range."

Currently, BioMarin's second product candidate for PKU, PEG-PAL is in human clinical trials. The company is also planning to develop an at-home Phe monitoring device, much like a portable glucose monitor used by people with diabetes.

"ADVANCEMENTS IN THE TREATMENT OF PKU HAVE MADE A HUGE IMPACT IN MY LIFE IN AN INCREDIBLY SHORT PERIOD OF TIME. I FEEL A MAJOR IMPROVEMENT, ESPECIALLY WHEN I TRAIN FOR RUNS AND TRIATHLONS."



Julie, an industrial interior designer, is also looking forward to future advancements in PKU treatment. "I can't wait until a blood Phe monitoring device is available," Julie said. "Having access to immediate results will help me quickly respond to my Phe levels, especially while training for sports and planning for pregnancy."

Please see [www.bmrn.com](http://www.bmrn.com) for important product and safety information.



"We've got the racing spirit here at BioMarin but it's not one driver that makes things happen. It's about a cohesive team working together to accomplish one goal. Meeting that goal is the driving force behind everything we do. That goal is to quickly bring important therapies to patients with rare diseases."

*"BIOMARIN HAS BROUGHT THREE PRODUCTS TO MARKET IN JUST 12 YEARS—A TRACK RECORD THAT FAR SURPASSES TRADITIONAL BIOPHARMACEUTICAL DEVELOPMENT TIMELINES."*



"Team BioMarin has brought three products to market in just 12 years—a track record that far surpasses traditional biopharmaceutical development timelines. But what separates this company from others is our drive to develop therapies for patients who have no other treatment options. Our therapies are the only commercially available pharmaceutical treatments for patients with MPS I, MPS VI,

PKU and soon, Lambert Eaton Myasthenic Syndrome (LEMS). While impressive, we cannot just cruise, satisfied with our past successes; we have to think proactively and take measured risks. We have to keep moving, growing and developing, try new things, seek alternate directions, move faster and maximize every opportunity to make a difference in patients' lives. We might get a bit bruised up in the process, but when we accomplish all that, it's an incredibly moving experience."

"Quite candidly, we only have a limited amount of time and we have to maximize our resources, passion and professional expertise in the race to come up with new therapeutic solutions for patients with rare diseases."



*TREMENDOUS  
PROGRESS IS BEING  
MADE IN BOTH  
NEW AND EXISTING  
MARKETS IN THE  
IDENTIFICATION  
OF PATIENTS WHO  
CAN BENEFIT  
FROM NAGLAZYME  
THERAPY.*

BioMarin is leveraging its global commercial infrastructure to meet increasing demands for its commercial products. The company anticipates the launch of its fourth product, Firdapse™ (amifampridine phosphate) for Lambert Eaton Myasthenic Syndrome (LEMS) in Europe early in the second quarter of 2010, while clinical and regulatory teams coordinate with the FDA to establish development plans for approval and commercialization in the United States.

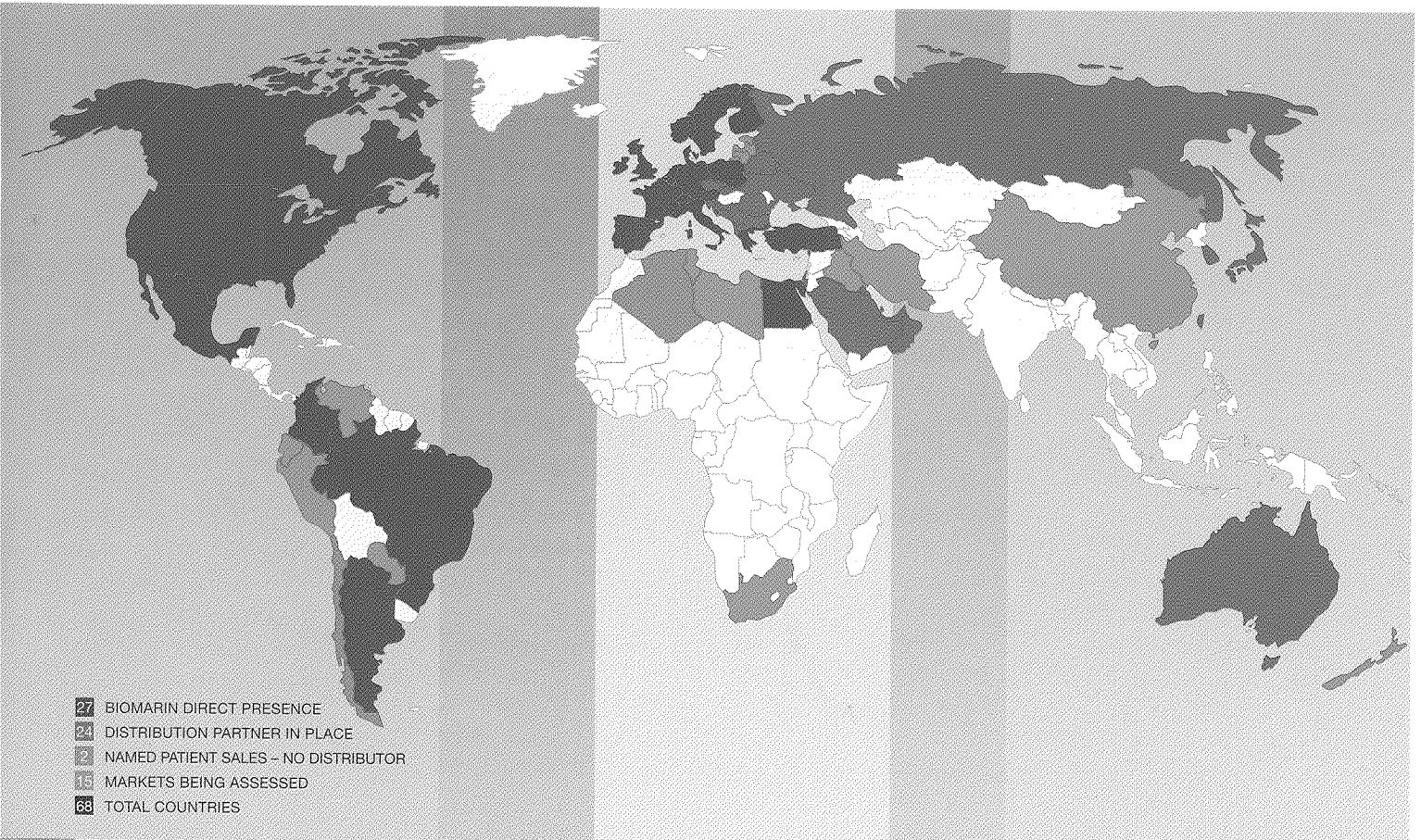
Since the launch of Naglazyme in 2005, tremendous progress in both new and existing markets is being made in the identification of patients who can benefit from Naglazyme therapy. Aggressive international sales and marketing

efforts have yielded higher than expected growth rates and the commercial use of Naglazyme. Currently, multiple additional markets are being assessed.

The graphic shown here illustrates BioMarin's direct, partnered and named-patient distribution efforts for Naglazyme. In total, Naglazyme is treating hundreds of patients in multiple countries around the world. Sales of Aldurazyme also continue with steady growth.

Kuvan commercialization efforts in the U.S. incorporate a variety of innovative approaches to engage clinicians and patients. BioMarin received the 2009 Medical Marketing and Media Award for Best Interactive

Initiative for Consumers for its Facebook PKU Awareness Month web page engaging thousands of patients with PKU. Promising post-marketing data for Kuvan will also extend the benefits of this treatment to many other patients.



## CORPORATE INFORMATION

BIOMARIN PHARMACEUTICAL INC. DEVELOPS AND COMMERCIALIZES INNOVATIVE BIOPHARMACEUTICALS FOR SERIOUS DISEASES AND MEDICAL CONDITIONS. THE COMPANY'S PRODUCT PORTFOLIO COMPRISES FOUR APPROVED PRODUCTS AND MULTIPLE CLINICAL AND NON-CLINICAL DRUG PRODUCT CANDIDATES.

### CORPORATE HEADQUARTERS

**BioMarin Pharmaceutical Inc.**  
105 Digital Drive  
Novato, CA 94949  
Tel. 415.506.6700  
Fax. 415.382.7889  
Email. [ir@bmrn.com](mailto:ir@bmrn.com)  
[www.bmrn.com](http://www.bmrn.com)

### STOCK LISTING

BioMarin Pharmaceutical Inc. is listed on the Nasdaq Global Select Market under the symbol BMRN (NASDAQ: BMRN).

### INDEPENDENT ACCOUNTANTS

**KPMG LLP**  
San Francisco, CA

### TRANSFER AGENT

**Bank of New York Mellon**  
Transfer Agent  
Bank of New York Mellon  
480 Washington Boulevard  
Jersey City, NJ 07310  
U.S. Tel. 800.522.6645  
International Tel. 201.680.6578

### EXECUTIVES

**Jean-Jacques Bienaimé**  
Chief Executive Officer

**Stephen Aselage**  
Executive Vice President and  
Chief Business Officer

**Henry J. Fuchs, M.D.**  
Executive Vice President,  
Chief Medical Officer

**Robert A. Baffi, Ph.D.**  
Executive Vice President,  
Technical Operations

**Jeffrey H. Cooper**  
Senior Vice President,  
Chief Financial Officer

**G. Eric Davis**  
Senior Vice President and  
General Counsel

**Daniel P. Maher**  
Senior Vice President,  
Product Development

**Mark Wood**  
Vice President, Human Resources

**Jeff Ajer**  
Vice President,  
Sales & Marketing Operations

**Luisa Bigornia**  
Vice President, Intellectual Property

**Lewis Chapman**  
Vice President, Global Marketing

**Joshua A. Grass**  
Vice President,  
Corporate & Business Development

**Steven Jungles**  
Vice President, Supply Chain

**James K. Lennertz, Jr**  
Vice President, Commercial Operations

**Brian Mueller**  
Vice President, Controller

**Charles A. O'Neill, Ph.D.**  
Vice President, Pharmacological Sciences

**Dan Oppenheimer, Ph.D.**  
Vice President, Portfolio Strategy

**Leonard Post, Ph.D.**  
Vice President, Drug Discovery

**R. Andrew Ramelmeier**  
Vice President,  
Manufacturing & Process Development

**Victoria Sluzky, Ph.D.**  
Vice President,  
Quality & Analytical Chemistry

**Eduardo Thompson**  
Vice President, General Manager,  
Latin America

**Gordon Vehar, Ph. D.**  
Vice President, Research

**Ed Von Pervieux**  
Vice President & Chief Information Officer

**Jackie Walling, M.D., Ph.D.**  
Vice President, Clinical Development

**Amy Waterhouse**  
Vice President,  
Regulatory & Government Affairs

### BOARD OF DIRECTORS

**Jean-Jacques Bienaimé**  
Chief Executive Officer

**Michael Grey**  
Former President & Chief Executive Officer,  
Auspex Pharmaceuticals, Inc.

**Elaine Heron**  
Chairman & Chief Executive Officer,  
Amlyx Pharmaceuticals, Inc.

**Pierre Lapalme**  
Former President & Chief Executive Officer,  
North America Ethypharm, Inc.

**V. Bryan Lawlis**  
President and Chief Executive Officer,  
Itero Biopharmaceuticals, Inc.

**Alan Lewis**  
President & Chief Executive Officer,  
Juvenile Diabetes Research Foundation

**Randy Meier**  
Executive Vice President &  
Chief Financial Officer,  
Teleflex, Inc.

**FORWARD-LOOKING STATEMENT:** This Annual Report contains 'forward-looking statements' as defined under securities laws. These statements can generally be identified by the use of terminology such as 'believes', 'expects', 'anticipates', 'plans', 'intends', 'may', 'will', 'projects', 'continues', 'estimates', 'potential', 'opportunity', and so on. The company's actual results or experience may differ significantly from the forward-looking statement. Factors that could cause or contribute to these differences include the results of current clinical trials, the company's ability to obtain regulatory approval for product candidates, its ability to successfully market products and other factors discussed in the enclosed Form 10-K and the section entitled 'Risk Factors' therein.

One should not place undue influence on these forward-looking statements that 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 the company may issue in the future. BioMarin Pharmaceutical Inc. does not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the distribution of this Annual Report to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**Form 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2009

Or

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

to  
Commission file number: 000-26727

**BioMarin Pharmaceutical Inc.**

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

Delaware

(State of other jurisdiction of incorporation or organization)

68-0397820

(I.R.S. Employer Identification No.)

105 Digital Drive,  
Novato, California

(Address of principal executive offices)

94949

(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  
Common Stock, \$.001 par value  
Preferred Share Purchase Rights

Name of Each Exchange on Which Registered  
The NASDAQ Global Select Market

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  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

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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer  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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 101,131,358 shares common stock, par value \$0.001, outstanding as of February 17, 2010. The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2009 was \$758.5 million.

The documents incorporated by reference are as follows:

Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held May 12, 2010, are incorporated by reference into Part III.



**BIOMARIN PHARMACEUTICAL INC.**  
**2009 FORM 10-K ANNUAL REPORT**  
**TABLE OF CONTENTS**

<b>Part I</b>		
Item 1.	Business .....	1
Item 1A.	Risk Factors .....	16
Item 1B.	Unresolved Staff Comments .....	32
Item 2.	Properties .....	32
Item 3.	Legal Proceedings .....	33
Item 4.	Submission of Matters to a Vote of Security-Holders .....	33
<b>Part II</b>		
Item 5.	Market for Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities .....	34
Item 6.	Selected Consolidated Financial Data .....	36
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations .....	38
Item 7A.	Quantitative and Qualitative Disclosure About Market Risk .....	56
Item 8.	Financial Statements and Supplementary Data .....	58
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	58
Item 9A.	Controls and Procedures .....	58
Item 9B.	Other Information .....	59
<b>Part III</b>		
Item 10.	Directors and Executive Officers of the Registrant .....	60
Item 11.	Executive Compensation .....	60
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	60
Item 13.	Certain Relationships and Related Transactions and Director Independence .....	60
Item 14.	Principal Accounting Fees and Services .....	60
<b>Part IV</b>		
Item 15.	Exhibits, Financial Statement Schedules .....	60
<b>SIGNATURES</b> .....		66

BioMarin®, Naglazyme® and Kuvan® are our registered trademarks and Firdapse™ is our common law trademark. Aldurazyme® is a registered trademark of BioMarin/Genzyme LLC. All other brand names and service marks, trademarks and other trade names appearing in this report are the property of their respective owners.

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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,” “potential,” “opportunity” and similar expressions. These forward-looking statements may be found in “*Risk Factors*,” “*Business*,” and other sections of this Annual Report on Form 10-K. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in “*Risk Factors*,” as well as those discussed elsewhere in this Annual Report on Form 10-K. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these statements, which speak only as of the date that they were made. These cautionary statements should be considered in connection with any written or oral forward-looking statements that we may issue in the future. We do not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Annual Report on Form 10-K to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes thereto appearing elsewhere in this annual report. In addition to the other information in this Annual Report Form 10-K, investors should carefully consider the following discussion and the information under “*Risk Factors*” when evaluating us and our business.

#### Item 1. Business

##### Overview

BioMarin Pharmaceutical Inc. (BioMarin, we, us or our) develops and commercializes innovative pharmaceuticals for serious diseases and medical conditions. We select product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride) tablets, Aldurazyme (laronidase) and Firdapse (amifampridine phosphate).

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

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

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

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

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

## Recent Developments

### Acquisition of Huxley Pharmaceuticals, Inc.

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

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

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

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

### **Acquisition of LEAD Therapeutics, Inc.**

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

### **Commercial Products**

#### *Naglazyme*

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

Naglazyme was granted marketing approval in the U.S. in May 2005 and in the EU in January 2006. Naglazyme has been granted orphan drug status in the U.S. and the EU, which confers seven years of market exclusivity in the U.S. and ten years of market exclusivity in the EU for the treatment of MPS VI, expiring in 2012 and 2016, respectively. However, different drugs can be approved for the same condition and even the same active ingredient can be approved for the same condition if the new product has a better safety or efficacy profile than Naglazyme. We market Naglazyme in the U.S., EU, Latin America, Turkey, and parts of the Middle East and North Africa using our own sales force and commercial organization. Additionally, we use local distributors in several other countries to help us pursue registration and/or market Naglazyme on a named patient basis. Naglazyme net product sales for 2009 totaled \$168.7 million, as compared to \$132.7 million for 2008. Naglazyme net product sales for 2007 were \$86.2 million.

#### *Kuvan*

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

Kuvan was granted marketing approval for the treatment of PKU in the U.S. in December 2007. We market Kuvan in the U.S. using our own sales force and commercial organization. Kuvan has been granted orphan drug status in the U.S., which confers seven years of market exclusivity in the U.S for the treatment of PKU, expiring in 2014. Kuvan net product sales for 2009 were \$76.8 million, as compared to \$46.7 million for 2008. Kuvan net product sales for the two-week period after approval and launch in December 2007 were \$0.4 million.

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

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

### *Aldurazyme*

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

Aldurazyme has been granted orphan drug status in the U.S. and the EU, which gives Aldurazyme seven years of market exclusivity in the U.S. and ten years of market exclusivity in the EU for the treatment of MPS I, expiring in 2010 and 2013, respectively. However, different drugs can be approved for the same condition and even the same active ingredient can be approved for the same condition if the new product has a better safety or efficacy profile than Aldurazyme. We developed Aldurazyme through a 50/50 joint venture with Genzyme Corporation. Prior to the restructuring of our collaboration with Genzyme in January 2008, as discussed below, we were responsible for product development, manufacturing and U.S. regulatory submissions while Genzyme was responsible for sales, marketing, distribution, obtaining reimbursement for Aldurazyme worldwide and international regulatory submissions.

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

Effective January 1, 2008, Genzyme, the joint venture limited liability company founded by Genzyme and BioMarin (the LLC) and we amended and restated our collaboration agreement. The LLC no longer engages in commercial activities related to Aldurazyme and its sole activities are to (1) hold the intellectual property relating to Aldurazyme and other collaboration products and license all such intellectual property on a royalty-free basis to us and Genzyme to allow us to exercise our rights and perform our obligations under the agreements related to the restructuring, and (2) engage in research and development activities that are mutually selected and funded by Genzyme and us. Genzyme and we license rights related to Aldurazyme to the LLC, and the LLC sublicenses these rights to Genzyme and us such that each may perform our obligations under the restructuring agreements. Pursuant to a Members Agreement entered into by Genzyme, the LLC and us related to the restructuring, in February 2008 the LLC distributed cash and inventory to us and cash, accounts receivable and certain other assets and liabilities to Genzyme, such that the fair value of the net assets distributed to us and to Genzyme was equivalent to both parties according to the terms of the restructuring. The value of the assets, including cash and inventory, that we received was \$43.5 million.

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

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

#### *Firdapse*

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

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

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

### **Products in Clinical Development**

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

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

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

### **Manufacturing**

We manufacture Naglazyme and Aldurazyme, which are both recombinant enzymes, in our approved Good Manufacturing Practices, or GMP, production facility located in Novato, California. Vialing and packaging are performed by contract manufacturers. We believe that we have ample operating capacity to support the commercial demand of both Naglazyme and Aldurazyme through at least the next five years.



Our facilities have been licensed by the FDA, the European Commission and health agencies in other countries for the commercial production of Aldurazyme and Naglazyme. Our facilities and those of any third-party manufacturers will be subject to periodic inspections confirming compliance with applicable law. Our facilities must be GMP certified before we can manufacture our drugs for commercial sales.

Kuvan is manufactured on a contract basis by a third party. There are two approved manufacturers of the active pharmaceutical ingredient, or API, for Kuvan. Firdapse is manufactured on a contract basis by a third party. There is one approved manufacturer of the API for Firdapse.

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

### **Raw Materials**

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

### **Sales and Marketing**

We have established a commercial organization to support our product lines directly in the U.S., Europe, Latin America and Turkey. For other selected markets, we have signed agreements with other companies to act as distributors of Naglazyme. Most of these agreements generally grant the distributor the right to market the product in the territory and the obligation to secure all necessary regulatory approvals for commercial or named patient sales. Additional markets are being assessed at this time and additional agreements may be signed in the future. We maintain a relatively small sales force in the U.S. that markets Naglazyme and Kuvan and in the EU that markets Naglazyme and will market Firdapse. We believe that the size of our sales force is appropriate to effectively reach our target audience in markets where Naglazyme, Kuvan and Firdapse are directly marketed. We utilize third-party logistics companies to store and distribute Naglazyme, Kuvan and Firdapse.

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

### **Customers**

Our Naglazyme and Kuvan customers include a limited number of specialty pharmacies and end-users, such as hospitals, which act as retailers. We also sell Naglazyme to our authorized European distributors and to certain larger pharmaceutical wholesalers, which act as intermediaries between us and end-users and generally do not

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

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

## **Competition**

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

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

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

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

### ***Kuvan and PEG-PAL***

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

With respect to Kuvan, we are aware of one other company that produces forms of 6R-BH<sub>4</sub>, or BH<sub>4</sub>, for sale outside of Japan, and that BH<sub>4</sub> has been used in certain instances for the treatment of PKU. We do not believe, but cannot know for certain, that this company is currently actively developing BH<sub>4</sub> in sponsored trials as a drug product to treat PKU in the U.S. or EU. Although a significant amount of specialized knowledge and resources would be required to develop and commercially produce BH<sub>4</sub> as a drug product to treat PKU in the U.S. and EU, this company may build or acquire the capability to do so. Additionally, we are aware that another company is developing an oral enzyme therapy to treat PKU; however, we understand that the therapy is in an early stage of preclinical development.

### ***Firdapse and LEMS***

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

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

### **Patents and Proprietary Rights**

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

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

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

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

We have 19 issued patents, including six U.S. patents, related to Aldurazyme. These patents cover our ultra-pure alpha-L-iduronidase composition of Aldurazyme, methods of treating deficiencies of alpha-L-iduronidase by administering pharmaceutical compositions comprising such ultra-pure alpha-L-iduronidase, a method of purifying such ultra-pure alpha-L-iduronidase and the use of compositions of ultra-pure biologically active fragments of alpha-L-iduronidase. Three U.S. patents on alpha-L-iduronidase are owned by an affiliate of Women's and Children's Hospital Adelaide. We have examined such issued U.S. patents, the related U.S. and foreign applications and their file histories, the prior art and other information. Corresponding foreign applications were filed in Canada, Europe and Japan. The European application was rejected and abandoned and cannot be re-filed. After a failure to timely file a court challenge to the Japanese Board of Appeals' decision upholding the final rejection of all claims in the corresponding Japanese application, the Japanese application has also lapsed and cannot be re-filed. Claims in the related Canadian application have recently issued. We believe that such patents may not survive a challenge to patent validity. However, the processes of patent law are uncertain and any patent proceeding is subject to multiple unanticipated outcomes. We believe that it is in the best interest of our joint venture with Genzyme to market Aldurazyme with commercial diligence, in order to provide MPS I patients with the benefits of Aldurazyme. We believe that these patents and patent applications do not affect our ability to market Aldurazyme in Europe.

### **Government Regulation**

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

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

### ***FDA Approval Process***

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

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

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

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

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

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

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or

indications, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices or cGMPs, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the NDA, the FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual, however, for the FDA to issue a complete response letter because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

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

### ***The Hatch-Waxman Act***

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or FDA approved method of using this product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of

pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

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

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

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

### ***Other Regulatory Requirements***

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

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

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state

agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### ***Pediatric Information***

Under the Pediatric Research Equity Act of 2007, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted.

### ***Accelerated Approval***

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

### ***Fast Track Designation***

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

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

### ***Priority Review***

Under the FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is submitted, if the drug candidate provides a significant improvement

compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA's criteria for priority review.

### ***Section 505(b)(2) New Drug Applications***

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

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

To the extent that the Section 505(b)(2) applicant is relying on prior FDA findings of safety and efficacy, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be delayed until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) NDA applicant.

### ***Food and Drug Administration Amendments Act of 2007***

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

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

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

### ***Orphan Drug Designation***

Naglazyme, Aldurazyme, Kuvan and Firdapse have received orphan drug designations from the FDA. Orphan drug designation is granted by the FDA to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of less than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug



designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug.

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

- that we will be the first to obtain approval for any drug for which we obtain orphan drug designation;
- that orphan drug designation will result in any commercial advantage or reduce competition; or
- that the limited exceptions to this exclusivity will not be invoked by the relevant regulatory authority.

#### ***U.S. Foreign Corrupt Practices Act***

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

#### ***Regulation in the European Union***

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

A similar system for orphan drug designation exists in the EU. Naglazyme, Aldurazyme and Kuvan received orphan medicinal product designation by the European Committee for Orphan Medicinal Products. Orphan designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for ten years in the EU.

#### **Employees**

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

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

#### **Research and Development**

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

## Geographic Area Financial Information

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

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

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

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

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

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

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

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

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

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

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

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

**To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain.**

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

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

- slow or insufficient patient enrollment;
- slow recruitment of, and completion of necessary institutional approvals at, clinical sites;
- longer treatment time required to demonstrate efficacy;
- lack of sufficient supplies of the product candidate;
- adverse medical events or side effects in treated patients;
- lack of effectiveness of the product candidate being tested; and
- regulatory requests for additional clinical trials.

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

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

Since we began operations in March 1997, we have been engaged in very substantial research and development and have operated at a net loss until 2008. Although we were profitable in 2008, we operated at a

slight net loss in 2009. Depending on our future investments in research and development for existing and new programs; we could operate at an annual net loss for 2010 and possibly beyond. Our future profitability depends on our marketing and selling of Naglazyme, Kuvan and Firdapse, the successful commercialization of Aldurazyme by Genzyme, the receipt of regulatory approval of our product candidates, our ability to successfully manufacture and market any approved drugs, either by ourselves or jointly with others, our spending on our development programs and the impact of any possible future business development transactions. The extent of our future losses and the timing of profitability are highly uncertain. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

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

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

Due to the complexity of the processes used to manufacture our products and product candidates, we may be unable to continue to pass or initially pass federal or international regulatory inspections in a cost effective manner. For the same reason, any potential third-party manufacturer of Naglazyme, Kuvan, Aldurazyme and Firdapse or our product candidates may be unable to comply with GMP regulations in a cost effective manner.

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

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

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

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

- our ability to successfully market and sell Naglazyme, Kuvan and Firdapse;
- Genzyme's ability to continue to successfully commercialize Aldurazyme;
- the progress, timing and scope of our preclinical studies and clinical trials;

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

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

- additional licenses and collaborative agreements;
- additional contracts for product manufacturing; and
- additional financing facilities

We believe that our cash, cash equivalents and short-term investment securities at December 31, 2009 will be sufficient to meet our operating and capital requirements for the foreseeable future based on our current long-term business plans. These estimates are based on assumptions and estimates, which may prove to be wrong. We may need to raise additional funds from equity or debt securities, loans or collaborative agreements if we are unable to satisfy our liquidity requirements. The sale of additional securities may result in additional dilution to our stockholders. Furthermore, additional financing may not be available in amounts or on terms satisfactory to us or at all. This could result in the delay, reduction or termination of our research, which could harm our business.

**If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program.**

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

Improvements in manufacturing processes typically are very difficult to achieve and are often very expensive and may require extended periods of time to develop. If we contract for manufacturing services with an unproven process, our contractor is subject to the same uncertainties, high standards and regulatory controls, and may therefore experience difficulty if further process development is necessary.

Even a developed manufacturing process can encounter difficulties due to changing regulatory requirements, human error, mechanical breakdowns, malfunctions of internal information technology systems, and other events that cannot always be prevented or anticipated. Many of the processes include biological systems, which add significant complexity, as compared to chemical synthesis. We expect that, from time to time, consistent with biotechnology industry expectations, certain production lots will fail to produce product that meets our quality control release acceptance criteria. To date, our historical failure rates for all of our product programs, including Naglazyme and Aldurazyme, have been within our expectations, which are based on industry norms.

In order to produce product within our time and cost parameters, we must continue to produce product within our expected success rate and yield expectations. Because of the complexity of our manufacturing

processes, it may be difficult or impossible for us to determine the cause of any particular lot failure and we must effectively take corrective action in response to any failure in a timely manner.

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

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

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

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

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

**Supply interruptions may disrupt our inventory levels and the availability of our products and cause delays in obtaining regulatory approval for our product candidates, or harm our business by reducing our revenues.**

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

- timing, scheduling and prioritization of production by our contract manufacturers or a breach of our agreements by our contract manufacturers;
- labor interruptions;
- changes in our sources for manufacturing;
- the timing and delivery of shipments;
- our failure to locate and obtain replacement manufacturers as needed on a timely basis; and
- conditions affecting the cost and availability of raw materials.

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

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

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

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

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

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

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

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

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

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

We make a significant portion of our international sales of Naglazyme through special access or “named patient” programs, which do not require full product approval. The specifics of the programs vary from country to country. Generally, special approval must be obtained for each patient. The approval normally requires an application or a lawsuit accompanied by evidence of medical need. Generally, the approvals for each patient must be renewed from time to time.



These programs are not well defined in some countries and are subject to changes in requirements and funding levels. Any change to these programs could adversely affect our ability to sell our products in those countries and delay sales. If the programs are not funded by the respective government, there could be insufficient funds to pay for all patients. Further, governments have in the past undertaken and may in the future undertake, unofficial measures to limit purchases of our products, including initially denying coverage for purchasers, delaying orders and denying or taking excessively long to approve customs clearance. Any such actions could materially delay or reduce our revenues from such countries.

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

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

Our competitors may develop, manufacture and market products that are more effective or less expensive than ours. They may also obtain regulatory approvals for their products faster than we can obtain them (including those products with orphan drug designation) or commercialize their products before we do. If we do not compete successfully, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product.

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

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

International operations are also generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property portfolio. As part of these cost containment measures, some countries have imposed or threatened to impose revenue caps limiting the annual volume of sales of Naglazyme. To the extent that these caps are significantly below actual demand, our future revenues and gross margins may be adversely affected.

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

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

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

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

Neither the government nor the courts have provided definitive guidance on the application of these laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we are required to pay a penalty or are suspended or excluded from participation in federal or state health care programs, our business, financial condition and results of operation may be adversely affected.

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

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

- changes in foreign regulatory requirements;
- fluctuations in foreign currency exchange rates;
- political and economic instability;
- diminished protection of intellectual property in some countries outside of the United States;
- trade protection measures and import or export licensing requirements;

- difficulty in staffing and managing foreign operations;
- differing labor regulations and business practices; and
- potentially negative consequences from changes in tax laws or if foreign jurisdictions successfully challenge our interpretation of local taxation.

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

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

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

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

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

We own or have licensed patents and patent applications related to Naglazyme, Kuvan, Aldurazyme and Firdapse and certain of our product candidates. However, these patents and patent applications do not ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- With respect to pending patent applications, unless and until actually issued, the protective value of these applications is impossible to determine. We do not know whether our patent applications will result in issued patents. For example, we may not have developed a method for treating a disease before others developed identical or similar methods, in which case we may not receive a granted patent.
- Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors may also claim that we are infringing on their patents and therefore we cannot practice our technology. Competitors may also contest our patents by showing the patent examiner or a court that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our issued patents are not valid or are unenforceable for a number of reasons. If a court agrees, we would not be able to enforce that patent. We have no meaningful experience with competitors interfering with our patents or patent applications.
- Enforcing patents is expensive and may absorb significant time of our management. Management would spend less time and resources on developing products, which could increase our operating expenses and delay product programs. We may not have the financial ability to sustain a patent infringement action, or it may not be financially reasonable to do so.

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

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

- Defending a lawsuit, which takes significant time and resources and can be very expensive.
- If a court decides that our product infringes a competitor's intellectual property, we may have to pay substantial damages.
- With respect to patents, a court may prohibit us from making, selling, offering to sell, importing or using our product unless the patent holder licenses the patent to us. The patent holder is not required to grant us a license. If a license is available, it may not be available on commercially reasonable terms. For example, we may have to pay substantial royalties or grant cross licenses to our patents and patent applications.
- Redesigning our product so it does not infringe the intellectual property rights of competitors may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. Our employees or consultants may unintentionally or willfully disclose our information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, such as patent litigation, is expensive and time consuming, requires significant resources and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Furthermore, our competitors may independently develop equivalent knowledge, methods and know-how, in which case we would not be able to enforce our trade secret rights against such competitors.

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

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

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

The USPTO has issued three patents to Women's and Children's Hospital Adelaide that cover composition-of-matter, isolated genomic nucleotide sequences, vectors including the sequences, host cells containing the vectors, and method of use claims for human, recombinant alpha-L-iduronidase. Aldurazyme is based on human, recombinant alpha-L-iduronidase. Corresponding foreign patent applications were filed in Europe, Japan and Canada. The European patent application was rejected over prior art, was withdrawn and cannot be re-filed. The corresponding Japanese application was finally rejected by the Japanese Board of Appeals, lapsed after failure to timely file a court challenge, and cannot be re-filed. A corresponding Canadian

patent issued and covers enzyme, pharmaceutical composition, nucleic acid encoding the enzyme, host cells and vectors. We believe that these patents are invalid or not infringed on a number of grounds. However, under U.S. law, issued patents are entitled to a presumption of validity, and a challenge to the U.S. patents may be unsuccessful. Even if we are successful, challenging the patents may be expensive, require our management to devote significant time to this effort and may adversely impact marketing of Aldurazyme in the U.S. and Canada.

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

Either party may terminate the Manufacturing, Marketing and Sales Agreement, or MMS Agreement, between Genzyme and us related to Aldurazyme for specified reasons, including if the other party is in material breach of the MMS, has experienced a change of control, or has declared bankruptcy and also is in breach of the MMS. Although we are not currently in breach of the MMS and we believe that Genzyme is not currently in breach of the MMS, there is a risk that either party could breach the MMS in the future. Either party may also terminate the MMS upon one year prior written notice for any reason.

If the MMS Agreement is terminated for breach, the breaching party will transfer its interest in the LLC to the non-breaching party, and the non-breaching party will pay a specified buyout amount for the breaching party's interest in Aldurazyme and in the LLC. If we are the breaching party, we would lose our rights to Aldurazyme and the related intellectual property and regulatory approvals. If the MMS Agreement is terminated without cause, the non-terminating party would have the option, exercisable for one year, to buy out the terminating party's interest in Aldurazyme and in the LLC at a specified buyout amount. If such option is not exercised, all rights to Aldurazyme will be sold and the LLC will be dissolved. In the event of termination of the buy out option without exercise by the non-terminating party as described above, all right and title to Aldurazyme is to be sold to the highest bidder, with the proceeds to be split between Genzyme and us in accordance with our percentage interest in the LLC.

If the MMS Agreement is terminated by either party because the other party declared bankruptcy, the terminating party would be obligated to buy out the other party and would obtain all rights to Aldurazyme exclusively. If the MMS Agreement is terminated by a party because the other party experienced a change of control, the terminating party shall notify the other party, the offeree, of its intent to buy out the offeree's interest in Aldurazyme and the LLC for a stated amount set by the terminating party at its discretion. The offeree must then either accept this offer or agree to buy the terminating party's interest in Aldurazyme and the LLC on those same terms. The party who buys out the other party would then have exclusive rights to Aldurazyme. The Amended and Restated Collaboration Agreement between us and Genzyme will automatically terminate upon the effective date of the termination of the MMS Agreement and may not be terminated independently from the MMS Agreement.

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

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

Merck Serono may terminate the agreement forming our strategic alliance with them at any time by giving 90 days prior written notice if such termination occurs prior to the commercialization of any of the products licensed under our agreement, or by giving 180 days prior written notice if such termination occurs after the

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

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

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

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

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

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

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

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

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

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

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

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. While certain of our senior executive officers are parties to employment agreements with us, these agreements do not guarantee that they will remain employed with us in the future. In addition, in many cases, these agreements do not restrict our senior executive officers' ability to compete with us after their employment is terminated. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

**Our success depends on our ability to manage our growth.**

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

development and marketing of these products, if approved, we will need to significantly expand our operations. To manage expansion effectively, we need to continue to develop and improve our research and development capabilities, manufacturing and quality capacities, sales and marketing capabilities and financial and administrative systems. Our staff, financial resources, systems, procedures or controls may be inadequate to support our operations and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third parties.

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

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

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

We are exposed to the potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceuticals. We maintain insurance against product liability lawsuits for commercial sale of our products and for the clinical trials of our product candidates. Pharmaceutical companies must balance the cost of insurance with the level of coverage based on estimates of potential liability. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been unpredictable. Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with our clinical trials and commercial use of Naglazyme, Kuvan, Aldurazyme and Firdapse, or our clinical trials for PEG-PAL, GALNS and our small molecule for Duchenne muscular dystrophy, for which our insurance coverage may not be adequate.

The product liability insurance we will need to obtain in connection with the commercial sales of our product candidates if and when they receive regulatory approval may be unavailable in meaningful amounts or at a reasonable cost. In addition, while we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we may incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercialization of our product programs.

**Our business is affected by macroeconomic conditions.**

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



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

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

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

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

In addition, the value of our common stock may fluctuate because it is listed on the Nasdaq Global Select Market. Listing on the exchange may increase stock price volatility due to:

- trading in different time zones;
- different ability to buy or sell our stock;
- different market conditions in different capital markets; and
- different trading volume.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities. In addition, the current decline in the financial markets and related factors beyond our control, including the credit and mortgage crisis in the U.S. and worldwide, may cause our stock price to decline rapidly and unexpectedly.

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

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change

in control would be beneficial to the stockholders. Our anti-takeover provisions include provisions in our certificate of incorporation providing that stockholders' meetings may only be called by the board of directors and provisions in our bylaws providing that the stockholders may not take action by written consent and requiring that stockholders that desire to nominate any person for election to the board of directors or to make any proposal with respect to business to be conducted at a meeting of our stockholders be submitted in appropriate form to our Secretary within a specified period of time in advance of any such meeting. Additionally, our board of directors has the authority to issue an additional 249,886 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

In 2002, our board of directors authorized a stockholder rights plan and related dividend of one preferred share purchase right for each share of our common stock outstanding at that time. In connection with an increase in our authorized common stock, our board approved an amendment to this plan in June 2003. Our board of directors approved an additional amendment to the stockholder rights plan in February 2009. As long as these rights are attached to our common stock, we will issue one right with each new share of common stock so that all shares of our common stock will have attached rights. When exercisable, each right will entitle the registered holder to purchase from us one two-hundredth of a share of our Series B Junior Participating Preferred Stock at a price of \$35.00 per 1/200 of a Preferred Share, subject to adjustment.

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

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

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

<u>Location</u>	<u>Approximate Square Feet</u>	<u>Use</u>	<u>Lease Expiration Date</u>
Several locations in Novato, California	201,500	Corporate headquarters, office and laboratory	2011-2019
Galli Drive facility, Novato, California	70,000	Clinical and commercial manufacturing and laboratory	NA: owned property
Bel Marin Keys facility, Novato, California	85,400	Technical operations, 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, and Istanbul, Turkey. During 2010 and beyond, we plan to expand the capacity of our production facilities in order to meet future market demands and product development requirements. We believe that, to the extent required, we will be able to lease or buy additional facilities at commercially reasonable rates. We plan to use contract manufacturing when appropriate to provide product for both clinical and commercial requirements until such time as we believe it prudent to develop additional in-house clinical and/or commercial manufacturing capacity.

**Item 3. Legal Proceedings**

We have no material legal proceedings pending.

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

No matters were submitted to a vote of our security holders during the quarter ended December 31, 2009.

## Part II

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

Our common stock is listed under the symbol “BMRN” on the Nasdaq Global Select Market. The following table sets forth the range of high and low quarterly closing sales prices for our common stock for the periods noted, as reported by Nasdaq.

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

On February 17, 2010, the last reported sale price on the Nasdaq Global Select Market for our common stock was \$20.71. We have never paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

#### Equity Compensation Plans

We incorporate information regarding the securities authorized for issuance under our equity compensation plans into this section by reference from the section captioned “Equity Compensation Plans” in the proxy statement for our 2010 annual meeting of stockholders.

#### Issuer Purchases of Equity Securities

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

#### Holder

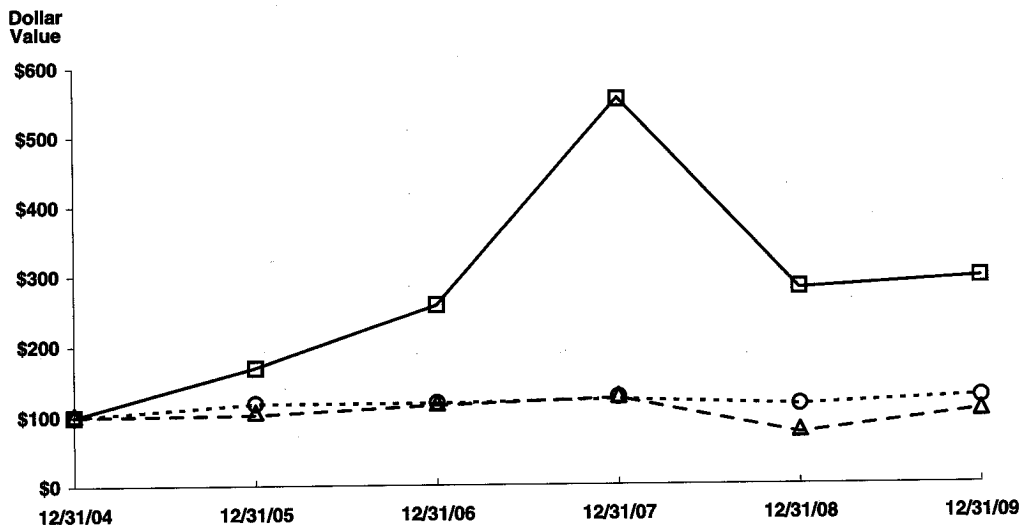
As of February 17, 2010, there were 72 holders of record of 101,131,358 outstanding shares of our common stock. Additionally, on such date, options to acquire 13.8 million shares of our common stock were outstanding.

**Performance Graph**

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

The following graph shows the value of an investment of \$100 on December 31, 2004 in BioMarin common stock, the Nasdaq Composite Index (U.S.) and the Nasdaq Biotechnology Index. All values assume reinvestment of the pretax value of dividends paid by companies included in these indices and are calculated as of December 31 of each year. Our common stock is traded on the Nasdaq Global Select Market and is a component of both the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock.

**COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN**  
 Among BioMarin Pharmaceutical, Inc., The NASDAQ Composite Index  
 And The NASDAQ Biotechnology Index



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

—■— BioMarin Pharmaceutical, Inc.      -▲- NASDAQ Composite      -○- NASDAQ Biotechnology

## Item 6. Selected Consolidated Financial Data

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

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

	Years ended December 31, (in thousands, except for per share data)				
	2005	2006	2007	2008	2009
<b>Consolidated statements of operations data:</b>					
Revenues:					
Net product revenues	\$ 13,039	\$ 49,606	\$ 86,802	\$251,851	\$315,721
Collaborative agreement revenues	12,630	18,740	28,264	38,907	2,379
Royalty and license revenues	—	15,863	6,515	5,735	6,556
Total revenues	<u>25,669</u>	<u>84,209</u>	<u>121,581</u>	<u>296,493</u>	<u>324,656</u>
Operating expenses:					
Cost of sales	2,629	8,740	18,359	52,509	65,909
Research and development	56,391	66,735	78,600	93,291	115,116
Selling, general and administrative	41,556	48,507	77,539	106,566	124,290
Amortization of acquired intangible assets	1,144	3,651	4,371	4,371	2,914
Total operating expenses	<u>101,720</u>	<u>127,633</u>	<u>178,869</u>	<u>256,737</u>	<u>308,229</u>
Income (loss) from operations	<u>(76,051)</u>	<u>(43,424)</u>	<u>(57,288)</u>	<u>39,756</u>	<u>16,427</u>
Equity in the income (loss) of BioMarin/Genzyme LLC	11,838	19,274	30,525	(2,270)	(2,594)
Interest income	1,861	12,417	25,932	16,388	5,086
Interest expense	(11,918)	(13,411)	(14,243)	(16,394)	(14,090)
Debt conversion expense	—	(3,315)	—	—	—
Impairment loss on equity investments	—	—	—	(4,056)	(5,848)
Net gain from sale of investments	—	—	—	—	1,585
Income (loss) before income taxes	<u>(74,270)</u>	<u>(28,459)</u>	<u>(15,074)</u>	<u>33,424</u>	<u>566</u>
Provision for income taxes	<u>—</u>	<u>74</u>	<u>729</u>	<u>2,593</u>	<u>1,054</u>
Net income (loss)	<u>\$ (74,270)</u>	<u>\$ (28,533)</u>	<u>\$ (15,803)</u>	<u>\$ 30,831</u>	<u>\$ (488)</u>
Net income (loss) per share, basic	<u>\$ (1.08)</u>	<u>\$ (0.34)</u>	<u>\$ (0.16)</u>	<u>\$ 0.31</u>	<u>\$ (0.00)</u>
Net income (loss) per share, diluted	<u>\$ (1.08)</u>	<u>\$ (0.34)</u>	<u>\$ (0.16)</u>	<u>\$ 0.29</u>	<u>\$ (0.00)</u>
Weighted average common shares outstanding, basic	<u>68,830</u>	<u>84,582</u>	<u>95,878</u>	<u>98,975</u>	<u>100,271</u>
Weighted average common shares outstanding, diluted	<u>68,830</u>	<u>84,582</u>	<u>95,878</u>	<u>103,572</u>	<u>100,271</u>

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

You should read the following tables presenting our unaudited quarterly results of operations in conjunction with the consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. We have prepared this unaudited information on the same basis as our audited consolidated financial statements. Our quarterly operating results have fluctuated in the past and may continue to do so in the future as a result of a number of factors, including, but not limited to, the timing and nature of research and development activities.

	Quarter Ended (In thousands, except per share data, unaudited)			
	March 31	June 30	September 30	December 31
<b>2009:</b>				
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
<b>2008:</b>				
Total revenue .....	\$ 60,396	\$64,174	\$72,646	\$99,277
Net income .....	1,686	3,810	829	24,506
Net income per share, basic .....	0.02	0.04	0.01	0.25
Net income per share, diluted .....	0.02	0.04	0.01	0.21

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

This Annual Report on Form 10-K contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "anticipates," "plans," "may," "will," "projects," "continues," "estimates," "potential," "opportunity" and similar expressions. These forward-looking statements may be found in "Overview," and other sections of this Annual Report on Form 10-K. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these statements, which speak only as of the date that they were made. These cautionary statements should be considered in connection with any written or oral forward-looking statements that we may issue in the future. We do not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Annual Report on Form 10-K to reflect later events or circumstances, or to reflect the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and notes to those statements included elsewhere in this Annual Report on Form 10-K.

### Overview

We develop and commercialize innovative biopharmaceuticals for serious diseases and medical conditions. We select product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. Our product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme, Aldurazyme, Kuvan and Firdapse.

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

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

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

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

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



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

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

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

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

### **Critical Accounting Policies and Estimates**

In preparing our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. (GAAP) and pursuant to the rules and regulations promulgated by the SEC, we make assumptions, judgments and estimates that can have a significant impact on our net income/loss and affect the reported amounts of certain assets, liabilities, revenue and expenses, and related disclosures. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates. We also discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for the impairment of long-lived assets, revenue recognition and related reserves, income taxes, inventory, research and development, stock-based compensation and business combinations have the greatest impact on our consolidated financial statements, so we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

### ***Business Combinations***

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

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

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

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

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

### ***Impairment of Long-Lived Assets***

Our long-lived assets include our investment in BioMarin/Genzyme LLC, long-term investments, property, plant and equipment, intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of our equity investments is measured by available external market data, including quoted prices on public stock exchanges and other relevant information. If the carrying amount of the asset is not recoverable, an impairment loss is recorded for the amount that the carrying value of the asset exceeds its fair value.

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

We currently operate in one business segment, the biopharmaceutical development and commercialization segment. When reviewing goodwill for impairment, we assess whether goodwill should be allocated to operating levels lower than our single operating segment for which discrete financial information is available and reviewed for decision-making purposes. These lower levels are referred to as reporting units. Currently, we have identified only one reporting unit as per Financial Accounting Standards Board, or FASB Accounting Standards Codification, or ASC Topic 350-20, *Intangibles – Goodwill and Other*. The majority of our goodwill originated from the acquisition of the Orapred business in 2004. The Orapred business was eliminated as a reporting unit following the sublicense of North American rights for Orapred, which was previously our only separate reporting unit. Immediately prior to the sublicense, which was considered a triggering event, we performed an impairment test at the Orapred reporting unit level and determined that there was no impairment at March 2006. We perform an annual impairment test in the fourth quarter of each fiscal year by assessing the fair value and recoverability of our goodwill by comparing the carrying value of the reporting unit to its fair value as determined by available market value unless facts and circumstances warrant a review of goodwill for impairment before that time. We performed our annual impairment test in the fourth quarter of 2009 and determined no impairment of goodwill existed as of December 31, 2009.

Determining whether an impairment has occurred typically requires various estimates and assumptions, including determining which cash flows are directly related to the potentially impaired asset, the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. In turn, measurement of an impairment loss requires a determination of fair value, which is based on the best information available. We use internal cash flow estimates, quoted market prices when available and independent appraisals as appropriate to determine fair value. We derive the required cash flow estimates from our historical experience and our internal business plans and apply an appropriate discount rate.

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

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

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

### ***Revenue Recognition***

We recognize revenue in accordance with ASC Topic 605-15, *Revenue Recognition—Products* and ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*. Our revenues consist of net product revenues from Naglazyme, Kuvan and Aldurazyme, revenues from our collaborative agreement with Merck Serono and other license and royalty revenues. Milestone payments are recognized in full when the related milestone performance goal is achieved and we have no future performance obligations related to that payment.

*Net Product Revenues*—We recognize net product revenue when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in our statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

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

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

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

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

The nature and amount of our current estimates of the applicable revenue dilution items that are currently applied to aggregate world-wide gross sales of Naglazyme and Kuvan to derive net sales are described in the table below.

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

We maintain a policy to record allowances for doubtful accounts for estimated losses resulting from our customers' inability to make required payments. As of December 31, 2009, we have experienced no significant bad debts and have not recorded an allowance for doubtful accounts.

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

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

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

### ***Inventory***

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the average-cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of sales on the consolidated statements of operations.

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

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

### ***Research and Development***

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

deliverables. We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the vendors that perform the activities.

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

### ***Stock-Based Compensation***

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

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

### ***Income Taxes***

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

### ***Recent Accounting Pronouncements***

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

## Results of Operations

### *Net Income (Loss)*

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

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

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

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

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

The increase in Naglazyme gross profit during 2008 as compared to 2007 is primarily a result of additional patients initiating therapy outside the U.S. and the EU as well as the favorable impact of foreign currency exchange rates on Naglazyme sales from customers outside the U.S. The increase in Aldurazyme gross profit is attributed to the restructuring of our joint venture with Genzyme effective January 1, 2008. Prior to the restructuring we recognized our 50% share of the net income of BioMarin/Genzyme LLC as equity in the income of BioMarin/Genzyme LLC in our consolidated statements of operations. The increase in Kuvan gross profit in 2008 compared to 2007 is attributed to the FDA approval of Kuvan in December 2007, which resulted in approximately two weeks of Kuvan sales in 2007 compared to twelve months in 2008. The increase in Kuvan royalty and license revenues is primarily attributed to the \$30.0 million milestone received in 2008 from Merck Serono for the EMEA approval of Kuvan offset by the absence of the \$15.0 million milestone received in 2007 for the acceptance of the Kuvan EMEA filing. The increase in selling, general and administrative expense was primarily due to the continued international expansion of Naglazyme and commercialization of Kuvan in the U.S. The increase in research and development expense was primarily due to increases in development expense for GALNS, a licensed product for the treatment of Duchenne muscular dystrophy, and other early stage programs. See below for additional information related to the primary net income/loss fluctuations presented above, including details of our operating expense fluctuations.

***Net Product Revenues, Cost of Sales and Gross Profit***

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

	Year Ended December 31,				
	2007	2008	2009	2007 vs. 2008	2008 vs. 2009
Naglazyme .....	\$86.2	\$132.7	\$168.7	\$ 46.5	\$36.0
Kuvan .....	0.4	46.7	76.8	46.3	30.1
Aldurazyme .....	—	72.5	70.2	72.5	(2.3)
Orapred .....	0.2	—	—	(0.2)	—
Total Net Product Revenues .....	<u>\$86.8</u>	<u>\$251.9</u>	<u>\$315.7</u>	<u>\$165.1</u>	<u>\$63.8</u>



## 2009 as Compared to 2008

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

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

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

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

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

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

## 2008 as Compared to 2007

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

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

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

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

## Collaborative Agreement Revenues

Collaborative agreement revenues include both license revenue and contract research revenue under our agreement with Merck Serono, which was executed in May 2005. License revenues are related to amortization of the \$25.0 million up-front license payment received from Merck Serono and contract research revenues are related to shared development costs that are incurred by us, of which approximately 50% is reimbursed by Merck Serono. Our performance obligations related to the initial \$25.0 million up-front license payment were completed in December 2008. Therefore, periods subsequent to December 31, 2008 do not include amortization amounts related to this payment. As shared development spending increases or decreases, contract research revenues will also change proportionately. Reimbursable revenues are expected to increase if PEG-PAL successfully completes Phase 2 clinical trials and Merck Serono exercises its option to co-develop it. The related costs are included in research and development expenses. The following table details the components of collaborative agreement revenues for the three years ended December 31, 2007, 2008 and 2009 (in millions):

	Year Ended December 31,		
	2007	2008	2009
Amortization of the \$25.0 million up-front license payment from Merck Serono . . . . .	\$ 6.9	\$ 5.2	\$—
Reimbursable Kuvan development costs . . . . .	6.4	3.7	2.4
Kuvan EMEA approval milestone from Merck Serono . . . . .	—	30.0	—
Kuvan EMEA filing acceptance milestone from Merck Serono . . . . .	15.0	—	—
Total . . . . .	<u>\$28.3</u>	<u>\$38.9</u>	<u>\$ 2.4</u>

## Royalty and License Revenues

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

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

### ***Research and Development Expense***

Our research and development expense includes personnel, facility and external costs associated with the research and development of our product candidates and products. These research and development costs primarily include preclinical and clinical studies, manufacturing of our product candidates prior to regulatory approval, quality control and assurance and other product development expenses, such as regulatory costs.

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

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

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

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

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

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

#### *Selling, General and Administrative Expense*

Our selling, general and administrative expense includes commercial and administrative personnel, corporate facility and external costs required to support our commercialized products and product development programs. These selling, general and administrative costs include: corporate facility operating expenses and depreciation; marketing and sales operations; human resources; finance; legal and support personnel expenses; and other external corporate costs such as insurance, audit and legal fees.

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

Selling, general and administrative expense for the year ended December 31, 2008 ..	\$106.6
Increased Naglazyme sales and marketing expenses .....	2.9
Increased Kuvan commercialization expenses .....	3.7
Increased stock-based compensation expense .....	3.4
Increased depreciation expense .....	2.3
Increased information technology expense .....	1.9
Increased foreign exchange gains on un-hedged transactions .....	(2.1)
Net increase in corporate overhead and other administrative expenses .....	5.6
Selling, general and administrative expense for the year ended December 31, 2009 ..	<u>\$124.3</u>

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

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

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

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

***Amortization of Intangible Assets***

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

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

Kuvan license payments, recorded as intangible assets, made to third parties as a result of the FDA approval of Kuvan in December 2007 and the EMEA approval of Kuvan in December 2008 are being amortized over approximately 7.0 years and 10.0 years, respectively. Amortization of the Kuvan intangible assets is recorded as a component of cost of sales and is expected to approximate \$0.6 million annually through 2014 and \$0.3 million annually through 2018. Amortization expense related to the Kuvan intangible assets for the years ended 2008 and 2009 was \$0.4 million and \$0.6 million, respectively. Amortization expense related to the Kuvan intangible asset was insignificant in 2007. The increase in Kuvan related amortization expense in 2009 is attributed to the EMEA approval milestone paid to us in December 2008.

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

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

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

### ***Interest Income***

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

### ***Interest Expense***

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

### **Changes in Financial Position**

#### ***December 31, 2009 Compared to December 31, 2008***

From December 31, 2008 to December 31, 2009, our cash, cash equivalents, and short-term and long-term investments decreased by \$90.9 million, primarily as a result of the settlement the Medicis obligation, the acquisition of Huxley Pharmaceuticals and increased capital expenditures. These decreases in cash and investments were substantially offset by the receipt of the \$30.0 million milestone for Kuvan EMEA approval and cash flows from operating activities. Our accounts receivable increased by \$19.2 million due to increased sales of Naglazyme and Kuvan and receivables from Genzyme for Aldurazyme product transfer and royalty revenues. Other current assets decreased approximately \$35.6 million from December 31, 2008 to December 31, 2009, primarily as a result of the receipt of the \$30.0 million related to the EMEA milestone earned from Merck Serono in December 31, 2008 that was paid in January 2009, and the reclassification of \$6.2 million in cash which was restricted from use until June 2009 when we paid the remaining acquisition obligation resulting from the Ascent Pediatrics transaction to Medicis. Our net property, plant and equipment increased by approximately \$74.2 million from December 31, 2008 to December 31, 2009, primarily as a result of continued expansion and improvements to our facilities during the period. We expect property, plant and equipment to increase in future periods, due to several ongoing facility improvement projects, and we expect depreciation expense to increase as the assets are placed into service.

## Liquidity and Capital Resources

### Cash and Cash Flow

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

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

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

The net decrease in operating spend includes increases in cash receipts from net revenues, partially offset by increases in cash payments made for operating activities, such as research and development and sales and marketing efforts, as discussed in “*Results of Operations*” above. Increased capital purchases primarily relate to continued expansion of corporate and manufacturing facilities at our Novato, California campus. Net payments for working capital in 2009 primarily include decreased inventory build of \$8.4 million, which excluded the inventory distribution from the joint venture and the decreased accounts receivable build of \$18.1 million, and the receipt of the Merck Serono \$30.0 million milestone payment earned in December 2008 related to the EMEA approval of Kuvan.

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

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

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

We have historically financed our operations primarily by the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. During 2010, and for the foreseeable future, we will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing. Further, depending on market conditions, our financial position and performance and other factors, in the future we may choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

### ***Funding Commitments***

We expect to fund our operations with our net product revenues from our commercial products; cash; cash equivalents; short-term and long-term investments supplemented by proceeds from equity or debt financings; and loans or collaborative agreements with corporate partners, each to the extent necessary. We expect our current cash, cash equivalents, and short-term and long-term investments will meet our operating and capital requirements for the foreseeable future based on our current long-term business plans and assuming that we are able to achieve our long-term goals. This expectation could also change depending on how much we elect to spend on our development programs and for potential licenses and acquisitions of complementary technologies, products and companies.

Our investment in our product development programs and continued development of our existing commercial products has a major impact on our operating performance. Our research and development expenses for the three years ended December 31, 2007, 2008 and 2009 and for the period since inception (March 1997 for the portion not allocated to any major program) represent the following (in millions):

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

We cannot estimate the cost to complete any of our product development programs. Additionally, except as disclosed under “*Overview*” above, we cannot estimate the time to complete any of our product development programs or when we expect to receive net cash inflows from any of our product development programs. Please see “*Risk Factors*” in this Annual Report on Form 10-K, for a discussion of the reasons that we are unable to estimate such information, and in particular the following risk factors included in this Annual Report on Form 10-K “*—If we fail to maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased;*” “*—To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain;*” “*—If we are unable to successfully develop manufacturing processes for our drug products to produce sufficient quantities at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program;*” “*—If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be*



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

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

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

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

#### ***Off-Balance Sheet Arrangements***

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

#### ***Borrowings and Contractual Obligations***

In April 2007, we sold approximately \$324.9 million of senior subordinated convertible debt due April 2017. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately \$20.36 per share, subject to adjustment in certain circumstances. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2017. We also must repay the debt if there is a qualifying change in control or termination of trading of our common stock. In March 2006, we sold approximately \$172.5 million of senior subordinated convertible notes due 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. There is a no call provision included and we are unable to unilaterally redeem the debt prior to maturity in 2013. The debt is convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately \$16.58 per share, subject to adjustment in certain circumstances. However, we must repay the debt prior to maturity if there is a qualifying change in control or termination of trading of our common stock. Our \$497.1 million of convertible debt will impact our liquidity due to the semi-annual cash interest payments and the scheduled repayments of the debt.

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of December 31, 2009 is presented below (in thousands).

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

We are also subject to contingent payments related to various development activities totaling approximately \$167.5 million, which are due upon achievement of certain regulatory and licensing milestones, and if they occur before certain dates in the future.

### Related Party Transactions

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

### Item 7A. Quantitative and Qualitative Disclosure About Market Risk

#### *Interest Rate Market Risk*

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. By policy, we place our investments with highly rated credit issuers and limit the amount of credit exposure to any one issuer. As stated in our policy, we seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk.

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

As of December 31, 2009, our investment portfolio did not include any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at December 31, 2009, we believe that a 100 basis point decrease in interest rates could result in a potential loss in fair value of our investment portfolio of approximately \$4.7 million. Changes in interest rates may affect the fair value of our investment portfolio. However, we will not recognize such gains or losses in our consolidated statement of operations unless the investments are sold.

The table below presents the carrying value of our cash and investment portfolio, which approximates fair value at December 31, 2009 (in thousands):

	<u>Carrying Value</u>
Cash and cash equivalents .....	\$167,171*
Short-term investments .....	133,506**
Long-term investments .....	<u>169,849***</u>
Total .....	<u>\$470,526</u>

- \* 89% of cash and cash equivalents invested in money market instruments and 11% in uninvested cash.
- \*\* 44% of short-term investments invested in corporate securities, 26% invested in U.S. government treasuries, 23% in certificates of deposit, 6% in commercial paper and 1% in equity securities.
- \*\*\* 28% of long-term investments invested in U.S. government treasuries, 61% in corporate securities and 11% in certificates of deposit.

Our debt obligations consist of our convertible debt, which carries a fixed interest rate and, as a result, we are not exposed to interest rate market risk on our convertible debt. The carrying value of our convertible debt approximates its fair value at December 31, 2009.

#### ***Foreign Currency Exchange Rate Market Risk***

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

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

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

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

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

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

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

## **Item 8. Financial Statements and Supplementary Data**

The information required to be filed in this item appears on pages F-1 to F-42 of this report.

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

None.

## **Item 9A. Controls and Procedures**

### *Evaluation of Disclosure Controls and Procedures*

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

### *Management's Annual Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining an adequate internal control structure and procedures for financial reporting. Under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, our management has assessed the effectiveness of our internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act as of December 31, 2009. Our management's assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, Internal Control-Integrated Framework.

Based on using the COSO criteria, we believe our internal control over financial reporting as of December 31, 2009 was effective.

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

### *Changes in Internal Control Over Financial Reporting*

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

### ***Scope of the Effectiveness of Controls***

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

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

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

### **Item 9B. Other Information**

None

### Part III

#### Item 10. Directors and Executive Officers and Corporate Governance

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

#### Item 11. Executive Compensation

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

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

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

#### Item 13. Certain Relationships and Related Transactions and Director Independence

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

#### Item 14. Principal Accounting Fees and Services

We incorporate information regarding our principal accountant fees and services into this section by reference from the section captioned "Auditors" in the proxy statement for our 2010 annual meeting of stockholders.

### Part IV

#### Item 15. Exhibits, Financial Statement Schedules

##### Financial Statements

Reports of Independent Registered Public Accounting Firm .....	F-1
Consolidated Balance Sheets .....	F-3
Consolidated Statements of Operations .....	F-4
Consolidated Statements of Changes in Stockholders' Equity (Deficit) and Comprehensive Income (Loss) . . . .	F-5
Consolidated Statements of Cash Flows .....	F-6
Notes to Consolidated Financial Statements .....	F-7

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

## Exhibit Index

- 2.1 Asset Purchase Agreement dated as of April 20, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 2.2 Securities Purchase Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 2.3 License Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.3 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 2.4 Settlement Agreement and Mutual Release dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.4 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 2.5 Amendment to Securities Purchase Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.5 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 2.6 Amendment to License Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.6 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 3.1 Amended and Restated Certificate of Incorporation, as amended June 12, 2003, previously filed with the Commission on June 23, 2003 as Exhibit 3.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 3.2 Certificate of Correction to Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioMarin Pharmaceutical Inc., previously filed with the Commission on April 4, 2005 as Exhibit 3.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 3.3 Amended and Restated By-Laws of BioMarin Pharmaceutical Inc., previously filed with the Commission on February 27, 2009 as Exhibit 3.3 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 4.1 Amended and Restated Rights Agreement, dated as of February 27, 2009, between BioMarin Pharmaceutical Inc. and Mellon Investor Services LLC, as Rights Agent, previously filed with the Commission on February 27, 2009 as Exhibit 4.1 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 4.2 Indenture dated June 23, 2003, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on August 12, 2003 as Exhibit 4.1 to the Company's Quarterly report on Form 10-Q, which is incorporated herein by reference.
- 4.3 Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.

- 4.4 First Supplemental Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 4.5 Form of 2.5% Senior Subordinated Convertible Notes due 2013, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.1† Form of Indemnification Agreement for Directors and Officers, previously filed with the Commission on May 4, 1999 as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.2† Amended and Restated Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on May 12, 2009, previously filed with the Commission on July 31, 2009 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated by reference herein.
- 10.3† Amendment to 1997 Stock Plan, as amended, as adopted March 20, 2002, previously filed with the Commission on March 21, 2002 as Exhibit 99.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.4† Amendment No. 2 to 1997 Stock Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.5† Amended and Restated BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, as adopted on June 21, 2006, previously filed with the Commission on June 16, 2006 as Exhibit 99.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.6† 1998 Director Option Plan and forms of agreements thereunder, previously filed with the Commission on May 4, 1999 as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.7† Amendment to 1998 Director Plan as adopted March 26, 2003 previously filed with the Commission on May 15, 2003 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.8† Amendment No. 2 to 1998 Director Option Plan, as adopted June 12, 2003 and July 21, 2003, previously filed with the Commission on August 12, 2003 as Exhibit 10.1 to the Company's Quarterly report on Form 10-Q, which is incorporated herein by reference.
- 10.9† Amendment No. 3 to 1998 Director Option Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.10† Amended and Restated 2006 Employee Stock Purchase Plan, as adopted on June 21, 2006, previously filed with the Commission on August 3, 2006 as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.11† Amended and Restated BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan, as adopted on December 1, 2005 and as amended and restated on January 1, 2009, previously filed with the Commission on December 23, 2008 as Exhibit 10.8 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.12† Amended and Restated Employment Agreement with Jean-Jacques Bienaimé dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.



- 10.13† Amended and Restated Employment Agreement with Stephen Aselage dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.14† Amended and Restated Employment Agreement with Robert A. Baffi dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.3 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.15† Amended and Restated Employment Agreement with Emil D. Kakkis, M.D., Ph.D. dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.4 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.16† Severance Agreement with Dr. Emil D. Kakkis, dated May 28, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.17† Consulting Agreement between the Company and Dr. Emil D. Kakkis, dated July 1, 2009 previously filed with the SEC on June 3, 2009 as Exhibit 10.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.18† Amended and Restated Employment Agreement with Jeffrey H. Cooper dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.5 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.19† Amended and Restated Employment Agreement with G. Eric Davis dated January 1, 2009, previously filed with the Commission on December 23, 2005 as Exhibit 10.6 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.20† Amended and Restated Employment Agreement with Mark Wood dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.7 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.21† Employment Agreement with Stuart J. Swiedler, M.D., Ph.D., dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.22† Employment Agreement with Henry Fuchs, dated March 18, 2009, previously filed with the Commission on March 23, 2009 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.23 Grant Terms and Conditions Agreement between BioMarin Pharmaceutical Inc. and Harbor-UCLA Research and Education Institute dated April 1, 1997, as amended, previously filed with the Commission on July 21, 1999 as Exhibit 10.17 to the Company's Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.24 License Agreement dated July 30, 2004, between BioMarin Pharmaceutical Inc. and Daiichi Suntary Pharma Co., Ltd., as amended by Amendment No. 1 to License Agreement dated November 19, 2004, previously filed with the Commission on March 16, 2005 as Exhibit 10.25 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.

- 10.25 Development, License and Commercialization Agreement dated May 13, 2005, between BioMarin Pharmaceutical Inc. and Ares Trading S.A., previously filed with the Commission on July 6, 2005 as Exhibit 10.1 to the Company's Current Report on Form 8-K/A, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.26 Operating Agreement with Genzyme Corporation, previously filed with the Commission on July 21, 1999 as Exhibit 10.30 to the Company's Amendment No. 2 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.27† 2009 Technical Amendments to BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, effective January 1, 2009, previously filed with the Commission on December 23, 2008, as Exhibit 10.9 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.28 Amended and Restated License Agreement between BioMarin Pharmaceutical Inc. and Women's and Children's Hospital dated February 7, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.29 Manufacturing, Marketing and Sales Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2008 as Exhibit 10.30 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.30 Amended and Restated Collaboration Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.31 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.31 Members Agreement dated as of January 1, 2008 by and among BioMarin Pharmaceutical Inc., Genzyme Corporation, BioMarin Genetics Inc., and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.32 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.32 Development and Commercialization Agreement dated as of January 4, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.29 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.33 Securities Purchase Agreement dated as of January 4, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.30 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.34 Amendment No. 1 to the Development and Commercialization Agreement dated as of January 16, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.31 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.

- 10.35 Amendment No. 1 to the Securities Purchase Agreement dated as of January 16, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.32 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 10.36† Summary of Bonus Plan, previously filed with the Commission on February 27, 2009 as Exhibit 10.33 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 10.37 \*# Stock Purchase Agreement by and between BioMarin Pharmaceutical Inc., Huxley Pharmaceuticals, Inc., and the stockholders of Huxley Pharmaceuticals, Inc., dated October 20, 2009. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 21.1\* Subsidiaries of BioMarin Pharmaceutical Inc.
- 23.1\* Consent of KPMG LLP, Independent Registered Public Accounting Firm for BioMarin Pharmaceutical Inc.
- 23.2\* Consent of PricewaterhouseCoopers, LLP, Independent Registered Public Accounting Firm for BioMarin/Genzyme LLC.
- 24.1\* Power of Attorney (Included in Signature Page)
- 31.1\* Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2\* Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1\* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.
- 99.1\* BioMarin/Genzyme LLC Consolidated Financial Statements as of December 31, 2008, and for the years ended December 31, 2008 and 2007.

\* Filed herewith

† Management contract or compensatory plan or arrangement

# Confidential treatment requested for a portion of this agreement

## SIGNATURES

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

BIOMARIN PHARMACEUTICAL INC.

Dated: February 25, 2010

By:                     /s/ JEFFREY H. COOPER                    

**Jeffrey H. Cooper**  
**Senior Vice President, Chief Financial Officer**

## POWER OF ATTORNEY

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JEAN-JACQUES BIENAIMÉ</u> Jean-Jacques Bienaimé	Chief Executive Officer (Principal Executive Officer)	February 25, 2010
<u>/s/ JEFFREY H. COOPER</u> Jeffrey H. Cooper	Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2010
<u>/s/ PIERRE LAPALME</u> Pierre LaPalme	Chairman and Director	February 25, 2010
<u>/s/ ELAINE HERON</u> Elaine Heron	Director	February 25, 2010
<u>/s/ JOSEPH KLEIN, III</u> Joseph Klein, III	Director	February 25, 2010
<u>/s/ ALAN J. LEWIS</u> Alan J. Lewis	Director	February 25, 2010
<u>/s/ MICHAEL G. GREY</u> Michael G. Grey	Director	February 25, 2010
<u>/s/ RICHARD A. MEIER</u> Richard A. Meier	Director	February 25, 2010
<u>/s/ V. BRYAN LAWLIS</u> V. Bryan Lawlis	Director	February 25, 2010

**INDEX TO BIOMARIN PHARMACEUTICAL INC.  
CONSOLIDATED FINANCIAL STATEMENTS**

Reports of Independent Registered Public Accounting Firm .....	F-1
Consolidated Balance Sheets .....	F-3
Consolidated Statements of Operations .....	F-4
Consolidated Statements of Changes in Stockholders' Equity (Deficit) and Comprehensive Income (Loss) ...	F-5
Consolidated Statements of Cash Flows .....	F-6
Notes to Consolidated Financial Statements .....	F-7

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
BioMarin Pharmaceutical Inc.:

We have audited the accompanying consolidated balance sheets of BioMarin Pharmaceutical Inc. and subsidiaries (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the financial statements of BioMarin/Genzyme LLC (a 50 percent owned joint venture) for 2007. The Company's equity in income of BioMarin/Genzyme LLC (in thousands) was \$30,525 for the year ended December 31, 2007. The financial statements of BioMarin/Genzyme LLC for 2007 were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for BioMarin/Genzyme LLC for 2007, is based solely on the report of the other auditors.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioMarin Pharmaceutical Inc. and subsidiaries as of December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 25, 2010 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

San Francisco, California  
February 25, 2010

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
BioMarin Pharmaceutical Inc.:

We have audited BioMarin Pharmaceutical Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting in Item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of BioMarin Pharmaceutical Inc. and subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2009, and our report dated February 25, 2010 expressed an unqualified opinion on those consolidated financial statements. Our report refers to the report of other auditors.

/s/ KPMG LLP

San Francisco, California  
February 25, 2010



**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

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

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

See accompanying notes to the consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years ended December 31, 2007, 2008 and 2009**

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

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

See accompanying notes to the consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**

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

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

	Common stock		Additional Paid-in Capital	Company Common Stock held by Deferred Compensation Plan	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at January 1, 2007	91,726	\$ 92	\$709,359	—	\$ (25)	\$(591,624)	\$117,802
Net loss	—	—	—	—	—	(15,803)	(15,803)
Fair market value adjustments of available-for-sale investments	—	—	—	—	62	—	62
Foreign currency translation adjustment	—	—	—	—	102	—	102
Comprehensive loss	—	—	—	—	—	—	(15,639)
Issuance of common stock under ESPP	275	—	1,928	—	—	—	1,928
Exercise of common stock options	1,443	1	13,291	—	—	—	13,292
Conversion of convertible notes	3,670	4	50,925	—	—	—	50,929
Stock-based compensation	—	—	19,414	—	—	—	19,414
Balance at December 31, 2007	<u>97,114</u>	<u>\$ 97</u>	<u>\$794,917</u>	<u>—</u>	<u>\$ 139</u>	<u>\$(607,427)</u>	<u>\$187,726</u>
Net income	—	—	—	—	—	30,831	30,831
Fair market value adjustments of available-for-sale investments	—	—	—	—	1,201	—	1,201
Unrealized loss on foreign currency hedges	—	—	—	—	(212)	—	(212)
Foreign currency translation adjustment	—	—	—	—	(22)	—	(22)
Comprehensive income	—	—	—	—	—	—	31,798
Issuance of common stock under ESPP	209	—	2,634	—	—	—	2,634
Exercise of common stock options	2,489	3	25,813	—	—	—	25,816
Excess tax benefit from stock option exercises	—	—	960	—	—	—	960
Restricted stock vested during the period	39	—	—	—	—	—	—
Common stock held by nonqualified deferred compensation plan	—	—	—	(882)	—	—	(882)
Conversion of convertible notes	17	—	288	—	—	—	288
Stock-based compensation	—	—	28,335	—	—	—	28,335
Balance at December 31, 2008	<u>99,868</u>	<u>\$100</u>	<u>\$852,947</u>	<u>\$ (882)</u>	<u>\$1,106</u>	<u>\$(576,596)</u>	<u>\$276,675</u>
Net loss	—	—	—	—	—	(488)	(488)
Fair market value adjustments of available-for-sale investments	—	—	—	—	299	—	299
Unrealized loss on foreign exchange forward contracts	—	—	—	—	(477)	—	(477)
Foreign currency translation adjustment	—	—	—	—	5	—	5
Comprehensive loss	—	—	—	—	—	—	(661)
Issuance of common stock under ESPP	287	—	3,230	—	—	—	3,230
Exercise of common stock options	730	1	7,655	—	—	—	7,656
Excess tax benefit from stock option exercises	—	—	113	—	—	—	113
Restricted stock vested during the period	77	—	—	—	—	—	—
Common stock held by nonqualified deferred compensation plan	—	—	—	(833)	—	—	(833)
Stock-based compensation	—	—	36,005	—	—	—	36,005
Balance at December 31, 2009	<u>100,962</u>	<u>\$101</u>	<u>\$899,950</u>	<u>\$(1,715)</u>	<u>\$ 933</u>	<u>\$(577,084)</u>	<u>\$322,185</u>

See accompanying notes to the consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Three Years ended December 31, 2007, 2008 and 2009**

**(In thousands)**

	<u>Years Ended December 31,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (15,803)	\$ 30,831	\$ (488)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	13,654	17,616	20,975
Amortization of discount (premium) on investments	(12,453)	(6,487)	1,443
Imputed interest on acquisition obligation	4,527	4,378	2,577
Equity in the (income) loss of BioMarin/Genzyme LLC	(30,525)	2,270	2,594
Stock-based compensation	19,415	28,336	36,005
Impairment loss on equity investments	—	4,056	5,848
Net gain from sale of investments	—	—	(1,585)
Unrealized foreign exchange (gain) loss on forward contracts	165	(228)	602
Excess tax benefit from stock option exercises	—	(960)	(113)
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,306)	(37,322)	(19,242)
Inventory	(7,371)	(13,938)	(5,500)
Other current assets	(3,649)	(41,143)	37,415
Other assets	(4,745)	925	(1,286)
Accounts payable, accrued liabilities and other current liabilities	10,850	7,433	8,021
Other liabilities	3	78	687
Deferred revenue	(6,788)	(5,020)	(221)
Net cash provided by (used in) operating activities	<u>(35,026)</u>	<u>(9,175)</u>	<u>87,732</u>
<b>Cash flows from investing activities:</b>			
Purchase of property, plant and equipment	(22,413)	(56,368)	(89,801)
Maturities and sales of investments	693,814	761,178	475,312
Purchase of investments	(838,864)	(733,131)	(439,299)
Investments in BioMarin/Genzyme LLC	—	(1,750)	(2,120)
Distributions from BioMarin/Genzyme LLC	17,100	16,683	—
Investment in Summit Corporation plc	—	(5,689)	—
Acquisition of Huxley Pharmaceuticals, Inc.	—	—	(14,517)
Investment in La Jolla Pharmaceutical Company	—	—	(6,250)
Payment to LEAD Therapeutics, Inc.	—	—	(3,000)
Net cash used in investing activities	<u>(150,363)</u>	<u>(19,077)</u>	<u>(79,675)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from ESPP and exercise of stock options	15,220	28,443	10,886
Excess tax benefit from stock option exercises	—	960	113
Net proceeds from convertible debt offering	316,350	—	—
Repayment of acquisition obligation	(7,000)	(6,500)	(73,600)
Repayment of capital lease obligations	—	(94)	(185)
Payment of contingent acquisition payable	—	—	(1,000)
Net cash provided by (used in) financing activities	<u>324,570</u>	<u>22,809</u>	<u>(63,786)</u>
Net increase (decrease) in cash and cash equivalents	<u>139,181</u>	<u>(5,443)</u>	<u>(55,729)</u>
Cash and cash equivalents:			
Beginning of year	89,162	228,343	222,900
End of year	<u>\$ 228,343</u>	<u>\$ 222,900</u>	<u>\$ 167,171</u>
<b>Supplemental cash flow disclosures:</b>			
Cash paid for interest, net of interest capitalized into fixed assets	\$ 7,358	\$ 10,401	\$ 9,700
Cash paid for income taxes	296	1,277	2,824
Stock-based compensation capitalized into inventory	1,710	4,612	5,423
Depreciation capitalized into inventory	1,941	2,782	4,432
<b>Supplemental non-cash investing and financing activities disclosures:</b>			
Conversion of convertible notes	51,440	292	—
Distribution of inventory resulting from the joint venture restructure	—	26,780	—
Changes in accrued liabilities related to fixed assets	6,726	4,462	185
Equipment acquired through capital lease	—	546	—
Deferred offering costs reclassified to additional paid in capital as a result of convertible notes	512	9	—
Common shares transferred to Nonqualified Deferred Compensation Plan	—	(882)	(833)

See accompanying notes to the consolidated financial statements.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2008 and 2009**

**(1) NATURE OF OPERATIONS AND BUSINESS RISKS**

BioMarin Pharmaceutical Inc. (the Company or BioMarin®) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin selects product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. The Company's product portfolio is comprised of four approved products and multiple investigational product candidates. Approved products include Naglazyme® (galsulfase), Kuvan® (sapropterin dihydrochloride), Firdapse™ (amifampridine phosphate) and Aldurazyme® (aronidase).

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

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

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

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*(a) Basis of Presentation*

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

*(b) Use of Estimates*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

*(c) Cash and Cash Equivalents*

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

*(d) Investments*

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

*(e) Inventory*

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

*(g) Property, Plant and Equipment*

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

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

*(h) Revenue Recognition*

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

*Net Product Revenues*—The Company recognizes net product revenue when persuasive evidence of an arrangement exists, the product has been delivered to the customer, title and risk of loss have passed to the customer, the price to the buyer is fixed or determinable and collection from the customer is reasonably assured. Product sales transactions are evidenced by customer purchase orders, customer contracts, invoices and/or the related shipping documents. Amounts collected from customers and remitted to governmental authorities, which are primarily comprised of value-added taxes related to Naglazyme sales in foreign jurisdictions, are presented on a net basis in the Company's consolidated statements of operations, in that taxes billed to customers are not included as a component of net product revenues.

BioMarin receives a 39.5% to 50% royalty on worldwide net Aldurazyme sales by Genzyme depending on sales volume, which is included in net product revenues in the consolidated statements of operations. The Company recognizes a portion of this amount as product transfer revenue when product is released to Genzyme as all of the Company's performance obligations are fulfilled at that point and title to, and risk of loss for, the product has transferred to Genzyme. The product transfer revenue represents the fixed amount per unit of Aldurazyme that Genzyme is required to pay the Company if the product is unsold by Genzyme. The amount of product transfer revenue will eventually be deducted from the calculated royalty rate when the product is sold by Genzyme. The Company records the Aldurazyme royalty revenue based on net sales information provided by Genzyme and records product transfer revenue based on the fulfillment of Genzyme purchase orders in accordance with the terms of the related agreements with Genzyme and when the title and risk of loss for the product is transferred to Genzyme. As of December 31, 2009, accounts receivable included \$20.3 million of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme.

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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



**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

*(i) Research and Development*

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

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

*(j) Net Income (Loss) Per Share*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

	For the Year Ended December 31, 2008		
	Net Income (Numerator)	Weighted Average Shares Outstanding (Denominator)	Per Share Amount
Basic Earnings Per Share:			
Net Income .....	\$30,831	98,975	<u>\$0.31</u>
Effect of dilutive shares:			
Stock options using the treasury method .....	—	3,837	
Portion of acquisition obligation payable in common stock at the option of the Company .....	—	483	
Potentially issuable common stock for ESPP purchases .....	—	245	
Common stock held in the Nonqualified Deferred Compensation Plan using the treasury method ..	(308)	32	
Diluted Earnings Per Share:			
Net Income .....	<u>\$30,523</u>	<u>103,572</u>	<u>\$0.29</u>

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

*(k) Stock-Based Compensation*

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

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

*(l) Nonqualified Deferred Compensation Plan*

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

*(m) Income Taxes*

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

*(n) Foreign Currency and Other Hedging Instruments*

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

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

*(o) Fair Value of Financial Instruments*

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

*(q) Restricted Cash*

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

*(r) Recent Accounting Pronouncements*

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

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-6, *Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements*, which expands fair value disclosure requirements. Transition will be in two phases with expanded disclosures regarding activity for Level 1 and 2 applicable for the Company on January 1, 2010 and expanded disclosures for Level 3 activity effective on January 1, 2011.

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

ASC Topic 805, *Business Combinations* (ASC 805) requires an entity to recognize the assets acquired, liabilities assumed, contractual contingencies and contingent consideration at their fair value on the acquisition date. Subsequent changes to the estimated fair value of contingent consideration will be reflected in earnings until the contingency is settled. ASC 805 also requires acquisition-related costs and restructuring costs to be expensed as incurred rather than treated as part of the purchase price. The provisions of ASC 805 are effective for business combinations initiated on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which for the Company was January 1, 2009. The adoption of ASC 805 is reflected in the Company's accounting treatment of the Huxley Pharmaceuticals, Inc. acquisition discussed in Note 5.

*(s) Reclassifications and Adjustments*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

**(3) STOCKHOLDERS' EQUITY**

*(a) Share Incentive Plan*

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

*(b) Employee Stock Purchase Plan*

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

*(c) Board of Director Grants*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

*(d) Stock-based Compensation*

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

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

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

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

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

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



**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

***Determining the Fair Value of Stock Options and Stock Purchase Rights***

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

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

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

<u>Employee Stock Purchase Plan Valuation Assumptions</u>	<u>Year Ended December 31,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
Expected volatility .....	44-54%	47-51%	55%
Dividend yield .....	0.0%	0.0%	0.0%
Expected life .....	6-24 months	6-24 months	6-24 months
Risk-free interest rate .....	3.8-5.2%	1.1-2.4%	0.2-0.9%

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

*(e) Stockholders' Rights Plan*

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

**(4) INTANGIBLE ASSETS AND GOODWILL**

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

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

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

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

*(a) Orapred*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

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

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

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

*(b) Kuvan Intangible Assets*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

*(c) Firdapse*

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

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

**(5) ACQUISITION OF HUXLEY PHARMACEUTICALS, INC.**

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

*Intangible Assets*

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

In estimating fair value of the IPR&D assets, the Company compensated for the differing phases of development of each asset by probability-adjusting its estimation of the expected future cash flows associated with each asset. The Company then determined the present value of the expected future cash flows. The projected cash flows from the IPR&D assets were based on key assumptions such as estimates of revenues and operating profits related to the feasibility and timing of achievement of development, regulatory and commercial milestones, expected costs to develop the IPR&D into commercially viable products, and future expected cash flows from product sales.

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(6) SHORT-TERM AND LONG-TERM INVESTMENTS**

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

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

**(7) SUPPLEMENTAL BALANCE SHEET INFORMATION**

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

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

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

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



**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(8) PROPERTY, PLANT AND EQUIPMENT**

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

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

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

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

**(9) INVESTMENT IN SUMMIT CORPORATION PLC**

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

**(10) INVESTMENT IN LA JOLLA PHARMACEUTICAL COMPANY**

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

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

On March 26, 2009, the Company terminated its licensing agreement with La Jolla, triggering the preferred stock's automatic conversion feature at a rate of one preferred share to thirty shares of common stock. Thus, as of the conversion date, the Company held approximately 10.2 million shares of common stock, or approximately 15.5% La Jolla's outstanding common stock. The Company accounted for the converted La Jolla shares, which were traded on the NASDAQ Stock Exchange, as an available-for-sale investment. The investment was classified as available-for-sale, with changes in the fair value reported as a component of accumulated other comprehensive income/loss, exclusive of other-than-temporary impairment losses, if any. Losses determined to be other-than-temporary were reported in earnings in the period in which the impairment occurs.

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

**(11) CONVERTIBLE DEBT**

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

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

In March 2006, the Company sold \$172.5 million of Senior Subordinated Convertible Notes due 2013. The debt was issued at face value and bears interest at the rate of 2.5% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of Company common stock at a conversion price of approximately \$16.58 per share, subject to adjustment in certain circumstances. There is not a call provision included and the Company is unable to unilaterally redeem the debt prior to maturity on March 29, 2013. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock.

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(12) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES**

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

*Foreign Currency Exposure*

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

**(13) FAIR VALUE MEASUREMENTS**

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

	Fair Value Measurements at December 31, 2008			
	Total	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market instruments and overnight deposits (1) ..	\$222,900	\$12,959	\$209,941	\$ —
Corporate securities (3) .....	55,170	—	55,170	—
Equity securities (4) .....	3,965	2,332	1,633	—
Government agency securities (3) .....	221,891	—	221,891	—
Government-backed commercial paper (3) .....	24,375	—	24,375	—
Commercial paper (3) .....	33,124	—	33,124	—
Deferred compensation asset (8) .....	854	—	854	—
Foreign currency derivatives (5) .....	803	—	803	—
Total .....	<u>\$563,082</u>	<u>\$15,291</u>	<u>\$547,791</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Deferred compensation liability (6) .....	\$ 1,428	\$ 574	\$ 854	\$ —
Foreign currency derivatives (7) .....	1,129	—	1,129	—
Total .....	<u>\$ 2,557</u>	<u>\$ 574</u>	<u>\$ 1,983</u>	<u>\$ —</u>

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

- (1) These amounts are included in cash and cash equivalents investments in the Company's consolidated balance sheet.
- (2) 62% and 38% are included in short-term and long-term investments in the Company's consolidated balance sheet, respectively.
- (3) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2008, all balances were classified as short-term investments. At December 31, 2009, 64% of corporate securities and 58% of government agencies were included in long-term investments and the remaining balances are included in short-term investments.
- (4) These amounts are included in short-term investments and long-term investments in the Company's consolidated balance sheet. At December 31, 2008 and 2009, 41% and 22%, respectively, are included in long-term investments and the remaining balances are included in short-term investments.
- (5) These amounts are included in other current assets on the Company's consolidated balance sheet. Foreign currency derivatives at December 31, 2009 include forward foreign exchange contracts for the Euro. Foreign currency derivatives at December 31, 2008 include forward foreign exchange contracts for Euros and British Pounds.
- (6) At December 31, 2008 and 2009, 100% and 89%, respectively, was included in other long-term liabilities and the remainder is included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.
- (7) These amounts are included in accounts payable and accrued liabilities on the Company's consolidated balance sheet.
- (8) At December 31, 2008 and 2009 100% and 95%, respectively of this balance is included in other assets and the 5% of the December 31, 2009 balance is included in other current assets on the Company's consolidated balance sheet.
- (9) At December 31, 2009, 62% and 38% of these amounts are included in other long-term liabilities and accrued expenses, respectively. See Note 5 for additional discussion.



**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(14) INCOME TAXES**

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

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

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2009</u>
<b>Net deferred tax assets:</b>		
Net operating loss carryforwards . . . . .	\$ 114,536	\$ 117,544
Credit and contribution carryforwards . . . . .	117,254	119,207
Capitalized research expenses . . . . .	3,664	2,480
Property, plant and equipment . . . . .	8,041	9,278
Accrued expenses, reserves, and prepaids . . . . .	7,111	7,305
Intangible assets . . . . .	33,356	5,220
Deferred revenue . . . . .	425	33
Stock-based compensation . . . . .	6,275	12,623
Impairment on investment . . . . .	1,882	2,676
Inventory . . . . .	4,019	4,376
Capital loss carryforwards . . . . .	—	1,624
Gross deferred tax assets . . . . .	<u>\$ 296,563</u>	<u>\$ 282,366</u>
Deferred tax liability related to joint venture basis difference . . . . .	(1,601)	(1,991)
Deferred tax liability related to acquisition of Huxley Pharmaceuticals, Inc. . . . .	—	(14,291)
Other . . . . .	(222)	(464)
Valuation allowance . . . . .	<u>(294,740)</u>	<u>(268,080)</u>
Net deferred tax assets (liabilities) . . . . .	<u>\$ —</u>	<u>\$ (2,460)</u>

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

	<u>December 31,</u>		
	<u>2007</u>	<u>2008</u>	<u>2009</u>
Federal income tax expense .....	\$ —	\$ 716	\$ (362)
State income tax expense .....	—	1,055	(17)
Foreign income tax expense .....	729	822	1,433
Total income tax expense .....	<u>\$ 729</u>	<u>\$2,593</u>	<u>\$1,054</u>

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

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

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

**(15) REVENUE AND CREDIT CONCENTRATIONS**

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

**(16) COLLABORATIVE AGREEMENTS**

*(a) Merck Serono*

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

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

*(b) Other Agreements*

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(17) COMMITMENTS AND CONTINGENCIES**

*(a) Lease Commitments*

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

2010 .....	\$ 4,283
2011 .....	4,037
2012 .....	3,408
2013 .....	3,087
2014 .....	1,356
Thereafter .....	<u>3,260</u>
Total .....	<u>\$19,431</u>

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

*(b) Research and Development Funding and Technology Licenses*

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

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

*(c) Contingencies*

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

**(18) RELATED-PARTY TRANSACTIONS**

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

**(19) COMPENSATION AGREEMENTS AND PLANS**

*(a) Employment Agreements*

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

*(b) 401(k) Plan*

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

*(c) Deferred Compensation Plan*

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

**(20) JOINT VENTURE**

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

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

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

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

**BIOMARIN PHARMACEUTICAL INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**  
**December 31, 2008 and 2009**

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

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

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

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

**(21) SUBSEQUENT EVENT**

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



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-K/A  
(Amendment No. 1)**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009

Or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

For the transition period from

to

Commission file number: 000-26727

**BioMarin Pharmaceutical Inc.**

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

Delaware

(State of other jurisdiction of incorporation or organization)

68-0397820

(I.R.S. Employer Identification No.)

105 Digital Drive,  
Novato, California

(Address of principal executive offices)

94949

(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  
Common Stock, \$.001 par value  
Preferred Share Purchase Rights

Name of Each Exchange on Which Registered  
The NASDAQ Global Select Market

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  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

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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer" "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 101,131,358 shares common stock, par value \$0.001, outstanding as of February 17, 2010. The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2009 was \$758.5 million.

The documents incorporated by reference are as follows:

Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held May 12, 2010, are incorporated by reference into Part III.

## Explanatory Notes

In accordance with Rule 3-09 of Regulation S-X, BioMarin Pharmaceutical Inc. (“BioMarin” or the “Company”) is required to include in its Annual Report on Form 10-K for the year ended December 31, 2009, audited financial statements of BioMarin/Genzyme LLC, an equity investment in which BioMarin owns 50% of the common equity as of December 31, 2009. BioMarin is filing this Amendment No. 1 (this “Amendment”) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2009 as filed with the Securities and Exchange Commission on February 25, 2010 (the “Annual Report”), solely for the purpose of including the financial statements of BioMarin/Genzyme LLC, which are filed herewith as Exhibit 99.1. In addition, we are including as exhibits to this Amendment the certifications required under Sections 302 and 906 of the Sarbanes-Oxley Act of 2002.

No other amendments are being made to the Annual Report. Except as otherwise expressly stated below, this Amendment does not reflect events occurring after the date of the Annual Report nor does it modify or update the disclosure contained in the Annual Report in any way other than as required to reflect the amendment discussed above and reflected below.

### Item 15. Exhibits, Financial Statement Schedules

#### Exhibit Index

- 2.1 Asset Purchase Agreement dated as of April 20, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.1 to the Company’s Current Report on Form 8-K, which is incorporated herein by reference.
- 2.2 Securities Purchase Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.2 to the Company’s Current Report on Form 8-K, which is incorporated herein by reference.
- 2.3 License Agreement dated as of May 18, 2004, by and among BioMarin Pharmaceutical Inc., Medicis Pharmaceutical Corporation, Ascent Pediatrics, Inc. and BioMarin Pediatrics Inc., previously filed with the Commission on June 2, 2004 as Exhibit 2.3 to the Company’s Current Report on Form 8-K, which is incorporated herein by reference.
- 2.4 Settlement Agreement and Mutual Release dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.4 to the Company’s Annual Report on Form 10-K, which is incorporated herein by reference.
- 2.5 Amendment to Securities Purchase Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.5 to the Company’s Annual Report on Form 10-K, which is incorporated herein by reference.
- 2.6 Amendment to License Agreement dated January 12, 2005, by and among BioMarin Pharmaceutical Inc., BioMarin Pediatrics Inc., Medicis Pharmaceutical Corporation and Medicis Pediatrics, Inc. (f/k/a Ascent Pediatrics, Inc.), previously filed with the Commission on March 16, 2005 as Exhibit 2.6 to the Company’s Annual Report on Form 10-K, which is incorporated herein by reference.
- 3.1 Amended and Restated Certificate of Incorporation, as amended June 12, 2003, previously filed with the Commission on June 23, 2003 as Exhibit 3.1 to the Company’s Current Report on Form 8-K, which is incorporated herein by reference.

- 3.2 Certificate of Correction to Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioMarin Pharmaceutical Inc., previously filed with the Commission on April 4, 2005 as Exhibit 3.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 3.3 Amended and Restated By-Laws of BioMarin Pharmaceutical Inc., previously filed with the Commission on February 27, 2009 as Exhibit 3.3 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 4.1 Amended and Restated Rights Agreement, dated as of February 27, 2009, between BioMarin Pharmaceutical Inc. and Mellon Investor Services LLC, as Rights Agent, previously filed with the Commission on February 27, 2009 as Exhibit 4.1 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 4.2 Indenture dated June 23, 2003, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on August 12, 2003 as Exhibit 4.1 to the Company's Quarterly report on Form 10-Q, which is incorporated herein by reference.
- 4.3 Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 4.4 First Supplemental Indenture dated March 29, 2006, by and between BioMarin Pharmaceutical Inc. and Wilmington Trust Company, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 4.5 Form of 2.5% Senior Subordinated Convertible Notes due 2013, previously filed with the Commission on March 29, 2006 as Exhibit 4.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.1† Form of Indemnification Agreement for Directors and Officers, previously filed with the Commission on May 4, 1999 as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.2† Amended and Restated Severance Plan and Summary Plan Description as originally adopted on January 27, 2004 and amended and restated on May 12, 2009, previously filed with the Commission on July 31, 2009 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated by reference herein.
- 10.3† Amendment to 1997 Stock Plan, as amended, as adopted March 20, 2002, previously filed with the Commission on March 21, 2002 as Exhibit 99.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.4† Amendment No. 2 to 1997 Stock Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.5† Amended and Restated BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, as adopted on June 21, 2006, previously filed with the Commission on June 16, 2006 as Exhibit 99.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.6† 1998 Director Option Plan and forms of agreements thereunder, previously filed with the Commission on May 4, 1999 as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.7† Amendment to 1998 Director Plan as adopted March 26, 2003 previously filed with the Commission on May 15, 2003 as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.

- 10.8† Amendment No. 2 to 1998 Director Option Plan, as adopted June 12, 2003 and July 21, 2003, previously filed with the Commission on August 12, 2003 as Exhibit 10.1 to the Company's Quarterly report on Form 10-Q, which is incorporated herein by reference.
- 10.9† Amendment No. 3 to 1998 Director Option Plan, as adopted May 5, 2004, previously filed with the Commission on August 9, 2004 as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.10† Amended and Restated 2006 Employee Stock Purchase Plan, as adopted on June 21, 2006, previously filed with the Commission on August 3, 2006 as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.11† Amended and Restated BioMarin Pharmaceutical Inc. Nonqualified Deferred Compensation Plan, as adopted on December 1, 2005 and as amended and restated on January 1, 2009, previously filed with the Commission on December 23, 2008 as Exhibit 10.8 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.12† Amended and Restated Employment Agreement with Jean-Jacques Bienaimé dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.13† Amended and Restated Employment Agreement with Stephen Aselage dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.14† Amended and Restated Employment Agreement with Robert A. Baffi dated January 1, 2009 previously filed with the Commission on December 23, 2008, as Exhibit 10.3 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.15† Amended and Restated Employment Agreement with Emil D. Kakkis, M.D., Ph.D. dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.4 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.16† Severance Agreement with Dr. Emil D. Kakkis, dated May 28, 2009, previously filed with the SEC on June 3, 2009 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.17† Consulting Agreement between the Company and Dr. Emil D. Kakkis, dated July 1, 2009 previously filed with the SEC on June 3, 2009 as Exhibit 10.2 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.18† Amended and Restated Employment Agreement with Jeffrey H. Cooper dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.5 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.19† Amended and Restated Employment Agreement with G. Eric Davis dated January 1, 2009, previously filed with the Commission on December 23, 2005 as Exhibit 10.6 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.20† Amended and Restated Employment Agreement with Mark Wood dated January 1, 2009 previously filed with the Commission on December 23, 2008 as Exhibit 10.7 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.21† Employment Agreement with Stuart J. Swiedler, M.D., Ph.D., dated April 9, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
- 10.22† Employment Agreement with Henry Fuchs, dated March 18, 2009, previously filed with the Commission on March 23, 2009 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.

- 10.23 Grant Terms and Conditions Agreement between BioMarin Pharmaceutical Inc. and Harbor-UCLA Research and Education Institute dated April 1, 1997, as amended, previously filed with the Commission on July 21, 1999 as Exhibit 10.17 to the Company's Amendment No. 3 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.24 License Agreement dated July 30, 2004, between BioMarin Pharmaceutical Inc. and Daiichi Suntory Pharma Co., Ltd., as amended by Amendment No. 1 to License Agreement dated November 19, 2004, previously filed with the Commission on March 16, 2005 as Exhibit 10.25 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.25 Development, License and Commercialization Agreement dated May 13, 2005, between BioMarin Pharmaceutical Inc. and Ares Trading S.A., previously filed with the Commission on July 6, 2005 as Exhibit 10.1 to the Company's Current Report on Form 8-K/A, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.26 Operating Agreement with Genzyme Corporation, previously filed with the Commission on July 21, 1999 as Exhibit 10.30 to the Company's Amendment No. 2 to Registration Statement on Form S-1 (Registration No. 333-77701), which is incorporated herein by reference.
- 10.27<sup>†</sup> 2009 Technical Amendments to BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan, effective January 1, 2009, previously filed with the Commission on December 23, 2008, as Exhibit 10.9 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.
- 10.28 Amended and Restated License Agreement between BioMarin Pharmaceutical Inc. and Women's and Children's Hospital dated February 7, 2007, previously filed with the Commission on May 3, 2007 as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.29 Manufacturing, Marketing and Sales Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2008 as Exhibit 10.30 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.30 Amended and Restated Collaboration Agreement dated as of January 1, 2008, by and among BioMarin Pharmaceutical Inc., Genzyme Corporation and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.31 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a Request for Confidential Treatment filed pursuant to the Freedom of Information Act.
- 10.31 Members Agreement dated as of January 1, 2008 by and among BioMarin Pharmaceutical Inc., Genzyme Corporation, BioMarin Genetics Inc., and BioMarin/Genzyme LLC previously filed with the Commission on February 27, 2007 as Exhibit 10.32 to the Company's 2007 Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.32 Development and Commercialization Agreement dated as of January 4, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.29 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.

- 10.33 Securities Purchase Agreement dated as of January 4, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.30 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 10.34 Amendment No. 1 to the Development and Commercialization Agreement dated as of January 16, 2009 by and between BioMarin CF Limited and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.31 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 10.35 Amendment No. 1 to the Securities Purchase Agreement dated as of January 16, 2009 by and between BioMarin Pharmaceutical Inc. and La Jolla Pharmaceutical Company, previously filed with the Commission on February 27, 2009 as Exhibit 10.32 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 10.36† Summary of Bonus Plan, previously filed with the Commission on February 27, 2009 as Exhibit 10.33 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 10.37# Stock Purchase Agreement by and between BioMarin Pharmaceutical Inc., Huxley Pharmaceuticals, Inc., and the stockholders of Huxley Pharmaceuticals, Inc., dated October 20, 2009, previously filed with the Commission on February 26, 2010 as Exhibit 10.36 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference. Portions of this document have been redacted pursuant to a request for confidential treatment filed pursuant to the Freedom of Information Act.
- 21.1 Subsidiaries of BioMarin Pharmaceutical Inc., previously filed with the Commission on February 26, 2010 as Exhibit 21.1 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 23.1 Consent of KPMG LLP, Independent Registered Public Accounting Firm for BioMarin Pharmaceutical Inc., previously filed with the Commission on February 26, 2010 as Exhibit 23.1 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 23.2\* Consent of PricewaterhouseCoopers, LLP, Independent Registered Public Accounting Firm for BioMarin/Genzyme LLC.
- 24.1 Power of Attorney (Included in Signature Page), previously filed with the Commission on February 26, 2010 as Exhibit 24.1 to the Company's Annual Report on Form 10-K, which is incorporated herein by reference.
- 31.1\* Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2\* Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1\* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.
- 99.1\* BioMarin/Genzyme LLC Consolidated Financial Statements as of December 31, 2008 and 2009 and for the years ended December 31, 2009, 2008 and 2007.

\* Filed herewith

† Management contract or compensatory plan or arrangement

# Confidential treatment requested for a portion of this agreement

## SIGNATURES

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

BIOMARIN PHARMACEUTICAL INC.

Dated: March 25, 2010

By:                   /s/ JEFFREY H. COOPER                    
**Jeffrey H. Cooper**  
**Senior Vice President, Chief Financial Officer**

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**BioMarin/Genzyme LLC**

**Index to Consolidated Financial Statements**

	<u>Page(s)</u>
Report of Independent Registered Public Accounting Firm .....	1
Consolidated Balance Sheets as of December 31, 2009 and 2008 (unaudited) .....	2
Consolidated Statements of Operations for the Years Ended December 31, 2009, 2008 (unaudited) and 2007 .....	3
Consolidated Statements of Cash Flows for the Years Ended December 31, 2009, 2008 (unaudited) and 2007 .....	4
Consolidated Statements of Changes in Venturers' Capital for each of the Years Ended December 31, 2007, 2008 (unaudited) and 2009 .....	5
Notes to Consolidated Financial Statements .....	6 -11

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## **Report of Independent Registered Public Accounting Firm**

To the Steering Committee of BioMarin/Genzyme LLC:

In our opinion, the accompanying consolidated balance sheet and the related consolidated statement of operations, of cash flows and of changes of venturers' capital present fairly, in all material respects, the financial position of BioMarin/Genzyme LLC and its subsidiaries (the "Joint Venture") at December 31, 2009 and the results of their operations and their cash flows for the years ended December 31, 2009 and December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Joint Venture's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 25, 2010

**BioMarin/Genzyme LLC**  
**Consolidated Balance Sheets**  
(Amounts in thousands)

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$2,088	\$2,991
Total assets .....	\$2,088	\$2,991
<b>LIABILITIES AND VENTURERS' CAPITAL</b>		
Current liabilities:		
Due to BioMarin Companies .....	\$ 123	\$ 257
Due to Genzyme Corporation .....	1,051	988
Total liabilities .....	1,174	1,245
Commitments and contingencies (Note F) .....	—	—
Venturers' capital:		
Venturers' capital—BioMarin Companies .....	457	873
Venturers' capital—Genzyme Corporation .....	457	873
Total Venturers' capital .....	914	1,746
Total liabilities and Venturers' capital .....	\$2,088	\$2,991

The accompanying notes are an integral part of these consolidated financial statements.

**BioMarin/Genzyme LLC**  
**Consolidated Statements of Operations**  
**(Amounts in thousands)**

	<u>For the Years Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
	(Unaudited)		
Revenues:			
Net product sales .....	\$ —	\$ —	\$123,671
Operating costs and expenses:			
Cost of products sold .....	—	—	27,110
Selling, general and administrative .....	—	180	24,682
Research and development .....	5,079	4,452	11,825
Total operating costs and expenses .....	<u>5,079</u>	<u>4,632</u>	<u>63,617</u>
Income (loss) from operations .....	(5,079)	(4,632)	60,054
Interest income .....	7	198	766
Net income (loss) .....	<u>\$(5,072)</u>	<u>\$(4,434)</u>	<u>\$ 60,820</u>
Net income (loss) attributable to each Venturer:			
BioMarin Companies .....	<u>\$(2,536)</u>	<u>\$(2,217)</u>	<u>\$ 30,410</u>
Genzyme Corporation .....	<u>\$(2,536)</u>	<u>\$(2,217)</u>	<u>\$ 30,410</u>

The accompanying notes are an integral part of these consolidated financial statements.

**BioMarin/Genzyme LLC**  
**Consolidated Statements of Cash Flows**  
(Amounts in thousands)

	For the Years Ended December 31,		
	2009	2008	2007
	(Unaudited)		
<b>Cash Flows from Operating Activities:</b>			
Net income (loss) .....	\$(5,072)	\$ (4,434)	\$ 60,820
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:			
Amortization expense .....	—	—	73
Charge for impaired assets .....	—	138	—
Increase (decrease) in cash from working capital changes:			
Accounts receivable .....	—	—	(7,147)
Inventories .....	—	—	(1,417)
Prepaid expenses and other current assets .....	—	42	(602)
Due from (to) BioMarin Companies .....	(134)	257	491
Due from (to) Genzyme Corporation .....	63	988	(3,079)
Accrued expenses .....	—	—	(200)
Deferred revenue .....	—	—	8
Cash flows from operating activities .....	(5,143)	(3,009)	48,947
<b>Cash Flows from Investing Activities:</b>			
Change in restricted cash .....	—	—	340
Cash flows from investing activities .....	—	—	340
<b>Cash Flows from Financing Activities:</b>			
Capital distribution to BioMarin Companies .....	—	(18,770)	(17,100)
Capital distribution to Genzyme Corporation .....	—	(6,595)	(17,100)
Capital contribution from BioMarin Companies .....	2,120	1,750	—
Capital contribution from Genzyme Corporation .....	2,120	1,750	—
Cash flows from financing activities .....	4,240	(21,865)	(34,200)
Increase (decrease) in cash and cash equivalents .....	(903)	(24,874)	15,087
Cash and cash equivalents at beginning of period .....	2,991	27,865	12,778
Cash and cash equivalents at end of period .....	\$ 2,088	\$ 2,991	\$ 27,865

The accompanying notes are an integral part of these consolidated financial statements.

**BioMarin/Genzyme LLC**  
**Consolidated Statements of Changes in Venturers' Capital**  
**(Amounts in thousands)**

	<u>Venturers' Capital</u>		<u>Total Venturers' Capital</u>
	<u>BioMarin Companies</u>	<u>Genzyme Corporation</u>	
Balance at December 31, 2006 .....	\$ 31,695	\$ 31,694	\$ 63,389
2007 capital distributions .....	(17,100)	(17,100)	(34,200)
2007 net income .....	30,410	30,410	60,820
Balance at December 31, 2007 .....	45,005	45,004	90,009
2008 capital distributions (unaudited) .....	(43,665)	(43,664)	(87,329)
2008 capital contributions (unaudited) .....	1,750	1,750	3,500
2008 net loss (unaudited) .....	(2,217)	(2,217)	(4,434)
Balance at December 31, 2008 (unaudited) .....	873	873	1,746
2009 capital contributions .....	2,120	2,120	4,240
2009 net loss .....	(2,536)	(2,536)	(5,072)
Balance at December 31, 2009 .....	<u>\$ 457</u>	<u>\$ 457</u>	<u>\$ 914</u>

The accompanying notes are an integral part of these consolidated financial statements.

## BioMarin/Genzyme LLC

### Notes to Consolidated Financial Statements

#### A. Nature of Business and Organization

BioMarin/Genzyme LLC, or the Joint Venture, is a limited liability company organized under the laws of the State of Delaware. The Joint Venture is owned:

- 50% by BioMarin Pharmaceutical Inc., which is referred to as BioMarin, and BioMarin Genetics, Inc., a wholly-owned subsidiary of BioMarin. BioMarin and its subsidiary are referred to as the BioMarin Companies; and
- 50% by Genzyme Corporation, which is referred to as Genzyme.

The BioMarin Companies and Genzyme are collectively referred to as the Venturers and individually as a Venturer. The Joint Venture was organized in September 1998 to develop and commercialize Aldurazyme®, a recombinant form of the human enzyme alpha-L-iduronidase, used to treat a lysosomal storage disorder known as mucopolysaccharidosis I, or MPS I. The Joint Venture commenced operations as of September 4, 1998.

The Joint Venture, BioMarin Companies and Genzyme entered into a Collaboration Agreement dated as of September 4, 1998. Under the terms of the Collaboration Agreement, Genzyme and the BioMarin Companies granted to the Joint Venture a world-wide, exclusive, irrevocable, royalty-free right and license or sublicense to develop, manufacture and market Aldurazyme for the treatment of MPS I and other alpha-L-iduronidase deficiencies. All program-related costs are equally funded by BioMarin, on behalf of the BioMarin Companies, and Genzyme. BioMarin and Genzyme are required to make monthly capital contributions to the Joint Venture to fund budgeted operating costs, as necessary. If either BioMarin or Genzyme fails to make two or more of the monthly capital contributions, and the other party does not exercise its right to terminate the Collaboration Agreement or compel performance of the funding obligation, the defaulting party's (or, in the case of default by BioMarin, the BioMarin Companies') percentage interest in the Joint Venture and future funding responsibility will be adjusted proportionately. In 2008, both Venturers contributed \$1.8 million and in 2009, both Venturers contributed \$2.1 million to the Joint Venture. No contributions were made in 2007 because the Joint Venture was profitable.

The Steering Committee of the Joint Venture serves as the governing body of the Joint Venture and is responsible for determining the overall strategy for the program, coordinating activities of the Venturers as well as performing other such functions as appropriate. The Steering Committee is comprised of an equal number of representatives of each Venturer.

On April 30, 2003, the United States Food and Drug Administration, commonly referred to as the FDA, granted marketing approval for Aldurazyme as an enzyme replacement therapy for patients with the Hurler and Hurler-Scheie forms of MPS I, and Scheie patients with moderate to severe symptoms. Aldurazyme has been granted orphan drug status in the United States, which generally provides seven years of market exclusivity. On June 11, 2003, the European Commission granted marketing approval for Aldurazyme to treat the non-neurological manifestations of MPS I in patients with a confirmed diagnosis of the disease. Aldurazyme has been granted orphan drug status in the European Union, which generally provides ten years of market exclusivity. In October 2006, Japan's Health, Labor and Welfare Ministry granted marketing approval for Aldurazyme, the first specific treatment approved in Japan for patients with MPS I. Aldurazyme has been granted orphan drug status in Japan, which generally provides ten years of market exclusivity. To date, Aldurazyme has received marketing approval in over fifty countries. Aldurazyme is sold directly to physicians, hospitals, treatment centers, pharmacies and government agencies through a specialized sales force, as well as through distributors or wholesalers.



## BioMarin/Genzyme LLC

### Notes to Consolidated Financial Statements—(Continued)

#### A. Nature of Business and Organization (Continued)

On January 1, 2008, the BioMarin Companies and Genzyme restructured the Joint Venture. Instead of sharing all costs and profits equally, Genzyme will record sales of Aldurazyme and will pay BioMarin a tiered payment ranging from approximately 39.5% to 50% of worldwide net product sales, which will also be recorded by BioMarin as product revenue. Certain research and development activities related to Aldurazyme and intellectual property will continue to be managed by the Joint Venture on an equal basis.

#### B. Summary of Significant Accounting Policies

##### Basis of Presentation

The Joint Venture is considered a partnership for federal and state income tax purposes. As such, items of income, loss, deductions and credits flow through to the Venturers. The Venturers have responsibility for the payment of any income taxes on their proportionate share of the taxable income of the Joint Venture.

The consolidated financial statements for the years ended December 31, 2007 and December 31, 2009 have been audited.

##### Accounting Method

The consolidated financial statements have been prepared under the accrual method of accounting in conformity with accounting principles generally accepted in the United States of America.

##### Fiscal Year End

The Venturers have determined that the fiscal year end of the Joint Venture is December 31.

##### Use of Estimates

Under accounting principles generally accepted in the United States of America, the Joint Venture is required to make certain estimates and assumptions that affect reported amounts of assets, liabilities, revenues, expenses, and disclosure of contingent assets and liabilities in its consolidated financial statements. The Joint Venture's actual results could differ from these estimates.

##### Cash and Cash Equivalents

Cash and cash equivalents, consisting principally of money market funds with initial maturities of three months or less, are valued at cost plus accrued interest, which the Joint Venture believes approximates their fair market value. Money market funds are typically classified as Level 1 investments as these products do not require a significant degree of judgment. All of the Joint Venture's cash is held on deposit at one financial institution.

##### Inventories

Prior to January 1, 2008, inventories were valued at cost or, if lower, fair value. The Venturers determined the cost of raw materials using the average cost method and the cost of work in process and finished goods using the specific identification method. The Venturers analyzed the Joint Venture's inventory levels quarterly and wrote down to its net realizable value:

- inventory that had become obsolete;

## BioMarin/Genzyme LLC

### Notes to Consolidated Financial Statements—(Continued)

#### B. Summary of Significant Accounting Policies (Continued)

- inventory that had a cost basis in excess of its expected net realizable value;
- inventory in excess of expected requirements; and
- expired inventory.

In January 2008, all inventory was distributed to the BioMarin Companies and is described in Note E., “Venturers’ Capital”.

#### Comprehensive Income

The Joint Venture reports comprehensive income in accordance with Financial Accounting Standards Board Accounting Standards Codification, or ASC, 220, “Comprehensive Income.” Comprehensive income for the years ended December 31, 2009, 2008 and 2007 does not differ from the reported net income.

#### Transactions with Affiliates

Prior to January 1, 2008, Genzyme commercialized Aldurazyme in the United States, Canada, the European Union, Latin America and the Asia Pacific regions and, as a result, conducted sales and collected cash from product sales in those territories on behalf of the Joint Venture. The majority of the Joint Venture’s operating expenses consist of project expenses incurred by the Venturers, either for internal operating costs or for third-party obligations incurred by the Venturers on behalf of the Joint Venture which are then charged to the Joint Venture. All charges to the Joint Venture are subject to approval by the Steering Committee. The determination of the amount of internal operating costs incurred by each Venturer on behalf of the Joint Venture requires significant judgment by each Venturer. As a result, the consolidated financial statements for the Joint Venture may not be indicative of the results that would have occurred had the Joint Venture obtained all of its manufacturing, commercialization and research and development services from third-party entities. The Joint Venture owed Genzyme Corporation \$1.1 million at December 31, 2009 and \$1.0 million at December 31, 2008 for project expenses incurred on behalf of the Joint Venture. The Joint Venture owed BioMarin Companies \$0.1 million at December 31, 2009 and \$0.3 million at December 31, 2008 for project expenses incurred on behalf of the Joint Venture.

#### Translation of Foreign Currencies

Prior to January 1, 2008, the Joint Venture translated the financial transactions performed by Genzyme’s foreign subsidiaries on behalf of the Joint Venture from local currency into U.S. dollars using the average exchange rate prevailing during each period. The Joint Venture included any gains and losses on these transactions in selling, general and administrative expenses in its results of operations. Under the updated agreement only project expenses incurred by the Venturers are charged to the Joint Venture. In 2008 and 2009 all expenses incurred on behalf of the Joint Venture were in U.S. dollars and no foreign currency transaction gains or losses were incurred. Selling, general and administrative expenses include foreign currency transaction net gains of \$2.0 million in 2007.

#### Derivative Instruments

Prior to January 1, 2008, in accordance with ASC 815, “Derivatives and Hedging,” the Joint Venture recognized all derivative instruments as either assets or liabilities in its balance sheet and measured those instruments at fair value. Subsequent changes in fair value were reflected in current earnings or other

## BioMarin/Genzyme LLC

### Notes to Consolidated Financial Statements—(Continued)

#### B. Summary of Significant Accounting Policies (Continued)

comprehensive income, depending on whether the derivative instrument was designated as part of a hedge relationship and, if it was, the type of hedge relationship.

#### Revenue Recognition

Prior to January 1, 2008, the Joint Venture recognized revenue from product sales when persuasive evidence of an arrangement existed, the product had been delivered to the customer, title and risk of loss had passed to the customer, the price to the buyer was fixed or determinable and collection from the customer was reasonably assured. Revenue transactions were evidenced by customer purchase orders, customer contracts in certain instances, invoices and related shipping documents.

ASC 605, "Revenue Recognition," specifies that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue. That presumption is overcome and the consideration should be characterized as a cost incurred if, and to the extent that, both of the following conditions are met:

- the vendor receives, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and
- the vendor can reasonably estimate the fair value of the benefit received.

Prior to January 1, 2008, the Joint Venture recorded certain fees paid to its distributors for services as operating expenses where the criteria set forth above were met. In 2009 and 2008, no fees were incurred. In 2007 fees incurred for these services were \$0.7 million.

#### Research and Development

Research and development costs are expensed in the period incurred. These costs are primarily comprised of development efforts performed by the Venturers or payments to third parties made by the Venturers, both on behalf of the Joint Venture, during the respective periods.

#### Income Taxes

The Joint Venture is organized as a pass-through entity and accordingly, the consolidated financial statements do not include a provision for income taxes. Taxes, if any, are the liability of the BioMarin Companies and Genzyme, as Venturers.

#### C. Accounts Receivable

Prior to January 1, 2008, the Joint Venture's trade receivables primarily represented amounts due from distributors and healthcare service providers. The Joint Venture stated accounts receivable at fair value, after reflecting an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make payments. The Joint Venture believed that its credit risk associated with trade receivables was mitigated by the following factors:

- the product was sold to a number of customers over a broad geographic range;
- the Joint Venture performed credit evaluations of its customers on an ongoing basis; and
- the Joint Venture performed a detailed, monthly review of the receivable aging and specific customer balances.

## BioMarin/Genzyme LLC

### Notes to Consolidated Financial Statements—(Continued)

#### C. Accounts Receivable (Continued)

The Joint Venture has not written off any accounts receivables nor found it necessary to record an allowance for doubtful accounts. In January 2008, all accounts receivable was distributed to Genzyme and is described in Note E., "Venturers' Capital".

#### D. Technology License Fees

In 2005, the Joint Venture paid \$0.4 million for technology license fees. In 2008, as a result of the restructuring, the license fees which had a book value of \$138,000 were written off. Total amortization expense for the Joint Venture's technology license fees was approximately \$73,000 for the year ended December 31, 2007.

#### E. Venturers' Capital

Venturers' capital is comprised of capital contributions made by the Venturers to fund expenses of the Joint Venture in accordance with the Collaboration Agreement, and income (losses) allocated to the Venturers, net of cash distributions to the Venturers. All funding is shared equally by the two Venturers. As of December 31, 2009, the BioMarin Companies and Genzyme have each provided a total of \$71.2 million of funding to the Joint Venture, net of \$39.9 million of cash distributed by the Joint Venture to each Venturer.

On January 1, 2008 as part of the restructuring, the Joint Venture distributed the majority of its net assets to the Venturers. The BioMarin Companies received \$24.9 million in net assets and \$18.8 million in cash. Genzyme received \$37.1 million in net assets and \$6.6 million in cash. During 2007, the Joint Venture distributed \$17.1 million of cash to each Venturer in accordance with the terms of the Collaboration Agreement. The Venturers did not make any capital contributions to the Joint Venture in 2007 because the Joint Venture had sufficient cash to meet its financial obligations. In 2008 and 2009, each Venturer contributed \$1.8 million and \$2.1 million respectively, to cover the operating expenses.

#### F. Commitments and Contingencies

##### *Legal Proceedings*

Under the Joint Venture's operation agreement, the Joint Venture indemnifies its affiliates for acts performed under the agreement on behalf of the Joint Venture, including amounts paid by affiliates in connection with legal proceedings related to the Joint Venture or its operations.

There have been several lawsuits filed in Brazil alleging that an affiliate of a member of the Joint Venture is contractually obligated to provide drugs at no cost to several patients. The affiliate is vigorously defending against these actions. Management of the Joint Venture is not able to predict the outcome of these cases or estimate with certainty the amount or range of any possible loss the Joint Venture might incur if the affiliate does not prevail in the final, non-appealable determination of any or all of these matters and the Joint Venture has to indemnify the affiliate for amounts paid related to settlement of any of these lawsuits.

The Joint Venture periodically becomes subject to legal proceedings and claims arising in connection with its business. The Joint Venture is not able to predict the outcome of any legal proceedings, to which it may become subject in the normal course of business, or estimate the amount or range of any reasonably possible loss the Joint Venture might incur if it does not prevail in the final, non-appealable determinations of such matters. Therefore, the Joint Venture has no current accruals for these potential contingencies. The Joint Venture cannot provide you with assurance that legal proceedings will not have a material adverse impact on its financial condition or results of operations.

**BioMarin/Genzyme LLC**

**Notes to Consolidated Financial Statements—(Continued)**

**G. Segment Information**

The Joint Venture operates in one business segment—human therapeutics. Disclosures about revenues by geographic area and revenues from major customers are presented below.

The following table contains revenue information by geographic area (amounts in thousands):

	<u>For the Years Ended December 31,</u> <u>2007</u>
Revenues:	
U.S. ....	\$ 28,994
Europe .....	69,335
Other .....	<u>25,342</u>
Total .....	<u>\$123,671</u>

Prior to January 1, 2008, the Joint Venture's results of operations were solely dependent on sales of Aldurazyme. BioMarin manufactures Aldurazyme at a single manufacturing facility in Novato, California and outsources the fill-finish process. The percentage of sales of Aldurazyme to distributors, as compared to total revenues in 2007 were as follows:

	<u>% of Total Revenues</u> <u>2007</u>
Sales to Distributors:	
U.S. distributors .....	9%
European distributors .....	7%
Other distributors .....	<u>3%</u>
Total sales to distributors .....	<u>19%</u>

The percentage of sales of Aldurazyme to two U.S. distributors, as compared to total revenues in 2007 were as follows:

	<u>% of Total Revenues</u> <u>2007</u>
Sales to U.S. Distributors:	
Distributor A .....	3%
Distributor B .....	<u>6%</u>
Total sales to U.S. distributors .....	<u>9%</u>

**BIOMARIN PHARMACEUTICAL INC.**

**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS  
TO BE HELD ON MAY 12, 2010**

Dear Stockholder:

You are cordially invited to attend the Annual Meeting of the Stockholders of BioMarin Pharmaceutical Inc., a Delaware corporation ("BioMarin" or "the Company"). The Annual Meeting will be held on Wednesday, May 12, 2010 at 9:00 a.m. (Pacific Daylight Time), at the Inn Marin hotel, 250 Entrada Drive, Novato, California 94949 for the following purposes:

1. To elect the Board's seven nominees for director to the Board of Directors to serve until the next annual meeting and their successors are duly elected and qualified;
2. To approve an amendment and restatement of the Company's 2006 Share Incentive Plan, as amended, to increase the aggregate number of shares of common stock authorized for issuance under the plan by 8,000,000 shares and make certain other modifications;
3. To ratify the selection of KPMG LLP as the independent registered public accounting firm for BioMarin for the year ending December 31, 2010; and
4. To transact such other business as properly may be brought before the Annual Meeting or any adjournment thereof.

These items of business are more fully described in the Proxy Statement accompanying this Notice.

The Board of Directors has fixed the close of business on March 19, 2010 as the record date (the "Record Date") for determining the stockholders entitled to receive notice of, and to vote at, the Annual Meeting or any adjournment thereof. A complete list of such stockholders will be available for examination by any stockholder for any purpose germane to the Annual Meeting during ordinary business hours at the Company's executive offices at 105 Digital Drive, Novato, California 94949 for a period of 10 days before the Annual Meeting.

All stockholders are cordially invited to attend the Annual Meeting in person. To ensure your representation at the Annual Meeting, you are urged to sign and date the attached Proxy Card and return it today in the enclosed pre-addressed postage-paid envelope. You may also vote by Internet voting or by telephone. Any stockholder attending the Annual Meeting may vote in person even if that stockholder has returned a proxy.

**Important Notice Regarding the Availability of Proxy Materials for the Stockholder Meeting to be held on May 12, 2010.**

**The proxy statement and annual report to stockholders are available at: [www.proxyvote.com](http://www.proxyvote.com).**

If you have any questions or need assistance in voting your shares, please call the firm assisting the Company in the solicitation of proxies:

Morrow & Co., LLC  
470 West Avenue  
Stamford, CT 06902  
1-800-607-0088

By Order of the Board of Directors



G. Eric Davis  
Senior Vice President, General Counsel and Secretary  
Novato, California

April 1, 2010

**YOUR VOTE IS IMPORTANT. IN ORDER TO ENSURE YOUR REPRESENTATION AT THE ANNUAL MEETING, YOU ARE REQUESTED TO SIGN AND DATE THE ATTACHED PROXY CARD AND RETURN IT IN THE ENCLOSED PRE-ADDRESSED POSTAGE-PAID ENVELOPE, OR VOTE BY INTERNET OR TELEPHONE AS SOON AS POSSIBLE.**

**BioMarin Pharmaceutical Inc.**  
**105 Digital Drive**  
**Novato, California 94949**

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**Proxy Statement for 2010 Annual Meeting of Stockholders**

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**INFORMATION CONCERNING SOLICITATION OF PROXIES AND VOTING**

**General**

The enclosed proxy is solicited on behalf of the Board of Directors (the "Board") of BioMarin Pharmaceutical Inc., a Delaware corporation (the "Company," "we," "us" or "our"), for use at our 2010 Annual Meeting of Stockholders (the "Annual Meeting") to be held on Wednesday, May 12, 2010 at 9:00 a.m. (Pacific Daylight Time), or at any continuation, adjournment or postponement of the Annual Meeting, for the purposes stated in this proxy statement and in the Notice of the Annual Meeting. The Annual Meeting will be held at the Inn Marin hotel, 250 Entrada Drive, Novato, California 94949. The Notice of the Annual Meeting and information about how to access copies of this solicitation material and our Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission ("SEC") ("2009 Annual Report") is available on the Internet. These materials will be made available to our stockholders on or about April 1, 2010. Stockholders may request that copies of the solicitation material and 2009 Annual Report be sent to them by mail. Instructions on how to receive such copies is provided in the notice. Notice is also being furnished to brokerage houses, fiduciaries, and custodians to forward to beneficial owners of our common stock held in their names on or about April 1, 2010. Our 2009 Annual Report is provided with this proxy statement.

**Record Date; Outstanding Shares**

The voting securities entitled to vote at the Annual Meeting consist of only shares of common stock. Only stockholders of record at the close of business on March 19, 2010 (the "Record Date") are entitled to notice of and to vote at the Annual Meeting. At the close of business on the Record Date, there were 101,533,115 shares of BioMarin common stock, par value \$0.001 per share, issued and outstanding and entitled to vote. Each share of common stock is entitled to one vote.

**Revocability of Proxies**

A stockholder who signs and returns a Proxy Card, or who votes by Internet or telephone will have the power to revoke it at any time before it is voted. A proxy represented by a Proxy Card may be revoked by: (i) delivering to us at our mailing address appearing above (Attention: G. Eric Davis, Senior Vice President, General Counsel and Secretary) a written notice of revocation; or (ii) submitting a duly executed Proxy Card bearing a later date; (iii) re-voting through the Internet or by telephone (your latest Internet or telephone instructions submitted prior to the time the proxy is voted will be followed); or (iv) appearing at the Annual Meeting and voting in person. Attendance at the Annual Meeting in and of itself, without voting in person at the Annual Meeting, will not cause your previously granted proxy to be revoked. For shares you hold in street name, you may change your vote by submitting new voting instructions to your broker, bank, or other nominee or, if you have obtained a legal proxy from your broker, bank, or other nominee giving you the right to vote your shares at the Annual Meeting, by attending the Annual Meeting and voting in person.

**Voting**

Each stockholder is entitled to one vote for each share of common stock held. This includes shares held directly by stockholders of record and shares held through a stockbroker, bank, or nominee.

## **Solicitation of Proxies**

This solicitation of proxies is made by us and all related costs, including expenses in connection with preparing and mailing this proxy statement, will be borne by us. Copies of solicitation material will be available on the Internet, and for those who requested solicitation material by mail, will be mailed directly to such stockholders, or as appropriate will be furnished to brokerage firms and other persons representing beneficial owners of shares. In addition, if asked, we will reimburse brokerage firms and other persons representing beneficial owners of shares for their expenses incurred by them in forwarding solicitation material to such beneficial owners. We have requested brokerage firms and other persons representing beneficial owners of shares to forward all solicitation materials to the beneficial owners of the shares they hold of record who requested copies by mail of such solicitation materials. Proxies may also be solicited by some of our directors, officers, and regular employees, without additional compensation. The original solicitation by Internet and mail may also be supplemented by telephone, facsimile, e-mail, and personal solicitation by these directors, officers, and employees.

We have retained Morrow & Co., LLC to assist us in the solicitation of proxies. We have agreed to pay customary fees to Morrow & Co. for its services in soliciting proxies, which we estimate will be \$6,000, and have agreed to reimburse Morrow & Co. for reasonable out-of-pocket expenses for these services.

## **Quorum; Abstentions; Broker Non-Votes**

Our Bylaws provide that a majority of all the shares of the common stock entitled to vote, whether present in person or by proxy, shall constitute a quorum for the transaction of business at the Annual Meeting. Broker non-votes are shares held in street name for which the broker has not received instructions from the beneficial owners or other persons entitled to vote and the broker does not have discretionary voting authority. Abstentions and broker non-votes will be counted as shares present for purposes of determining whether a quorum is present. If a quorum is not present or represented, then either the chairman of the Annual Meeting or the stockholders entitled to vote at the Annual Meeting, present in person or represented by proxy, will have the power to adjourn the Annual Meeting from time to time, without notice other than an announcement at the Annual Meeting, until a quorum is present. At any adjourned Annual Meeting at which a quorum is present, any business may be transacted that might have been transacted at the Annual Meeting as originally notified. If the adjournment is for more than 30 days, or if after that adjournment a new record date is fixed for the adjourned Annual Meeting, a notice of the adjourned Annual Meeting shall be given to each stockholder of record entitled to vote at the adjourned Annual Meeting.

When proxies are properly executed and returned, the shares represented by such proxies will be voted at the Annual Meeting in accordance with the instructions of the stockholder. If no specific instructions are given, the shares represented by a valid proxy in response to this solicitation will be voted: (i) FOR the election of the seven nominees for director set forth herein; (ii) FOR approval of the proposed amendment and restatement of the Company's 2006 Share Incentive Plan; and (iii) FOR ratification of the selection of KPMG LLP as our independent registered public accounting firm for the year ending December 31, 2010. The Board knows of no other business that will be presented at the Annual Meeting. If, however, other matters are properly presented, the persons named in the enclosed Proxy Card will vote the shares represented thereby in accordance with their best judgment pursuant to the discretionary authority granted in the proxy.

If your shares are held in street name, your broker, bank, or nominee will include a voting instruction card with this proxy statement. You should vote your shares by following the instructions provided on the voting instruction card. Because of a change in New York Stock Exchange rules, we note that, unlike previous annual meetings, your broker will NOT be able to vote your shares with respect to the election of directors if you have not provided directions to your broker. We strongly encourage you to submit your Proxy Card and exercise your right to vote as a stockholder.



### **Attendance at Meeting**

If you plan to attend the Annual Meeting, please note that attendance will be limited to stockholders as of the Record Date. Admission will be on a first-come, first-served basis. Each stockholder may be asked to present valid picture identification, such as a driver's license or passport. Stockholders holding stock in brokerage accounts or by a bank or other nominee may be required to show a brokerage statement or account statement reflecting stock ownership as of the Record Date. Cameras, recording devices, and other electronic devices will not be permitted at the Annual Meeting.

### **Required Vote**

For the election of directors, the seven nominees receiving the most "For" votes from the holders of votes of shares present in person or represented by proxy at the Annual Meeting and entitled to vote on the election of directors will be elected. Shares represented by executed Proxy Cards will be voted, if authority to do so is not withheld, "FOR" the election of the director nominees named in Proposal No. 1. Votes may be cast in favor of, or withheld with respect to all of the director nominees, or any of them. Broker non-votes, if any, will not be counted as having been voted and will have no effect on the outcome of the vote on the election of directors. Stockholders may not cumulate votes in the election of directors.

To be approved, the proposed amendment and restatement of the Company's 2006 Share Incentive Plan, to increase the aggregate number of shares of common stock authorized for issuance under the plan by 8,000,000 shares and make certain other modifications, as specified in Proposal No. 2, must receive "For" votes from the holders of a majority of shares present in person or represented by proxy at the Annual Meeting and entitled to vote either in person or by proxy. If you "Abstain" from voting, it will have the same effect as an "Against" vote. Broker non-votes, if any, will have no effect on the vote for this proposal.

Ratification of the selection of KPMG LLP as the independent registered public accounting firm for the year ending December 31, 2010, as specified in Proposal No. 3, requires the affirmative vote of a majority of the shares of our common stock present or represented by proxy at the Annual Meeting and entitled to vote. Abstentions will be counted toward the tabulation of votes cast on these proposals and will have the same effect as votes against these proposals. Broker non-votes, if any, will have no effect on the vote for this proposal.

### **Submission of Stockholder Proposals for the 2011 Annual Meeting**

Our Bylaws provide a formal procedure for bringing business before an annual meeting of stockholders. Stockholders who intend to present a proposal at the 2011 Annual Meeting of Stockholders ("2011 Annual Meeting") must deliver or mail a notice to our Secretary, and the notice must be received at our executive offices at 105 Digital Drive, Novato, California 94949 no earlier than January 12, 2011 and no later than February 11, 2011. In the event that the 2011 Annual Meeting is called for a date that is not within 25 days before or 60 days after May 12, 2011, then the stockholder's notice must be received by the Secretary no later than the close of business on the 10th day following the day on which notice of the date of the 2010 Annual Meeting was mailed or we made a public announcement of such date, whichever first occurs.

The notice must contain a brief description of the business desired to be brought before the 2011 Annual Meeting, the reasons for conducting such business, the text of the proposal or business (including the text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend our Bylaws, the language of the proposed amendment), any material interest in the business of the stockholder and the beneficial owner, if any, on whose behalf the proposal is made, the name and address of the stockholder, the name and address of the beneficial owner, if any, on whose behalf the proposal is made, the class or series and number of shares of our capital stock which are owned beneficially or of record by the stockholder, a description of any agreement, arrangement or understanding with respect to the proposal between the stockholder and/or beneficial owner, any of their respective affiliates or associates, and others acting together, a description of any agreement, arrangement or understanding (including any derivative or short positions, profit interests, options,

warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder and such beneficial owners and whether the stockholder or any beneficial owner intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of at least the percentage of our outstanding capital stock required to approve or adopt the proposal and/or otherwise solicit proxies from stockholders in support of the proposal and a representation that the stockholder intends to appear in person or by proxy at the 2011 Annual Meeting to bring such business before the 2011 Annual Meeting. The notice requirement described above is deemed satisfied if the stockholder has notified us of his, her or its intent to present a proposal at an annual stockholder meeting in compliance with applicable rules and regulations promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and such proposal has been included in our proxy statement to solicit proxies for such annual meeting. In order for the proposed business to be transacted at the 2011 Annual Meeting, the stockholder (or the stockholder's representative) must attend and present the proposed business at the 2011 Annual Meeting.

**YOUR VOTE IS EXTREMELY IMPORTANT, NO MATTER HOW MANY OR HOW FEW SHARES YOU OWN. PLEASE SIGN AND DATE THE ENCLOSED PROXY CARD AND RETURN IT TODAY IN THE ENCLOSED PRE-ADDRESSED POSTAGE-PAID ENVELOPE OR VOTE BY INTERNET OR TELEPHONE.**

**IMPORTANT: If your shares are held in the name of a brokerage firm, bank, nominee, or other institution, only it can sign a Proxy Card with respect to your shares and only upon specific instructions from you. Please return the enclosed Proxy Card to your broker or bank and contact the person responsible for your account to ensure that a Proxy Card is voted on your behalf.**

**If you have any questions or need assistance in voting your shares, please call the firm assisting the Company in the solicitation of proxies:**

**Morrow & Co., LLC  
470 West Avenue  
Stamford, CT 06902  
1-800-607-0088**

## PROPOSAL ONE: ELECTION OF DIRECTORS

Pursuant to our Bylaws and a resolution of our Board effective on the date of the Annual Meeting our Board will consist of seven directors. At the Annual Meeting, stockholders will elect seven directors. All directors will serve until their successors are duly appointed at the next annual meeting, or until they resign or are otherwise removed. Unless otherwise instructed by you, the persons named in the enclosed Proxy Card will vote your proxy "FOR" the seven nominees named below, all of whom are presently our directors. If any of the Board's nominees are unable or decline to serve as director, the proxies will be voted for any substitute nominee who shall be designated by the Board. It is not expected that any of the Board's nominees will be unable to or will decline to serve as director. If a quorum is present, the seven nominees receiving the highest number of affirmative votes of the votes cast shall be elected as directors.

### Nominees for Director

Set forth below are the nominees to the Board and certain information regarding each nominee as of March 25, 2010:

<u>Name</u>	<u>Age</u>	<u>Position with BioMarin</u>	<u>Director Since</u>
Jean-Jacques Bienaimé . . . . .	56	Director, Chief Executive Officer	May 2005
Michael Grey(1)(3) . . . . .	57	Director	December 2005
Elaine J. Heron, Ph.D.(2)(3) . . . . .	62	Director	July 2002
Pierre Lapalme(2) . . . . .	69	Director, Chairman of the Board	January 2004
V. Bryan Lawlis, Ph.D.(1)(3) . . . . .	58	Director	June 2007
Alan J. Lewis, Ph.D.(1) . . . . .	64	Director	June 2005
Richard A. Meier(2) . . . . .	50	Director	December 2006

- (1) Member of BioMarin's Compensation Committee
- (2) Member of BioMarin's Audit Committee
- (3) Member of BioMarin's Corporate Governance and Nominating Committee

**Jean-Jacques Bienaimé** joined our Board in May 2005, at the same time he became our Chief Executive Officer. From November 2002 to April 2005, Mr. Bienaimé served as Chairman, Chief Executive Officer, and President of Genencor, a biotechnology company focused on industrial bioproducts and targeted cancer biotherapeutics. Prior to joining Genencor, Mr. Bienaimé was Chairman, President and Chief Executive Officer of SangStat Medical Corporation, another biotechnology company. He became President of SangStat Medical Corporation in 1998 and Chief Executive Officer in 1999. Prior to joining SangStat Medical Corporation, Mr. Bienaimé held various management positions from 1992 to 1998 with Rhône-Poulenc Rorer Pharmaceuticals (now known as Sanofi-Aventis), including Senior Vice President of Corporate Marketing and Business Development, and Vice President and General Manager of the advanced therapeutic and oncology division. Mr. Bienaimé currently serves on the boards of NeurogesX, Inc., Ensemble Discovery and The Biotech Industry Organization, and is a member of the advisory board of Bellevue Asset Management's BioVentures II fund. He received an M.B.A. from the Wharton School at the University of Pennsylvania and an undergraduate degree in economics from the Ecole Supérieure de Commerce de Paris.

The Board has nominated Mr. Bienaimé for his intimate knowledge of our business and extensive experience in the management of biotechnology organizations, business development, and sales and marketing of both biotechnology and pharmaceutical products.

**Michael Grey** joined our Board in December 2005. He currently serves as Venture Partner with Pappas Ventures, since January 2010. Between January and September 2009, he served as President and Chief Executive Officer of Auspex Pharmaceuticals, Inc., a private biotechnology company. From January 2005 until its acquisition in August 2008, Mr. Grey was President and Chief Executive Officer of SGX Pharmaceuticals, Inc., a publicly held biotechnology company, where he previously served as President from June 2003 to January 2005

and as Chief Business Officer from April 2001 until June 2003. Prior to joining SGX Pharmaceuticals, Mr. Grey acted as President, Chief Executive Officer and Board member of Trega Biosciences, Inc., a biotechnology company. From November 1994 to August 1998, Mr. Grey was the President of BioChem Therapeutic, Inc., the pharmaceutical operating division of BioChem Pharma, Inc. During 1994, Mr. Grey served as President and Chief Operating Officer for Ansan, Inc. From 1974 to 1993, he served in various roles with Glaxo, Inc. and Glaxo Holdings, plc, culminating in the position of Vice President, Corporate Development. Mr. Grey is currently a director of Achillion Pharmaceuticals, Inc. Mr. Grey previously served on the board of directors of two public companies during the past five years: SGX Pharmaceuticals, Inc. (from 2001 to 2008) and IDM Pharma, Inc. (from 1999 to 2009). He received a B.Sc. in chemistry from the University of Nottingham, United Kingdom.

The Board has nominated Mr. Grey for his extensive experience in managing biotechnology and pharmaceutical organizations, business development, compensation matters and finance and accounting.

**Elaine J. Heron, Ph.D.**, joined our Board in July 2002 and serves as the Chairman of the Corporate Governance and Nominating Committee. In February 2009, Dr. Heron became Chair and Chief Executive Officer of Amplyx Pharmaceuticals, Inc., a private early stage drug development company. From July 2001 to October 2008, Dr. Heron was Chairman and Chief Executive Officer of Labcyte Inc., a private biotechnology company and continues to serve on its board of directors. Before joining Labcyte, she spent six years in increasingly responsible positions at the Applied Biosystems Group of Applera Corporation, including the position of General Manager and Vice President of Sales and Marketing. Dr. Heron earned a B.S. in chemistry with highest distinction and a Ph.D. in analytical biochemistry from Purdue University and an M.B.A. from Pepperdine University.

The Board has nominated Dr. Heron for her extensive experience in life science sales and marketing, finance and accounting, corporate governance matters and research and development.

**Pierre Lapalme** joined our Board in January 2004 and was named as Chairman in August 2004. From 1995 until his retirement in 2003, he served as the President and Chief Executive Officer of North America Ethypharm, Inc., a drug delivery company. Throughout his career, Mr. Lapalme held numerous senior management positions in the pharmaceutical industry, including Chief Executive Officer and Chairman of the Board of Rhône-Poulenc Pharmaceuticals, Inc. in Canada, and Senior Vice President and General Manager of North America Ethicals, a division of Rhône-Poulenc Rorer, Inc. (now known as Sanofi-Aventis), where he oversaw the development of the ethical pharmaceutical business in the United States, Canada, Mexico, and Central America. Mr. Lapalme served on the board of the National Pharmaceutical Council and was a board member of the Pharmaceutical Manufacturers Association of Canada, where he played a leading role in reinstating patent protection for pharmaceuticals. Mr. Lapalme previously served on the board of directors of two public companies during the past five years: Sciele Pharmaceuticals Inc. (from 1998 to 2008) and Bioxel Pharma (from 2004 to 2009). He also serves on the board of two private biotech companies and was appointed to the board of Aeterna Zentaris in December 2009. Mr. Lapalme studied at the University of Western Ontario and INSEAD France.

The Board has nominated Mr. Lapalme for his extensive experience in managing biotechnology and pharmaceutical organizations, and sales and marketing of pharmaceutical products.

**V. Bryan Lawlis, Ph.D.**, joined our Board in June 2007. He currently is a founder and the President and CEO of Itero Biopharmaceuticals, Inc., a privately held, early stage biopharmaceutical company that was founded in 2006. Dr. Lawlis served as President and Chief Executive Officer of Aradigm Corporation from August 2004, and served on its Board of Directors from February 2005, continuing in both capacities until August 2006. Dr. Lawlis served as Aradigm Corporation's President and Chief Operating Officer from June 2003 to August 2004 and its Chief Operating Officer from November 2001 to June 2003. Previously, Dr. Lawlis founded Covance Biotechnology Services, a contract biopharmaceutical manufacturing operation, served as its President and Chief Executive Officer from 1996 to 1999, and served as Chairman from 1999 to 2001, when it

was sold to Diosynth RTP, Inc., a division of Akzo Nobel, NV. From 1981 to 1996, Dr. Lawlis was employed at Genencor, Inc. and Genentech, Inc. His last position at Genentech was Vice President of Process Sciences. Dr. Lawlis holds a B.A. in microbiology from the University of Texas at Austin, and a Ph.D. in Biochemistry from Washington State University. In addition to BioMarin Pharmaceutical Inc., Dr. Lawlis holds board positions on two privately held companies, Itero Biopharmaceuticals, Inc. and Sutro Biopharma, Inc.

The Board has nominated Dr. Lawlis for his extensive experience in manufacturing biotechnology and other pharmaceutical products, research and development of drug products and managing and conducting clinical trials and drug regulatory processes.

*Alan J. Lewis, Ph.D.*, joined our Board in June 2005 and serves as the Chairman of the Compensation Committee. Since January 2009, Dr. Lewis has served as President and Chief Executive Officer of The Juvenile Diabetes Research Foundation. From February 2006 until December 2008, Dr. Lewis was the President and Chief Executive Officer of Novocell, Inc, a privately held regenerative disease biotechnology company. Prior to joining Novocell, starting in 2000, he was President of Celgene Signal Research, a wholly owned subsidiary of the Celgene Corporation, a pharmaceutical company. From February 1994 to August 2000, he was the President and Chief Executive Officer of Signal Pharmaceuticals, Inc., where he guided the company to its successful acquisition by Celgene. From 1979 to 1994, Dr. Lewis held a number of positions at Wyeth-Ayerst Research and its predecessor, Wyeth Laboratories, Inc., including Vice President of Research at Wyeth-Ayerst. Dr. Lewis has published over 120 full manuscripts and has written and edited seven books. Dr. Lewis was a Research Associate at Yale University from 1972 to 1973. Dr. Lewis received a B.Sc. in physiology and biochemistry from Southampton University, Southampton, Hampshire, U.K. and a Ph.D. in pharmacology from the University of Wales, Cardiff, U.K. Dr. Lewis currently serves as the director of private companies, Cytochroma, Inc., Ambit Biosciences and Biotica.

The Board has nominated Dr. Lewis for his extensive experience in managing biotechnology and pharmaceutical organizations, research and development, finance, compensation and corporate governance matters.

*Richard A. Meier* joined our Board in December 2006 and serves as the Chairman of the Audit Committee. Mr. Meier is currently Executive Vice President and Chief Financial Officer at TeleFlex, Incorporated, a position he assumed in January 2010. Prior to this, Mr. Meier served as President and Chief Operating Officer of Advanced Medical Optics from November 2007 to May 2009. From February 2007 to November 2007, Mr. Meier was Advanced Medical Optics' Chief Operating Officer and Chief Financial Officer. From April 2006 to February 2007, Mr. Meier was Advanced Medical Optics' Executive Vice President, Operations; President, Global Eye Care; and Chief Financial Officer. From February 2004 to April 2006, he was Advanced Medical Optics' Executive Vice President of Operations and Finance and Chief Financial Officer, and from April 2002 to February 2004, Mr. Meier was Corporate Vice President and Chief Financial Officer. Prior to joining Advanced Medical Optics, Mr. Meier was the Executive Vice President and Chief Financial Officer of Valeant Pharmaceuticals, Inc., from October 1999, and Senior Vice President & Treasurer from May 1998 to October 1999. Before joining Valeant, Mr. Meier was an executive with the investment banking firm of Schroder & Co. Inc. in New York, from 1996. Prior to Mr. Meier's experience at Schroder & Co., he held various financial and banking positions at Salomon Smith Barney, Manufacturers Hanover Corporation, Australian Capital Equity, and Greyhound Lines, Inc.

The Board has nominated Mr. Meier for his extensive experience in finance and accounting, capital markets, managing large organizations in the healthcare field and information technology.

**THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE "FOR" THE ELECTION OF ALL NOMINEES NAMED ABOVE. IF YOU SIGN AND RETURN THE ENCLOSED PROXY CARD, OR VOTE VIA INTERNET OR TELEPHONE, UNLESS YOU DIRECT TO THE CONTRARY ON THAT CARD, OR VIA INTERNET OR TELEPHONE, THE SHARES REPRESENTED BY THAT PROXY CARD WILL BE VOTED "FOR" THE ELECTION OF ALL NOMINEES LISTED ABOVE.**

## **INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE**

### **General**

This section describes key corporate governance guidelines and practices that we have adopted. Complete copies of our Corporate Governance Guidelines, the charters of the committees of our Board and our Standards of Business Conduct and Ethics described below may be found in the Corporate Governance section of the Investors section of the Company's website at [www.bmrn.com](http://www.bmrn.com). Alternatively, you can request a copy of any of these documents free of charge by writing to: G. Eric Davis, the Company's Senior Vice President, General Counsel and Secretary, c/o BioMarin Pharmaceutical Inc. 105 Digital Drive, Novato, California 94949.

### **Independence of the Board of Directors**

The Board has affirmatively determined that all of the nominees other than Mr. Bienaimé are independent directors within the meaning of the applicable NASDAQ listing standards and relevant securities and other laws and regulations regarding the definition of "independent." There are no family relationships between any Director and any of our executive officers.

### **Board Leadership Structure**

The Board has determined that having an independent director serve as Chairman of the Board is in the best interest of stockholders at this time. The structure ensures a greater role for the independent Directors in the oversight of the Company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of the Board. The Board believes that having an independent director serve as Chairman helps to ensure independence in the Board's oversight of the Company's risk management, but that otherwise its administration of its risk oversight function has not affected the Board's leadership structure.

### **Role in the Board in Risk Oversight**

The Board is actively involved in oversight of risks that could affect the Company. This oversight is conducted primarily through committees of the Board, and particularly the Audit Committee and Corporate Governance and Nominating Committee, but the full Board has retained responsibility for general oversight of risks. The Board satisfies this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within the Company.

### **Meetings of the Board of Directors**

Our Board manages our business. It establishes overall policies and standards and reviews the performance of management. During the fiscal year ended December 31, 2009, the Board held seven meetings and took action by unanimous written consent on one occasion. Each Board member attended 75% or more of the aggregate meetings of the Board and of the committees, on which he or she served, held during the period for which he or she was a director or committee member. Applicable NASDAQ listing standards require that the independent directors meet from time to time in executive session. In fiscal 2009, our independent directors met in regularly scheduled executive sessions at which only independent directors were present. It is our policy to request that all Board members attend the annual meeting of stockholders. However, we also recognize that personal attendance by all directors is not always possible. All of the directors but one serving at the time of the 2009 Annual Meeting of Stockholders attended such meeting.

## Information Regarding Committees of the Board of Directors

The Board has a number of committees that perform certain functions for the Board. The current committees of the Board of Directors are the Audit Committee, Compensation Committee, and the Corporate Governance and Nominating Committee. Below is a description of each committee of the Board. Each of the committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities. The Board has determined that each member of each committee meets the applicable NASDAQ rules and regulations regarding “independence” and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to the Company.

### Audit Committee

The Board has a separately designated standing Audit Committee established in accordance with Section 3(a)(58) of the Exchange Act. The Audit Committee of the Board was established by the Board to oversee the Company’s corporate accounting and financial reporting processes, systems of internal control over financial reporting and the quality and integrity of the Company’s financial statements and reports. In addition, the Audit Committee oversees the qualification, independence and performance of the Company’s independent registered public accounting firm. The Audit Committee also recommends to the Board the appointment of our independent registered public accounting firm.

The Audit Committee is currently composed of three directors: Mr. Meier, Chairman, Dr. Heron and Mr. Lapalme. Mr. Joseph Klein served as Chairman of the Audit Committee during 2009 until his resignation on March 19, 2010. Mr. Meier was appointed as Chairman of the Committee following Mr. Klein’s resignation. In 2009, the Audit Committee met ten times. The Audit Committee is governed by a written Audit Committee Charter adopted by the Board that was last amended in May 2008. The Audit Committee charter can be found in the Corporate Governance section of the Investors section of the Company’s website at [www.bmrn.com](http://www.bmrn.com). Information on our website is not incorporated by reference in this proxy statement. The charter of the Audit Committee grants the Audit Committee full access to all books, records, facilities and personnel of the Company, as well as authority to obtain, at the expense of the Company, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the Audit Committee considers necessary or appropriate in the performance of its duties.

As required by its charter, the Audit Committee conducts a self evaluation at least annually. The Audit Committee also periodically reviews and assesses the adequacy of its charter, including the Audit Committee’s role and responsibilities, and recommends any proposed changes to the Board for its consideration.

The Board annually reviews the NASDAQ listing standards’ definition of independence for Audit Committee members and has determined that all members of the Company’s Audit Committee are independent (as independence is currently defined in NASDAQ Listing Rules 5605(c)(2)(A)(i) and (ii)). The Board has determined that Mr. Meier qualifies as an “audit committee financial expert,” as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Meier’s level of knowledge and experience based on a number of factors, including his experience as the chief financial officer of several public companies, and his finance and investment banking experiences. In making that determination, the Board relied on the past business experience of Mr. Meier. Please see the description of the business experience for Mr. Meier under the heading “Nominees for Director.”

## REPORT OF THE AUDIT COMMITTEE(1)

The Audit Committee reviews the Company's financial reporting process on behalf of the Board. Management has the primary responsibility for the financial statements and the reporting process, including the system of internal financial controls. In this context, during fiscal year 2009, the Audit Committee met and held discussions with management and the independent registered public accounting firm. Management has represented to the Audit Committee that the Company's consolidated financial statements for the fiscal year ended December 31, 2009 were prepared in accordance with generally accepted accounting principles, and the Audit Committee has reviewed and discussed the audited financial statements of the Company with management of the Company and KPMG LLP, the Company's independent registered public accounting firm. In addition, the Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by Statement on Auditing Standards No. 61, as amended (AICPA, *Professional Standards*, Vol. 1. AU section 380), as adopted by the Public Company Accounting Oversight Board ("PCAOB") in Rule 3200T. The Audit Committee has also received from KPMG LLP the written disclosures and the letter required by the applicable requirements of the PCAOB regarding KPMG LLP's communications with the audit committee concerning independence and has discussed with KPMG LLP the firm's independence from the Company and its management. Based on the foregoing, the Audit Committee has recommended to the Board, and the Board has approved, that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 for filing with the Securities and Exchange Commission. The Audit Committee and the Board also have recommended the selection of KPMG LLP as the Company's independent registered public accounting firm for the year ending December 31, 2010.

Respectfully submitted on February 24, 2010 by the members of the Audit Committee of the Board of Directors:

Joseph Klein, III, Chairman  
Elaine J. Heron, Ph.D.  
Richard A. Meier  
Pierre Lapalme

### Compensation Committee

The Compensation Committee of the Board acts on behalf of the Board to review, adopt and oversee our compensation strategy, policies, plans and programs, including:

- reviews and recommends to the Board for approval, the compensation (i.e., salary, bonus, and stock-based compensation grants) and other terms of employment or service of our chief executive officer and outside directors;
- reviews and approves compensation and other terms of employment or service of our other executive officers and other officers reporting to our chief executive officer;
- reviews with management the Company's Compensation Discussion and Analysis and considers whether to recommend that it be included in proxy statements and other SEC filings;
- approves the goals and performance requirements, thresholds, and maximum funding for our annual bonus program; and
- administering our 2006 Share Incentive Plan, our Non-Qualified Deferred Compensation Plan (the "Deferred Compensation Plan") and our Amended and Restated 2006 Employee Stock Purchase Plan.

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(1) The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of BioMarin under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



The Compensation Committee is currently composed of three directors: Dr. Lewis, Chairman, Mr. Grey and Dr. Lawlis. The Board has determined that all members of the Company's Compensation Committee are independent (as independence is currently defined in NASDAQ Listing Rule 5605(a)(2)). During 2009, the Compensation Committee met six times.

The Compensation Committee has adopted a written charter that can be found in the Corporate Governance section of the Investors section of the Company's website at [www.bmrn.com](http://www.bmrn.com). Information on our website is not incorporated by reference in this proxy statement. The charter of the Compensation Committee grants the Compensation Committee full access to all books, records, facilities and personnel of the Company, as well as authority to obtain, at the expense of the Company, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. In particular, the Compensation Committee has the sole authority to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Information regarding consultants engaged by the Compensation Committee is provided in the Compensation Discussion and Analysis section of this proxy statement.

As required by its charter, the Compensation Committee conducts a self evaluation at least annually. The Compensation Committee also periodically reviews and assesses the adequacy of its charter, including the Compensation Committee's role and responsibilities, and recommends any proposed changes to the Board for its consideration.

The performance and compensation process and specific determinations of the Compensation Committee with respect to executive compensation for 2009 and for certain elements of compensation for 2010 are described in greater detail in the Compensation Discussion and Analysis section of this proxy statement.

#### **Compensation Committee Interlocks and Insider Participation**

No member of our Compensation Committee has ever been an executive officer or employee of the Company or any of our subsidiaries. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our Board or Compensation Committee. During 2009, no members of our Compensation Committee had any relationships requiring disclosure by us under the SEC's rules requiring disclosure of certain relationships and related party transactions.

#### **Corporate Governance and Nominating Committee**

The Corporate Governance and Nominating Committee (the "CGN Committee") is responsible for overseeing the selection of qualified candidates to serve as members of the Board and guiding our corporate governance philosophy and practices. To that end, the CGN Committee is responsible for identifying individuals to fill vacancies on the Board, recommending nominees to be voted upon at the annual meeting of stockholders, recommending to the Board appointees to serve on committees of the Board, and overseeing the development and implementation of BioMarin's corporate governance policies and code of ethics. A detailed discussion of the CGN Committee's procedures for recommending candidates for election as a Director appears below under the caption *Procedures of the Corporate Governance and Nominating Committee*.

The CGN Committee also oversees policies including, but not limited to:

- adopting of corporate governance guidelines;
- establishing written charters for each Board committee and recommending changes to those charters from time to time when it deems appropriate;
- reviewing and approving related party transactions with our directors, executive officers and 5% stockholders;
- maintaining independence standards for each independent Board member;

- requiring sessions of Board meetings without management present;
- mandating execution of a standard of business ethics for every employee and Board member;
- implementing, in conjunction with the Audit Committee, the independent audit function, and
- establishing a toll-free telephone number for employees to anonymously report complaints relating to financial fraud, environmental hazards, illegal or unfair employment practices, and unethical behavior.

The members of the CGN Committee are Dr. Heron, Chairman, Dr. Lawlis and Mr. Grey. Mr. Klein served on the CGN Committee during 2009 until his resignation on March 19, 2010 when Mr. Grey was appointed to replace him. The CGN Committee met six times during 2009.

The CGN Committee has adopted a written charter that can be found in the Corporate Governance section of the Investors section of the Company's website at [www.bmrn.com](http://www.bmrn.com). The Company's Corporate Governance Guidelines can also be found in the Corporate Governance section of the Investors section of the Company's website at [www.bmrn.com](http://www.bmrn.com). Information on our website is not incorporated by reference in this proxy statement. The charter of the CGN Committee grants the CGN Committee full access to all books, records, facilities and personnel of the Company, as well as authority to obtain, at the expense of the Company, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the CGN Committee considers necessary or appropriate in the performance of its duties.

As required by its charter, the CGN Committee conducts a self evaluation at least annually. The CGN Committee also periodically reviews and assesses the adequacy of its charter, including the CGN Committee's role and responsibilities, and recommends any proposed changes to the Board for its consideration.

#### **Procedures of the Corporate Governance and Nominating Committee**

The CGN Committee is responsible for overseeing the selection of qualified candidates to serve as members of the Board and guiding our corporate governance philosophy and practices. The CGN Committee is composed of three Directors, each of whom is "independent" under the listing qualifications of NASDAQ. The CGN Committee operates according to a charter that complies with the guidelines established by NASDAQ.

In connection with nominating directors for election at the annual meeting and periodically throughout the year, the CGN Committee considers the composition of the Board and each Committee of the Board to evaluate its effectiveness and whether or not changes should be considered to either the Board or any of the Committees. In support of this process, the Board has determined that the Board as a whole must have the right diversity, mix of characteristics and skills for the optimal functioning of the Board in its oversight of the Company. The Board believes that it should be comprised of persons with skills in areas such as:

- leadership of large complex organizations, particularly in related industries;
- sales and marketing of biotechnology and pharmaceutical products;
- manufacturing of biotech and small molecule drug products;
- managing and conducting clinical trials and drug regulatory process;
- medicine;
- finance and accounting;
- capital markets;
- business development;
- legal and intellectual property;
- research and development of drug products; and
- information technology.

As part of its periodic self-assessment process, the CGN Committee has implemented a process that involves the entire Board to annually determine the diversity of specific skills and characteristics necessary for the optimal functioning of the Board in its oversight of the Company over both the short- and longer-term. The CGN Committee considers the skill areas currently represented on the Board, as well as recommendations of Directors regarding skills that could improve the overall quality and ability of the Board to carry out its functions in determining Director nominations and whether to consider adding new Directors.

Once the CGN Committee and the Board determine that it is appropriate to add a new director, either as a replacement or as a new position, the CGN Committee uses a flexible set of procedures in selecting individual Director candidates. It utilizes general guidelines that allow it to adjust the process to best satisfy the objectives it is attempting to accomplish in any director search. The first step in the general process is to identify the type of candidate the CGN Committee may desire for a particular opening, including establishing the specific target skill areas, experiences and backgrounds that are to be the focus of a Director search. Once identified, the CGN Committee looks to the best method of finding a candidate who satisfies the specified criteria. The CGN Committee may consider candidates recommended by management, by other members of the CGN Committee, by the Board, by stockholders, or it may engage a third party to conduct a search for possible candidates. In considering candidates submitted by stockholders, the CGN Committee will take into consideration the needs of the Board and the qualifications of the candidate.

In order for a stockholder to have a candidate considered by the CGN Committee, a stockholder should submit a written recommendation that includes: (i) the name and record address of the stockholder (and beneficial owner, if any, on whose behalf the nomination is made) and evidence of the stockholder's and beneficial owner's ownership of Company stock, including the number of shares owned and the length of time of ownership; (ii) a description of any agreement, arrangement or understanding with respect to the nomination between or among such stockholder and/or such beneficial owner and affiliates or others acting together; (iii) a description of any agreement, arrangement or understanding (including any derivative or short positions, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder and such beneficial owners; (iv) a representation that the stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice; (v) whether the stockholder or any beneficial owner intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of at least the percentage of our outstanding capital stock required to elect the nominee and/or otherwise to solicit proxies from stockholders in support of such nomination; and (vi) any other information relating to such stockholder that would be required to be disclosed in a proxy statement or other required to be made in connection with solicitation of proxies for election of directors pursuant to Section 14 of the Exchange Act. With respect to each person whom the stockholder proposes to nominate for election as a director, the stockholder must include (i) the name, age, business address and residence address of the director candidate, (ii) the candidate's resume or a listing of his or her qualifications to be a director (including principal occupation or employment), (iii) the class or series and number of shares of stock which are owned beneficially or of record by the person, (iv) any other information relating to the person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitation of proxies for election of directors pursuant to Section 14 of the Exchange Act. The notice must also be accompanied by a written consent of each proposed nominee to being named as a nominee if selected by the CGN Committee and nominated by the Board. Stockholder recommendations should be addressed to the Corporate Governance and Nominating Committee in care of the Secretary of the Company at the address set forth under the heading *Stockholder Communications with the Board of Directors*.

Once candidates are identified, the CGN Committee conducts an evaluation of qualified candidates. The evaluation generally includes interviews and background and reference checks. There is no difference in the evaluation process of a candidate recommended by a stockholder as compared to the evaluation process of a candidate identified by any of the other means described above. While the CGN Committee has not established minimum criteria for a candidate, it has established important factors to consider in evaluating a candidate. These factors include: strength of character, mature judgment, business understanding, experience with the

pharmaceutical and/or biotechnology industries, availability and level of interest, capacity to devote time to BioMarin Board activities, career specialization, relevant technical skills, diversity, and the extent to which the candidate would fill a present need on the Board.

If the CGN Committee determines that a candidate should be nominated as a candidate for election to the Board, the candidate's nomination is then recommended to the Board, and the Directors may in turn conduct their own review to the extent they deem appropriate. When the Board has agreed upon a candidate, such candidate is recommended to the stockholders for election at an annual meeting of stockholders or appointed as a Director by a vote of the Board as appropriate.

All of the current Directors have been recommended by the CGN Committee to the Board for re-election as our Directors at the Annual Meeting, and the Board has approved such recommendations.

### **Chairman of the Board**

In 2009, the independent Board members re-appointed Mr. Lapalme as Chairman of the Board. The Chairman of the Board is responsible for:

- approving Board meeting schedules and meeting agendas;
- approving Board meeting materials;
- leading executive sessions of the independent Board members;
- setting meetings of independent Board members; and
- being available for consultation with major stockholders.

### **Director and Officer Stock Ownership Guidelines**

The Compensation Committee has approved stock ownership guidelines for the directors, our chief executive officer, and senior vice presidents, which have been approved by the Board. Under these guidelines, executives are expected to use the shares of common stock obtained on the exercise of stock options or the shares of restricted stock received to establish significant level of direct ownership in BioMarin. The guidelines recommend that our directors hold shares equal to the lesser of 10,000 shares of common stock or three times the director's annual cash retainer amount, our chief executive officer hold shares of the Company with a value equal to at least three times his or her base salary and the senior vice presidents hold shares of the Company with a value equal to at least two times his or her base salary. All shares of restricted stock held by our officers and directors, whether or not vested, are included in the calculations. To give the officers and directors time to comply with this recommendation, the Compensation Committee determined that our directors and officers should have until June 2013 to comply with these guidelines. As of December 31, 2009, Mr. Bienaimé beneficially held shares equal to 3.1 times his base salary, Drs. Fuchs and Baffi held shares equal to 0.9 and 4.3 times their base salary, respectively, and Messrs. Cooper and Aselage held shares equal to 2.0 and 4.1 times their base salary, respectively. In addition, as of December 31, 2009, all of our directors held shares equal to three times their respective annual cash retainer amounts. Although the guidelines are not mandatory, the Compensation Committee will consider compliance with the guidelines in setting an officer's compensation and the Corporate Governance and Nominating Committee will consider compliance with the guidelines when making decisions on nominating Directors for re-election. Please see *Compensation Discussion and Analysis* for more information regarding these guidelines.

### **2009 Director Compensation**

Our directors play a critical role in guiding our strategic direction and overseeing the management of BioMarin. The many responsibilities and risks and the substantial time commitment of being a director require that we provide adequate compensation commensurate with our directors' workload and opportunity costs. Non-employee directors receive a combination of annual cash retainers, restricted stock grants, and stock option

grants in amounts that correlate to their responsibilities in his or her service to us, based upon their respective levels of Board participation and responsibilities, including service on Board committees. Our only employee director, Mr. Bienaimé, receives no separate compensation for his service as a director.

The following table is a summary of the annual cash compensation paid to non-employee directors. Each applicable line item is an additional element of compensation.

<u>Director Position</u>	<u>Annual Cash Compensation</u>
All Independent Members .....	\$40,000
Chairman of the Board .....	\$30,000
Audit Committee Chair .....	\$25,000
Audit Committee (Non-Chair) .....	\$12,000
Compensation Committee Chair .....	\$15,000
Compensation Committee (Non-Chair) .....	\$ 7,500
Corporate Governance and Nominating Committee Chair .....	\$10,000
Corporate Governance and Nominating Committee (Non-Chair) .....	\$ 5,000
Liaison to Scientific Advisory Board .....	\$ 8,000

Each non-employee director is automatically granted an initial options grant to purchase 30,000 shares of our common stock on the date that such person first becomes a non-employee director. On the date of our annual meeting of stockholders each re-elected director is granted options to purchase 15,000 shares of common stock and 2,500 restricted stock units. The restricted stock units vest in full on the one-year anniversary of the grant date. The option grant for a director that has served for less than a year is prorated to the nearest quarter. The shares subject to these options vest quarterly over one year. These options and restricted stock units continue to vest only while the director serves. The exercise price per share of each of these options is 100% of the fair market value of a share of our common stock on the date of the grant of the option. These options have a term of 10 years.

In fiscal year 2009, options to purchase, in the aggregate, 105,000 shares were issued to the non-employee directors and 17,500 restricted stock units were awarded to the non-employee directors under the 2006 Share Incentive Plan. The following table lists actual compensation paid to each of the directors during 2009 other than Mr. Bienaimé, who also served as a Named Executive Officer, as defined below.

Our Board members are eligible to enroll in our Deferred Compensation Plan under which participants may elect to defer all or a portion of their fees and restricted stock unit awards otherwise payable to them, and thereby defer taxation of these deferred amounts until actual payment of the deferral amounts in future years.

#### Director Compensation in 2009

<u>Name</u>	<u>Fees Earned or Paid in Cash \$(1)</u>	<u>Stock Awards \$(2)</u>	<u>Option Awards \$(3)</u>	<u>Total (\$)</u>
Michael Grey .....	47,500	35,975	113,850	197,325
Elaine J. Heron, Ph.D. ....	62,000	35,975	113,850	211,825
Joseph Klein, III(4) .....	70,000	35,975	113,850	219,825
Pierre Lapalme .....	82,000	35,975	113,850	231,825
V. Bryan Lawlis, Ph.D. ....	52,500	35,975	113,850	202,325
Alan J. Lewis, Ph.D. ....	63,000	35,975	113,850	212,825
Richard A. Meier .....	52,000	35,975	113,850	201,825

- (1) Director fees are generally paid quarterly in arrears within four weeks after the close of a quarter.
- (2) The amounts in this column reflect the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. The grant date fair value was \$14.39 per share. For assumptions used in determining these values, see Note 3 the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

- (3) The amounts in this column reflect the full grant date fair values in accordance with FASB ASC Topic 718. For assumptions used in determining these values, see Note 3 the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
- (4) Mr. Klein resigned from the Board of Directors on March 19, 2010.

#### **Stockholder Communication with the Board of Directors**

The Board has adopted a process for stockholders and others to send communications to the Board or any Director. All such communications should be sent by mail addressed to the Board or any particular Director at 105 Digital Drive, Novato, California 94949, c/o G. Eric Davis, the Company's Senior Vice President, General Counsel and Secretary. All communications received by Mr. Davis will be sent directly to the Board or any particular Director.

#### **Standards of Business Conduct and Ethics**

The Board has adopted Standards of Business Conduct and Ethics that are applicable to all employees and directors, including our chief executive officer, chief financial officer, other executive officers and senior financial personnel. A copy of our Standards of Business Conduct and Ethics is available in the Corporate Governance section of the Investors section of our website at [www.bmrn.com](http://www.bmrn.com). Information on our website is not incorporated by reference in this proxy statement. If the Company makes any substantive amendments to the Standards of Business Conduct and Ethics or grants any waiver from a provision of the Standards of Business Conduct and Ethics to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver on its website. The Company intends to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Standards of Business Conduct and Ethics by disclosing such information on the same website.

## PROPOSAL 2

### APPROVAL OF AMENDED AND RESTATED 2006 SHARE INCENTIVE PLAN

#### Background and Purpose of Proposal

The BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan (the “2006 Plan”) was adopted by the Board in May 2006. The 2006 Plan was approved by our stockholders on June 21, 2006. The Board approved a technical amendment to the 2006 Plan in January 2009 to comply with the changes to Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”). A total of 15,000,000 shares of BioMarin common stock have been reserved for issuance under the 2006 Plan. Of the 15,000,000 shares of common stock originally authorized under the 2006 Plan, after all award grants made by our Compensation Committee from May 2006 to December 31, 2009, only 3,175,506 shares remain available for grant. As of March 1, 2010, 3,292,017 shares remain available for grant.

The Board of Directors unanimously approved and adopted, subject to the approval of the Company’s stockholders at the Annual Meeting, the BioMarin Pharmaceutical Inc. Amended and Restated 2006 Share Incentive Plan (Amended and Restated as of March, 2010) ( the “Restated Plan”). If the Restated Plan is approved by the stockholders, it will become effective on the day of the Annual Meeting. Outstanding awards under the 2006 Plan will continue in effect in accordance with their terms.

The Company is proposing approval of the Restated Plan because it is necessary for the Company to continue to grant stock incentive awards to employees, consultants, directors and advisors as part of their compensation to provide appropriate incentives. The Board believes that the purpose of the Restated Plan is to encourage ownership in the Company by its employees, directors, consultants and advisors whose long-term employment by or involvement with the Company is considered essential to the Company’s continued progress and, thereby, align the interests of the award recipients and stockholders and permit the award recipients to share in the Company’s success. If the Restated Plan is not approved, the Company will not have sufficient authorized shares under the 2006 Plan to continue to make competitive equity awards and the Company will need to substantially increase other components of compensation.

Our principal reason for amending and restating the 2006 Plan is to increase the number of shares of common stock available for issuance. The Restated Plan will increase the maximum number of shares available for awards by 8,000,000 shares, thereby increasing the maximum number of shares in the reserve from 15,000,000 to 23,000,000 shares of common stock. The Restated Plan includes several other changes, each of which is described below. The description of the changes is followed by a summary description of the entire Restated Plan. The full text of the Restated Plan is attached to this proxy statement as *Appendix A*, and the following description of the Restated Plan is qualified in its entirety by reference to *Appendix A*. Capitalized terms used in this summary and not otherwise defined will have the meanings ascribed to such terms in the Restated Plan.

#### Why the Board of Directors Believed You Should Vote for this Proposal

- *Attracting and retaining talent.* A talented, motivated and effective management team and workforce are essential to the Company’s continued progress. Equity compensation has been an important component of total compensation at BioMarin for many years because it is effective at getting managers and employees to think and act like owners. If the Restated Plan is approved, our ability to offer competitive compensation packages to attract new talent and to retain our best performers will be enhanced.
- *Avoiding disruption in compensation programs.* If the Restated Plan is approved, we will not have to restructure existing compensation programs throughout the Company for reasons not directly related to the achievement of our business objectives. To remain competitive without an employee equity plan, it will likely be necessary to replace components of compensation previously awarded in equity with cash, or with other instruments that may not necessarily align employee interests with those of stockholders as well as equity awards would have. Additionally, replacing equity with cash will increase cash compensation expense and be a drain on cash flow that would be better utilized if reinvested in our core products.

- *Plan features designed to protect stockholder interests.* As described below, the Restated Plan includes a number of enhancements from the 2006 Plan, which are designed to further protect stockholder interests. With a term of only six years and a limited amount of additional shares authorized for the reserve (as discussed below), the Restated Plan ensures that stockholders will have more frequent opportunities to review and approve our equity compensation practices.
- *The Company has demonstrated commitment to sound equity compensation practices.* We recognize that equity compensation awards dilute stockholder equity and must be used judiciously. Our equity compensation practices are designed to be in line with industry norms, and we believe our historical share usage has been responsible and mindful of stockholder interests. As described below, our average burn rate (total shares used for equity compensation awards each year divided by weighted average outstanding shares for the year) for the last three years has been less than 4%, which is at or below the average usage for our peer companies. The Company's dilution level or "overhang" (shares subject to equity compensation awards outstanding at fiscal year-end or available to be used for equity compensation, divided by fully diluted shares outstanding) at the end of fiscal year 2009 was 14.3%; and for fiscal years 2008 and 2007 it was 11.9% and 12.1%, respectively. Of the total overhang, as of December 31, 2009, approximately 45% of the shares reflected in the overhang were subject to fully vested, "in the money" stock options (i.e., options that have an exercise price less than the market price of the underlying shares). The Company believes that holding these options is positive for our stockholders as it represents a long term interest in the value of our common stock.

### **Key Features of the Restated Plan**

The Restated Plan contains features that the Board believes are consistent with the interests of stockholders and sound governance principles. These features include the following:

- *Flexibility and Performance Ties.* The variety of awards permitted under the Restated Plan affords flexibility with respect to the design of long-term incentives that are responsive to evolving regulatory changes and compensation best practices and incorporate tailored, performance-based measures.
- *Compensation Committee Oversight.* The Restated Plan will be administered by our Compensation Committee which is comprised solely of non-employee, independent directors.
- *No Discount Options.* Stock options may not be granted or awarded with an exercise price less than 100% of the fair market value of our common stock on the date of grant or award.
- *No Re-pricings.* Except in the connection with a corporate transaction involving the Company, the direct or indirect re-pricing of stock options and stock appreciation rights is prohibited without stockholder approval. This prohibition applies both to re-pricings that involve lowering the exercise price of a stock option as well as re-pricings that are accomplished by canceling an existing award and replacing it with a lower-priced award.
- *No Liberal Share Accounting.* Shares withheld for tax payments or to pay the exercise price, shares repurchased on the open market with the proceeds of an option exercise price, or shares not issued or delivered as a result of the net settlement of an outstanding award, will not be added back into the Restated Plan share reserve.
- *1.62:1 Grant Ratio on Full-Value Award Grants.* The Restated Plan recognizes the greater intrinsic value of full value share awards, including restricted stock, restricted stock units and performance awards. Accordingly, the Restated Plan's share reserve is reduced by 1.62 shares for every one full value share awarded. Stock option awards reduce the reserve on a 1:1 basis.
- *No Annual "Evergreen" Provision.* The Restated Plan provides a specific number of shares of our common stock available for awards and does not contain an annual or automatic increase in the number of available shares.



## Summary of Material Changes

*Increase in the Number of Available Shares.* The 2006 Plan currently provides that no more than 15,000,000 shares of common stock may be issued pursuant to Awards (as defined in the 2006 Plan) under the 2006 Plan. The Restated Plan will increase the maximum number of shares of common stock available for Awards by 8,000,000 shares, thereby increasing the maximum number of shares from 15,000,000 to 23,000,000 shares of common stock. Of the 15,000,000 shares of common stock originally authorized under the 2006 Plan, after all award grants made by our Compensation Committee from May 2006 to December 31, 2009, only 3,175,506 shares remain available for grant. As of March 1, 2010, 3,292,017 shares remain available for grant. Based on current plans and expectations, the Company believes that the increase in the number of shares available under the Restated Plan to 23,000,000 will provide the Company with sufficient shares reserved for issuance to cover the awards it anticipates granting over approximately the next three years to eligible participants.

*More Restrictive Method for Counting Full-Value Awards.* The 2006 Plan currently provides that any Awards made under the 2006 Plan whether, option, full-value restricted share unit (“RSU”) or otherwise, are treated identically for purposes of calculating the remaining the share reserve. This means that a grant of 1,000 options or a grant of 1,000 RSUs will each reduce the aggregate number of shares available under the Restated Plan by 1,000 shares. The Restated Plan includes a change in the way “full value” awards such as restricted stock or restricted stock units are treated for purposes of calculating their impact on the shares available for issuance under the Restated Plan. Under the Restated Plan, with respect to any award that is not a stock option, 1.62 shares of common stock will be subtracted from the total number of shares of common stock available under the Restated Plan for every share issued or transferred in respect of those awards or added back to the reserve in the event an award is forfeited or cancelled. The new ratio would apply to all awards made on or after May 12, 2010. The ratio of 1:1.62 is based on the historical volatility of the price of the Company’s common stock and is intended to ensure that the equity compensation effect of each type of award on the Company’s financial statements are approximately equivalent. Also, the Company believes that having such a ratio will reduce the potential dilution impact of the Restated Plan.

*Removal of Annual Share Cap Restriction.* The 2006 Plan currently limits the aggregate number of shares subject to awards granted during any calendar year to the sum of 3.5% of the total number of shares of the Company’s common stock outstanding. The Restated Plan does not contain a restriction on the number of shares underlying Awards that can be granted during any calendar year. The Company believes that this change is appropriate as it provides our Board and Compensation with flexibility in granting awards. Based on current plans, the Company expects to continue to award approximately the same level of equity awards as it has done over the last several years.

*Elimination of Liberal Share Counting Provision.* The current 2006 Plan currently allows the Company to “recycle” shares of common stock back into the reserve pool if they were not exercised for any reason. In reviewing the 2006 Plan, the Company noted that this liberal recycling plan was contrary to what several of our stockholders consider appropriate. The Restated Plan removes the ability of the Company to “recycle” shares back into the Restated Plan that are forfeited to the Company to reduce a liability that the recipient of the award would otherwise have to the Company or tax authorities. For instance, shares that are withheld for tax payments or to pay the exercise price, or shares not issued or delivered as a result of the whole or partial cash settlement of an outstanding award will not be added back into the Restated Plan reserve. The Company believes that this practice better aligns the share reserve calculation with the intent of providing for a limit on the number of shares available without seeking the consent of our stockholders.

*Deferred Dividends or Other Distributions on Performance-Based Awards.* The 2006 Plan currently provides that current dividends may be paid on awards of restricted stock, restricted stock units and performance shares. The Restated Plan requires that dividends and other distributions on restricted stock, restricted stock units and performance shares with restrictions or restriction periods that lapse upon the achievement of management objectives be deferred until and paid contingent on the achievement of the applicable management objectives.

Although the Company has never declared a dividend in the past and has not current plans to declare a dividend, the Company believes that this modification better implements the intent of restricted or performance awards that the employee should not receive a benefit from such awards until they are vested.

*No Repricing of Option Rights or Stock Appreciation Rights.* The current 2006 Plan prohibits amending an option right to reduce its exercise price without stockholder approval. The Restated Plan strengthens the prohibition against “repricing” option rights. Under the Restated Plan, except in connection with certain adjustment events, we may not, without stockholder approval (i) reduce the exercise price of outstanding option rights; or (ii) replace outstanding option rights with lower-priced awards.

### **Description of the Restated Plan**

*Purpose of the Plan.* The purpose of the Restated Plan, as with the 2006 Plan, is to encourage ownership in the Company by its employees, directors, consultants and advisors whose long-term employment by or involvement with the Company is considered essential to the Company’s continued progress and, thereby, aligning the interests of the award recipients and stockholders and permitting the award recipients to share in the Company’s success. The Restated Plan provides an essential component of the total compensation package offered to the Company’s employees. It reflects the importance placed by the Company on motivating employees to achieve superior results over the long-term and paying employees based on that kind of achievement. The Company strongly believes that its equity compensation programs and emphasis on employee stock ownership have been integral to the Company’s progress and that a continuation of and emphasis on those programs is necessary for the Company to achieve superior performance in the future. All of the approximately 742 employees and directors of the Company and its affiliates are eligible to participate in the Restated Plan.

*Shares Subject to the Restated Plan.* The Restated Plan provides that no more than 23,000,000 shares of common stock may be issued pursuant to Awards under the Restated Plan. The number of shares available for Awards, as well as the terms of outstanding Awards, are subject to adjustment as provided in the Restated Plan for stock splits, stock dividends, recapitalizations and other similar events.

Each share of common stock issued or transferred pursuant to an award of option rights or SARs will reduce the aggregate number of shares available under the Restated Plan by one share of common stock. Each share of common stock issued or transferred (and in the case of shares of restricted stock, released from all substantial risk of forfeiture) pursuant to an award other than of option rights will reduce the aggregate number of shares available under the Restated Plan by: (i) one share of common stock if issued or transferred pursuant to an award granted prior to the approval of the Restated Plan by the Company’s stockholders, or (ii) 1.62 shares of common stock if issued or transferred pursuant to an award granted after the approval of the Restated Plan by the Company’s stockholders. Any shares of common stock that again become available for issuance under the Restated Plan due to a forfeiture of an award originally granted after the adoption of the Restated Plan will be added back to the aggregate plan limit in this same manner.

Shares of common stock that are subject to any Award that expires, or is forfeited, cancelled or becomes unexercisable will again be available for subsequent Awards, except as prohibited by law. Shares that the Company refrains from delivering pursuant to an Award as payment of either the exercise price of an Award or applicable withholding and employment taxes will be considered exercised for purposes of calculating the shares available and will not be available for subsequent Awards.

*Administration.* Either the Board of Directors or a committee appointed by the Board will administer the Restated Plan. The Board of Directors and any committee exercising discretion under the Restated Plan from time to time are referred to as the “Committee.” Unless otherwise provided by the Board, the Compensation Committee will serve as the administrator of the Restated Plan. The Board of Directors may at any time appoint additional members to the Committee, remove and replace members of the Committee with or without cause, and fill vacancies on the Committee. To the extent permitted by law, the Committee may authorize one or more persons who are reporting persons for purposes of Rule 16b-3 under the Exchange Act (or other officers), to

make Awards to eligible persons who are not reporting persons for purposes of Rule 16b-3 under the Exchange Act (or other officers whom the Company has specifically authorized to make Awards). With respect to decisions involving an Award intended to satisfy the requirements of Section 162(m) of the Code, the Committee is to consist of two or more directors who are “outside directors” for purposes of that Code Section. The Committee may delegate administrative functions to individuals who are reporting persons for purposes of Rule 16b-3 of the Exchange Act, officers or employees of the Company or its affiliates.

Subject to the terms of the Restated Plan, the Committee has express authority to determine the Eligible Persons who will receive Awards, the number of shares of common stock or units to be covered by each Award, and the terms and conditions of Awards. The Committee has broad discretion to prescribe, amend and rescind rules relating to the Restated Plan and its administration, to interpret and construe the Restated Plan and the terms of all Award agreements, and to take all actions necessary or advisable to administer the Restated Plan. Within the limits of the Restated Plan, the Committee may accelerate the vesting of any Award, allow the exercise of unvested Awards, and may modify, replace, cancel or renew them.

The Restated Plan provides that the Company and its affiliates will indemnify members of the Committee and their delegates against any claims, liabilities or costs arising from the good faith performance of their duties under the Restated Plan. The Restated Plan releases these individuals from liability for good faith actions associated with the Restated Plan’s administration.

*Eligibility.* The Committee may grant options that are intended to qualify as incentive stock options (“ISOs”) only to employees, and may grant all other Awards to Eligible Persons. The Restated Plan and the discussion below use the term “Participant” to refer to an Eligible Person who has received an Award.

*Options.* Options granted under the Restated Plan provide Participants with the right to purchase shares of common stock at a predetermined exercise price. The Committee may grant options that are intended to qualify as ISOs or options that are not intended to so qualify (“Non-ISOs”). The Restated Plan also provides that ISO treatment may not be available for options that become first exercisable in any calendar year to the extent the value of the underlying shares that are the subject of the option exceed \$100,000 (based upon the fair market value of the shares of common stock on the option grant date).

*Exercise Price for Options.* The exercise price of Options may not be less than 100% of the fair market value on the grant date of the shares of common stock subject to the Award. The exercise price of ISOs may not be less than 110% of the fair market value on the grant date of the underlying shares of common stock subject to the Award for Participants who own more than ten percent of the Company’s shares of common stock on the grant date. Neither the Company nor the Committee shall, without stockholder approval, allow for a repricing within the meaning of the federal securities laws applicable to proxy statement disclosures.

*Exercise of Options.* To the extent exercisable in accordance with the agreement granting them, an Option may be exercised in whole or in part, and from time to time during its term, subject to earlier termination relating to a holder’s termination of employment or service. With respect to Options, the Committee has the discretion to accept payment of the exercise price in any of the following forms (or combination of them): cash or check in U.S. dollars, certain shares of common stock, and cashless exercise under a program the Committee approves. Options granted under the Restated Plan are required to be exercised within three months after termination of the optionee’s service (12 months if termination is due to death or disability and 6 months if termination is due to retirement), but in no event later than the expiration of the option’s ten-year term. In addition, the Company has a policy of allowing Directors who have served 4.5 years the right to exercise their options any time prior to the original option expiration. The term over which Participants may exercise Options may not exceed ten years from the date of grant (five years in the case of ISOs granted to employees who, at the time of grant, own more than 10% of the Company’s outstanding shares of common stock).

*Prohibition on Repricing.* Under the Restated Plan except in connection with certain adjustment events, we may not, without stockholder approval (i) reduce the exercise price of outstanding option rights; or (ii) replace outstanding option rights with lower-priced awards.

*Restricted Shares, Restricted Share Units, Unrestricted Shares and Deferred Share Units.* Under the Restated Plan, the Committee may grant (i) restricted shares that are forfeitable until certain vesting requirements are met, (ii) restricted share units which represent the right to receive shares of common stock after certain vesting requirements are met, and (iii) unrestricted shares as to which the Participant's interest is immediately vested. For restricted Awards, the Restated Plan provides the Committee with discretion to determine the terms and conditions under which a Participant's interests in such Awards become vested. The Restated Plan provides for deferred share units in order to permit certain directors, consultants or select members of management to defer their receipt of compensation payable in cash or shares of common stock (including shares that would otherwise be issued upon the vesting of restricted shares and restricted share units). Deferred share units represent a future right to receive shares of common stock.

Whenever shares of common stock are released pursuant to these Awards, the Participant will be entitled to receive additional shares of common stock that reflect any stock dividends that the Company's stockholders received between the date of the Award and issuance or release of the shares of common stock. Likewise, a Participant will be entitled to receive a cash payment reflecting cash dividends paid to the Company's stockholders during the same period.

*Performance Awards.* The Restated Plan authorizes the Committee to grant performance-based awards in the form of Performance Units that the Committee may or may not designate as "Performance Compensation Awards" that are intended to be exempt from Code section 162(m) limitations. In either case, Performance Awards vest and become payable based upon the achievement, within the specified period of time, of performance objectives applicable to the individual, the Company or any affiliate. The Committee decides the length of performance periods, but the periods may not be less than one fiscal year of the Company.

With respect to Performance Compensation Awards, the Restated Plan requires that the Committee specify in writing the performance period to which the Award relates, and an objective formula by which to measure whether and the extent to which the Award is earned on the basis of the level of performance achieved with respect to one or more performance measures. Once established for a performance period, the performance measures and performance formula applicable to the Award may not be amended or modified in a manner that would cause the compensation payable under the Award to fail to constitute performance-based compensation under Code Section 162(m).

Under the Restated Plan, the possible performance measures for Performance Compensation Awards include basic, diluted or adjusted earnings per share; sales or revenue; earnings before interest, taxes and other adjustments (in total or on a per share basis); basic or adjusted net income; returns on equity, assets, capital, revenue or similar measure; economic value added; working capital; total stockholder return; and product development, product market share, research, licensing, litigation, human resources, information services, mergers, acquisitions, and sales of assets of affiliates or business units. Each measure will be, to the extent applicable, determined in accordance with generally accepted accounting principles as consistently applied by the Company (or such other standard applied by the Committee) and, if so determined by the Committee, and in the case of a Performance Compensation Award, to the extent permitted under Code section 162(m), adjusted to omit the effects of extraordinary items, gain or loss on the disposal of a business segment, unusual or infrequently occurring events and transactions and cumulative effects of changes in accounting principles. Performance measures may vary from performance period to performance period, and from Participant to Participant, and may be established on a stand-alone basis, in tandem or in the alternative.

*Income Tax Withholding.* As a condition for the issuance of shares of common stock pursuant to Awards, the SIP requires satisfaction of any applicable federal, state, local or foreign withholding tax obligations that may arise in connection with the Award or the issuance of shares of common stock.

*Transferability.* Awards may not be sold, pledged, assigned, hypothecated, transferred or disposed of other than by will or the laws of descent and distribution, except to the extent the Committee permits lifetime transfers to charitable institutions, certain family members or related trusts or as otherwise approved by the Committee.

*Certain Corporate Transactions.* The Committee shall equitably adjust the number of shares covered by each outstanding Award, and the number of shares that have been authorized for issuance under the Restated Plan but as to which no Awards have yet been granted or that have been returned to the Restated Plan upon cancellation, forfeiture or expiration of an Award, as well as the price per share covered by each such outstanding Award, to reflect any increase or decrease in the number of issued shares resulting from a stock split, reverse stock split, stock dividend, combination, recapitalization or reclassification of the shares of common stock, or any other increase or decrease in the number of issued shares effected without receipt of consideration by the Company. In the event of any such transaction or event, the Committee may provide in substitution for any or all outstanding Options under the Restated Plan such alternative consideration (including securities of any surviving entity) as it may in good faith determine to be equitable under the circumstances and may require in connection therewith the surrender of all Options so replaced. In any case, such substitution of securities will not require the consent of any person who is granted options pursuant to the Restated Plan.

In addition, in the event or in anticipation of a change in control, the Committee may at any time in its sole and absolute discretion and authority, without obtaining the approval or consent of the Company's stockholders or any Participant with respect to his or her outstanding Awards (except to the extent an Award provides otherwise), take one or more of the following actions: (a) arrange for or otherwise provide that each outstanding Award will be assumed or substituted with a substantially equivalent award by a successor corporation or a parent or subsidiary of such successor corporation; (b) accelerate the vesting of Awards for any period (and may provide for termination of unexercised Options at the end of that period) so that Awards shall vest (and, to the extent applicable, become exercisable) as to the shares of common stock that otherwise would have been unvested and provide that repurchase rights of the Company with respect to shares of common stock issued upon exercise of an Award shall lapse as to the shares of common stock subject to such repurchase right; (c) arrange or otherwise provide for payment of cash or other consideration to Participants in exchange for the satisfaction and cancellation of outstanding Awards; or (d) terminate upon the consummation of the transaction, provided that the Committee may in its sole discretion provide for vesting of all or some outstanding Awards in full as of a date immediately prior to consummation of the change in control. To the extent that an Award is not exercised prior to consummation of a transaction in which the Award is not being assumed or substituted, such Award shall terminate upon such consummation.

Notwithstanding the above, in the event a Participant holding an Award assumed or substituted by the successor corporation in a change in control is involuntarily terminated by the successor corporation in connection with, or within 12 months following consummation of, the change in control, then any assumed or substituted Award held by the terminated Participant at the time of termination shall accelerate and become fully vested (and exercisable in full in the case of Options), and any repurchase right applicable to any shares of common stock shall lapse in full. The acceleration of vesting and lapse of repurchase rights provided for in the previous sentence shall occur immediately prior to the effective date of the Participant's termination.

In the event of any distribution to the Company's stockholders of securities of any other entity or other assets (other than dividends payable in cash or stock of the Company) without receipt of consideration by the Company, the Committee may, in its discretion, appropriately adjust the price per share covered by each outstanding Award to reflect the effect of such distribution. Finally, if the Company dissolves or liquidates, all Awards will immediately terminate, subject to the ability of the Board to exercise any discretion that the Board may exercise in the case of a change in control.

As discussed above, In the event of a merger or the sale of substantially all of our assets, each option issued under the 2006 Share Incentive Plan may be assumed or substituted by the successor corporation. However, pursuant to our change in control policy all outstanding options vest on a change in control. If the successor corporation does not agree to assume or substitute options, each option becomes fully vested and exercisable for a period of 30 days from the date the Board notifies the optionee of the option's full exercisability, after which period the option terminates.

*Term of the Restated Plan; Amendments and Termination.* The term of the Restated Plan is ten years from the date of stockholder approval of the 2006 Plan. The Board of Directors may from time to time, amend, alter, suspend, discontinue or terminate the Restated Plan; provided that no amendment, suspension or termination of the Restated Plan shall materially and adversely affect Awards already granted unless it relates to an adjustment pursuant to certain transactions that change the Company's capitalization or it is otherwise mutually agreed between the Participant and the Committee. In addition, the Committee may not cancel an outstanding option that is out-of-the-money for the purpose of reissuing the option to the Participant at a lower exercise price or granting a replacement award of a different type. Notwithstanding the foregoing, the Committee may amend the Restated Plan to eliminate provisions which are no longer necessary as a result of changes in tax or securities laws or regulations, or in the interpretation thereof.

*Termination, Rescission and Recapture.* Each Award under the Restated Plan is intended to align the Participant's long-term interest with those of the Company. If the Participant engages in certain activities (such as disclosure of confidential or proprietary information without Company authorization, or breach of certain agreements relating to the protection of the Company's intellectual property), either during employment or after employment with the Company terminates for any reason, the Participant is deemed to be acting contrary to the long-term interests of the Company. In such cases, except as otherwise expressly provided in the Award Agreement, the Company may terminate any outstanding, unexercised, unexpired, unpaid, or deferred Awards, rescind any exercise, payment or delivery pursuant to the Award, or recapture any common stock (whether restricted or unrestricted) or proceeds from the Participant's sale of Shares issued pursuant to the Award.

*Expected U.S. Federal Income Tax Consequences.* The following is a brief summary of certain tax consequences of certain transactions under the Restated Plan. This summary is not intended to be complete and does not describe state or local tax consequences. Special rules may apply to the Company's officers, directors or greater than ten percent stockholders. Participants in the Restated Plan should review the current tax treatment with their individual tax advisors at the time of grant, exercise or any other transaction relating to an Award or the underlying shares.

Under the Code, the Company will generally be entitled to a deduction for federal income tax purposes at the same time and in the same amount as the ordinary income that Participants recognize pursuant to Awards (subject to the Participant's overall compensation being reasonable, and to the discussion below with respect to Code section 162(m)). For Participants, the expected U.S. federal income tax consequences of Awards are as follows:

*Non-ISOs.* A Participant will not recognize income at the time a Non-ISO is granted. At the time a Non-ISO is exercised, the Participant will recognize ordinary income in an amount equal to the excess of (a) the fair market value of the shares of common stock issued to the Participant on the exercise date over (b) the exercise price paid for the shares. At the time of sale of shares acquired pursuant to the exercise of a Non-ISO, the appreciation (or depreciation) in value of the shares after the date of exercise will be treated either as short-term or long-term capital gain (or loss) depending on how long the shares have been held.

*ISOs.* A Participant will not recognize income upon the grant of an ISO. There are generally no tax consequences to the Participant upon exercise of an ISO (except the amount by which the fair market value of the shares at the time of exercise exceeds the option exercise price is a tax preference item possibly giving rise to an alternative minimum tax). If the shares of common stock are not disposed of within two years from the date the ISO was granted or within one year after the ISO was exercised, any gain realized upon the subsequent disposition of the shares will be characterized as long-term capital gain and any loss will be characterized as long-term capital loss. If either of these holding period requirements are not met, then a "disqualifying disposition" occurs and (a) the Participant recognizes gain in the amount by which the fair market value of the shares at the time of exercise exceeded the exercise price for the ISO and (b) any remaining amount realized on disposition (except for certain "wash" sales, gifts or sales to related persons) will be characterized as capital gain or loss.

*Restricted Shares, Restricted Share Units, Deferred Share Units, and Performance Awards.* In general, a Participant will not recognize income at the time of grant of restricted shares, restricted share units, deferred share units or Performance Awards, unless the Participant elects with respect to restricted shares or restricted share units to accelerate income taxation to the date of the Award. In this event, a Participant would recognize ordinary income equal to the excess of the market value of the restricted shares over any amount the Participant pays for them (in which case subsequent gain or loss would be capital in nature). In the absence of an election to accelerate income taxation to the date of an Award, a Participant must recognize taxable compensation income equal to the value of any cash or shares of common stock that the Participant receives when the Award vests. The same tax consequences apply to Performance Awards.

*Special Tax Provisions.* Under certain circumstances, the accelerated vesting, cash-out or accelerated lapse of restrictions on Awards in connection with a change in control of the Company might be deemed an “excess parachute payment” for purposes of the golden parachute tax provisions of Code Section 280G, and the Participant may be subject to a 20% excise tax and the Company may be denied a tax deduction. Furthermore, the Company may not be able to deduct the aggregate compensation in excess of \$1,000,000 attributable to Awards that are not “performance-based” within the meaning of Code Section 162(m) in certain circumstances.

*Income Taxes and Deferred Compensation.* The Restated Plan provides that participants are solely responsible and liable for the satisfaction of all taxes and penalties that may arise in connection with Awards (including any taxes arising under Section 409A of the Code), and that the Company will not have any obligation to indemnify or otherwise hold any Participant harmless from any or all of such taxes. Nevertheless, the Restated Plan authorizes the Committee to organize any deferral program, to require deferral election forms, and to grant or to unilaterally modify any Award in a manner that (i) conforms with the requirements of Section 409A of the Code; (ii) that voids any Participant election to the extent it would violate Section 409A of the Code; and (iii) for any distribution election that would violate Section 409A of the Code, to make distributions pursuant to the Award at the earliest to occur of a distribution event that is allowable under Section 409A of the Code or any distribution event that is both allowable under Section 409A of the Code and is elected by the Participant, with the Committee’s consent, in accordance with Section 409A.

*New Plan Benefits.* The Committee will grant Awards under the Restated Plan at its discretion. Consequently, it is not possible to determine at this time the amount or dollar value of Awards to be provided under the Restated Plan, other than to note that the Committee has not granted Awards that are contingent upon the approval of the Restated Plan.

**THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE “FOR” THE APPROVAL OF THE AMENDED AND RESTATED BIOMARIN PHARMACEUTICAL INC. 2006 SHARE INCENTIVE PLAN. IF YOU SIGN AND RETURN THE ENCLOSED PROXY CARD, UNLESS YOU DIRECT TO THE CONTRARY ON THAT CARD, OR VIA INTERNET OR TELEPHONE, THE SHARES REPRESENTED BY THAT PROXY CARD WILL BE VOTED “FOR” THE APPROVAL OF THE AMENDED AND RESTATED BIOMARIN PHARMACEUTICAL INC. 2006 SHARE INCENTIVE PLAN. THE AFFIRMATIVE VOTE OF HOLDERS OF A MAJORITY OF THE SHARES OF COMMON STOCK WHICH ARE PRESENT IN PERSON OR BY PROXY AT THE ANNUAL MEETING, ENTITLED TO VOTE ON THIS PROPOSAL AND WHICH HAVE ACTUALLY VOTED IS REQUIRED FOR APPROVAL OF THIS PROPOSAL.**

**Equity Compensation Plan Information**

The following table provides certain information with respect to all of BioMarin's equity compensation plans in effect as of December 31, 2009.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights(1)</u>	<u>Weighted average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans</u>
Equity compensation plans approved			
by stockholders .....	14,046,895	\$19.04	23,178,558
Equity compensation plans not approved			
by stockholders .....	—	—	—
Total(2) .....	<u>14,046,895</u>	<u>\$19.04</u>	<u>23,178,558</u>

- (1) Does not include any shares of our common stock issuable under our Amended and Restated 2006 Employee Stock Purchase Plan. The Company issues shares under this plan once every six months based on employee elections in the preceding six months. Pursuant to the terms of this plan, the number of shares to be issued and the price per share is not determined until immediately before the date of issuance. Also, does not include 333,324 restricted stock units that were outstanding at December 31, 2009 with a weighted average exercise price of \$0.00 per share.
- (2) As of December 31, 2009, the weighted average remaining term of the 14,046,895 options outstanding was 6.5 years.



**PROPOSAL THREE: RATIFICATION OF SELECTION OF THE INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR BIOMARIN**

The Audit Committee of the Board has selected KPMG LLP, an independent registered public accounting firm, to audit our financial statements for the year ending December 31, 2010, and recommends that stockholders vote for ratification of such selection. Although stockholder ratification is not required by our Bylaws or otherwise, the Board has determined that it is desirable to request approval of this selection by the stockholders as a matter of good corporate practice. Notwithstanding this selection, the Audit Committee, in its discretion, may direct the appointment of a new independent registered public accounting firm at any time during the year if the Audit Committee feels that such a change would be in our best interests of our stockholders. In the event of a negative vote on ratification, the Audit Committee may reconsider its selection.

**Independent Registered Public Accounting Firm**

Since June 11, 2002, KPMG LLP has served as our independent registered public accounting firm.

Representatives of KPMG LLP plan to attend the Annual Meeting and will be available to answer appropriate questions from stockholders and, although they do not expect to do so, they will have the opportunity to make a statement if they so desire.

The following is a summary of the fees and services provided for fiscal years 2009 and 2008.

<u>Description of Services Provided by KPMG LLP</u>	<u>Year Ended December 31, 2009</u>	<u>Year Ended December 31, 2008</u>
<i>Audit Fees:</i> .....	\$987,440	\$886,418
<i>Audit Related Fees:</i> These services relate to assurance and related services reasonably related to the performance of the audit or review of financial statements not included in Audit Fees above. ....	none	none
<i>Tax Compliance Fees:</i> These services relate to the preparation of federal, state and foreign tax returns and other filings. ....	none	none
<i>Tax Consulting and Advisory Services:</i> These services primarily relate to the area of tax strategy and minimizing Federal, state, local and foreign taxes. ....	none	none
<i>All Other Fees:</i> .....	\$ 38,098(1)	67,465(2)

- (1) Reflects fees paid to KPMG for non-audit services performed in 2009 for an internal control review over our Enterprise Resource Planning System implementation.
- (2) Reflects fees paid to KPMG for non-audit services performed in 2008 for an internal control review over our Enterprise Resource Planning System implementation.

As provided in the Audit Committee charter, the Audit Committee pre-approves all of the services provided by its independent registered public accounting firm. 100% of the above services and estimates of the expected fees were reviewed and approved by the Audit Committee before the respective services were rendered.

The Audit Committee has considered the nature and amount of the fees billed by KPMG LLP and believes that the provision of the services for activities unrelated to the audit is compatible with maintaining KPMG LLP's independence.

**THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE "FOR" THE RATIFICATION OF THE SELECTION OF KPMG LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM. IF YOU SIGN AND RETURN THE ENCLOSED PROXY CARD, OR VOTE VIA INTERNET OR TELEPHONE UNLESS YOU DIRECT TO THE CONTRARY ON THAT CARD, OR VIA INTERNET OR TELEPHONE, THE SHARES REPRESENTED BY THAT PROXY CARD WILL BE VOTED "FOR" THE RATIFICATION OF THE SELECTION OF KPMG LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM.**

**OTHER INFORMATION RELATED TO BIOMARIN, THE DIRECTORS  
AND EXECUTIVE OFFICERS**

**Security Ownership of Certain Beneficial Owners**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 1, 2010 as to: (i) each person, or group of affiliated persons, who is known by us to own beneficially more than 5% of our common stock; (ii) each of our directors; (iii) each of our Named Executive Officers, as defined below; and (iv) all of the directors and current executive officers as a group.

Except as otherwise noted, the persons or entities in this table have sole voting and investing power with respect to all the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. The information with respect to each person specified was supplied or confirmed by such person or based upon statements filed with the SEC. Except as otherwise indicated, the mailing address for each stockholder in the table below is c/o BioMarin Pharmaceutical Inc., 105 Digital Drive, Novato, California 94949.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Subject To Options(1)</u>	<u>Percentage of Common Stock(2)</u>
Citadel Investment Group, L.L.C.(3) . . . . .	10,128,963	—	10.0%
Vanguard Horizon Funds(4) . . . . .	5,049,100	—	5.0%
PRIMECAP Management Company(5) . . . . .	8,991,724	—	8.9%
FMR LLC(6) . . . . .	11,015,504	—	10.9%
T.Rowe Price Associates, Inc.(7) . . . . .	8,184,090	—	8.1%
Michael Grey . . . . .	72,500	63,750	*
Elaine J. Heron, Ph.D. . . . .	136,250	101,250	*
Joseph Klein, III(8) . . . . .	76,250	41,250	*
Pierre Lapalme . . . . .	140,500	123,750	*
V. Bryan Lawlis, Ph.D. . . . .	58,750	56,250	*
Alan J. Lewis, Ph.D. . . . .	86,250	71,250	*
Richard A. Meier . . . . .	71,500	63,750	*
Jean-Jacques Bienaimé . . . . .	1,290,350	1,274,410	1.3%
Stephen Aselage . . . . .	264,568	256,713	*
Jeffrey H. Cooper . . . . .	193,959	183,375	*
Robert Baffi, Ph.D. . . . .	488,302	444,115	*
Henry J. Fuchs, M.D., Ph.D . . . . .	48,332	48,332	*
All current executive officers and directors as a group (14 persons) . . . . .	3,163,806	2,949,506	3.1%

\* Represents less than 1% of BioMarin's outstanding common stock.

- (1) The "Number of Shares Subject to Options" enumerates for each 5% stockholder, director and Named Executive Officer and for all executive officers and directors in the aggregate, the shares of common stock subject to options exercisable within 60 days of March 1, 2010. These shares are included in the amounts shown in the "Number of Shares Beneficially Owned" column.
- (2) The "Percentage of Common Stock" column is based on 101,144,731 shares of common stock outstanding on March 1, 2010. Shares of common stock subject to options that are exercisable within 60 days of March 1, 2010 are deemed outstanding and beneficially owned by the person holding the options or warrants for the purpose of computing the percentage ownership of the person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.
- (3) Information based upon statements filed on Schedule 13G/A with the SEC on February 16, 2010. The mailing address for Citadel Investment Group, L.L.C. is 131 S. Dearborn Street, 32<sup>nd</sup> Floor, Chicago, IL 60603. Citadel Investment Group II, L.L.C., Kenneth Griffin, Citadel Holdings I LP, Citadel Advisors LLC, Citadel Equity Fund Ltd. and Citadel Derivative Group LLC, each have shared voting power of 10,128,963 shares.

- (4) Information based upon statements filed on Schedule 13G with the SEC on February 4, 2010. The mailing address for Vanguard Horizon Funds-Vanguard Capital Opportunity Fund is 100 Vanguard Blvd., Malvern, PA 19355.
- (5) Information is based upon statements filed on Schedule 13G/A with the SEC on February 11, 2010. The mailing address for PRIMECAP Management Company is 225 South Lake Avenue, #400, Pasadena, CA 91101.
- (6) Information based upon statements filed on Schedule 13G/A with the SEC on February 17, 2009. The mailing address for FMR LLC is 82 Devonshire Street, Boston, MA 02109. Fidelity Management & Research Company (“Fidelity”), a wholly-owned subsidiary of FMR LLC, is the beneficial owner of 10,866,504 shares as a result of acting as investment advisor to various investment companies registered under Section 8 of the Investment Company Act of 1940, as amended. Each of Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, have sole power to dispose of the 10,866,504 shares. Neither FMR LLC nor Edward C. Johnson 3d has the sole power to vote or direct the voting of the shares owned directly by Fidelity, which power resides with the Fidelity Fund’s Board of Trustees.
- (7) Information based upon statements filed on Schedule 13G/A with the SEC on February 12, 2010. The mailing address for T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, MD 21202.
- (8) Mr. Klein resigned from the Board of Directors on March 19, 2010.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act, requires our directors and executive officers and persons who beneficially own more than 10% of a registered class of our equity securities to file reports of ownership and reports of changes in the ownership with the SEC. Executive officers, directors and greater than 10% stockholders are required by the SEC to furnish us with copies of all Section 16(a) forms they file.

To the best of our knowledge, except as noted below and based solely on a review of the copies of such reports furnished to us or written representation that no other reports were required, during the fiscal year ended December 31, 2009, all officers, directors, and greater than 10% stockholders complied with all Section 16(a) filing requirements.

**Executive Officers**

The following table sets forth certain information concerning our executive officers as of March 25, 2010.

<u>Name</u>	<u>Age</u>	<u>Position with BioMarin</u>
Jean-Jacques Bienaimé .....	56	Chief Executive Officer
Henry J. Fuchs, M.D., Ph.D. ....	52	Executive Vice President and Chief Medical Officer
Stephen Aselage .....	58	Executive Vice President and Chief Business Officer
Robert A. Baffi, Ph.D. ....	55	Executive Vice President, Technical Operations
Jeffrey H. Cooper .....	54	Senior Vice President, Chief Financial Officer
G. Eric Davis .....	39	Senior Vice President, General Counsel and Secretary
Mark Wood .....	43	Vice President, Human Resources

There are no family relationships between any of our Directors and any of our executive officers.

*Stephen Aselage* joined BioMarin in July 2005 and serves as our Executive Vice President and Chief Business Officer. From June 2005 to December 2009, Mr. Aselage served as Senior Vice President, Global Commercial Development. From February 2004 to June 2005, Mr. Aselage served as Executive Vice President of Global Commercial Operations at Cell Therapeutics, a biotechnology company focused on cancer therapeutics. From September 2003 to January 2004, Mr. Aselage served as Senior Vice President of North American Sales and Marketing for Genzyme Corporation following Genzyme’s acquisition of Sangstat Medical Corporation where he had worked since February 1999. While at Sangstat, Mr. Aselage restructured the company’s sales, marketing and medical affairs groups. From 1996 through 1999, Mr. Aselage served as Director

of Sales and Marketing at Advanced Tissue Sciences. Earlier in his career, Mr. Aselage held a variety of sales and sales management positions at biotechnology and pharmaceutical companies including Rhône-Poulenc Rorer Pharmaceuticals (now Sanofi-Aventis), Genentech, Inc., and Bristol Laboratories. Mr. Aselage holds a B.S. in biology from the University of Notre Dame.

**Robert A. Baffi, Ph.D.**, joined BioMarin in May 2000 and currently serves as our Executive Vice President of Technical Operations, responsible for overseeing manufacturing, process development, quality, compliance and analytical chemistry departments. From 2000 to December 2009, Dr. Baffi serviced as Senior Vice President of Technical Operations. From 1986 to 2000, Dr. Baffi served in a number of increasingly responsible positions at Genentech, primarily in the functional area of quality control. Prior to Genentech, Dr. Baffi worked for Cooper BioMedical as a research scientist and at Becton Dickson Research Center as a post-doctoral fellow. Dr. Baffi has contributed to more than 20 regulatory submissions for product approval in the United States and Europe and to more than 50 regulatory submissions for investigational new drug testing. Dr. Baffi received a Ph.D., M. Phil and a B.S. in biochemistry from the City University of New York and an M.B.A. from Regis University.

**Jeffrey H. Cooper, C.P.A. (inactive)**, joined BioMarin in October 2003 and currently serves as our Senior Vice President, Chief Financial Officer. Prior to joining BioMarin, Mr. Cooper served as Vice President of Finance at Matrix Pharmaceutical, where he worked since June 1998. In his career, he held numerous finance-related positions within the health care and pharmaceutical industries, including corporate controller at Foundation Health Systems, and director of business analysis at Syntex Corporation, a company he worked for from 1983 to 1995. Mr. Cooper, a certified public accountant, earned a B.A. in economics from the University of California, Los Angeles, and an M.B.A. from Santa Clara University.

**G. Eric Davis** joined BioMarin in March 2004, and currently serves as our Senior Vice President, General Counsel and Secretary. From 2004 to December 2005, Mr. Davis served as our Vice President, General Counsel and Secretary. From 2000 to 2004, Mr. Davis worked in the San Francisco office of Paul, Hastings, Janofsky & Walker LLP, where he served on the firm's national securities practice committee. Mr. Davis has represented public and private companies and venture capital and investment banking firms in a wide range of corporate and securities matters, mergers and acquisitions, strategic alliance matters, and intellectual property-related business transactions. His experience involves a variety of industries, including biotechnology and life sciences. Mr. Davis received a B.A. in political economy from the University of California, Berkeley, and a J.D. from the University of San Francisco School of Law.

**Henry J. Fuchs, M.D.**, joined BioMarin in March 2009, and currently serves as our Executive Vice President and Chief Medical Officer. From March 2009 to December 2009, Dr. Fuchs served as our Senior Vice President and Chief Medical Officer. From September 2005 until December 2008, Dr. Fuchs served as Executive Vice President and Chief Medical Officer for Onyx Pharmaceuticals, a biopharmaceutical company. Dr. Fuchs was Chief Executive Officer of IntraBiotics, a biotechnology company. He originally joined IntraBiotics in 1996 as Vice President of Clinical Affairs before assuming the role of President and Chief Operating Officer in 2001. From 1987 to 1996, Dr. Fuchs was employed by Genentech where he held a number of positions of increasing responsibility. While there he led the clinical team that played an integral role in the approval of Herceptin, a breast cancer treatment, as well as Pulmozyme, a therapeutic for cystic fibrosis. Dr. Fuchs earned an M.D. degree from George Washington University and a B.A. in biochemical sciences from Harvard College. Dr. Fuchs serves on the board of Ardea Biosciences.

**Mark Wood** joined BioMarin in May 2004 as Senior Director, Human Resources and was appointed to his current position as Vice President of Human Resources in June 2006. From June 2002 to May 2004, Mr. Wood was the sole proprietor of a human resources consulting practice assisting clients in the areas of compensation, leadership development, organizational effectiveness, and general human resources matters. From September 1999 to June 2002, Mr. Wood served as Vice President of Human Resources & Administration at AG Consulting, a global professional services firm that he joined in October 1998. Prior to joining AG Consulting, Mr. Wood was the manager of compensation and quantitative analysis at Genentech from 1993 to 1998 and held

a variety of human resources positions at Wells Fargo Bank from 1991 to 1993. Mr. Wood holds a Master's degree in Industrial and Labor Relations from Cornell University, and a Bachelor's degree in Psychology and Management from the State University of New York at Buffalo.

## EXECUTIVE COMPENSATION

### COMPENSATION DISCUSSION AND ANALYSIS

This section discusses the principles underlying our executive compensation decisions and the most important factors relevant to an analysis of these decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our Named Executive Officers (whom we refer to in this discussion as our NEOs) and places in perspective the data presented in the tables and other quantitative information that follows this section.

#### *Compensation Objectives and Philosophy*

We believe that attracting and retaining superior employees at all levels of the Company is a key to the success of our business and creating long-term stockholder value, and therefore is a primary goal of our compensation program. We recognize that highly qualified executives and other skilled professionals have many career opportunities and that their choices to pursue their careers with us may rest in part upon the compensation we offer. Accordingly, our compensation philosophy is to provide competitive overall compensation that attracts and retains top performers. To achieve these goals, our compensation program is structured to:

- provide total compensation and compensation elements that are competitive with those companies that are competing for available employees;
- provide a mix of compensation that provides a meaningful base compensation, with a potential to earn additional amounts based on achievement of defined corporate goals, generally with an expected completion within 12 months, and provide employees with the opportunity to share in the long-term growth of the Company through equity compensation; and
- reward exceptional performance by individual employees.

The market for talented individuals in the biotechnology industry is very competitive nationally, and particularly in the San Francisco Bay Area. While we consider peer groups, as discussed below, and receive advice from an independent compensation consultant, no single factor is determinative in setting compensation structure or allocating among elements of compensation. To ensure that we are appropriately compensating our employees and that we have appropriate human resources to execute on our business plans, our Compensation Committee and our Board consider a wide variety of information and use their judgment in making compensation decisions. In order to ensure that our compensation is competitive, our Compensation Committee has adopted a goal to target typical base salaries at the 50<sup>th</sup> percentile and total compensation at the 75<sup>th</sup> percentile of our peer group, although individuals may be paid above or below these levels based on their experience, performance, position requirements and/or future contribution to the business.

In reviewing the Company's 2009 performance, the Compensation Committee considered the Company's success during 2009, including advancing its product pipeline, the net product revenue growth for Naglazyme (27.1%) and Kuvan (64.5%) and a 9.5% growth in total revenue over 2008. In addition, the Compensation Committee considered the achievement of the Company's product pipeline, including the initiation of the clinical trials of GALNS and PEG-PAL, and the successful acquisition of Firdapse from Huxley Pharmaceuticals Inc. However, the Compensation Committee also noted the challenges affecting the broad economy and the Company's industry, which generally indicated that a more modest increase in compensation as compared to prior years, was appropriate.

### ***Our Compensation Committee***

Our Compensation Committee is composed entirely of independent directors, within the meaning of NASDAQ Listing Rule 5605(a)(2). Our Compensation Committee has responsibility for setting our general compensation policy, plans, and programs. The duties of the Compensation Committee include:

- Recommending to the full Board the compensation of the Chief Executive Officer and outside directors;
- Setting the compensation, both the specific elements (i.e., salary, bonus, and equity grants) and amount, of the other executive officers;
- Approving the peer group for executive and director compensation benchmarking;
- Approving the goals and performance requirements, thresholds, and maximum funding for our annual bonus program;
- Administering our 2006 Share Incentive Plan and our Non-Qualified Deferred Compensation Plan; and
- Consulting with outside experts in the review and analysis of executive and director compensation.

These responsibilities are detailed in the charter of the Compensation Committee. The full text of the Compensation Committee Charter can be found in the Corporate Governance section of the Investors section of our website at [www.bmrn.com](http://www.bmrn.com). The composition of the Compensation Committee is determined by our Board, after a recommendation by the Corporate Governance and Nominating Committee.

### ***Compensation Process***

The implementation of our compensation philosophy is done under the supervision of the Compensation Committee. The compensation for our Chief Executive Officer, Mr. Bienaimé (whom we refer to in this discussion as the CEO), is approved by our Board, after the Compensation Committee provides its analysis and recommendation. The Compensation Committee has direct responsibility for establishing the compensation for the direct reports to the CEO, including all of our executive officers. To assist the Compensation Committee, the CEO and the Vice President of Human Resources make recommendations to the Compensation Committee as to specific elements (i.e. salary, bonus and equity grants) of compensation. Management, under the guidelines and policies established by the Compensation Committee, makes decisions on all aspects of compensation for non-executive officer employees.

Our CEO, Mr. Davis, our Senior Vice President, General Counsel and Secretary, and Mr. Wood, our Vice President, Human Resources, in addition to the Committee's advisor, regularly attend portions of the Compensation Committee meetings for the purpose of providing analysis, information, and management's recommendations on various human resources and compensation matters. These employees generally do not participate in the executive sessions of the Compensation Committee.

Throughout 2009 and continuing through the date of this proxy statement, the Compensation Committee engaged Radford Surveys Consulting ("Radford"), an Aon Consulting Company, as an independent advisor to the Compensation Committee. Radford conducted analysis and provided advice on, among other things, the appropriate peer group, CEO and executive compensation, equity compensation, and compensation trends in the biotechnology industry. Radford reports directly to the Compensation Committee, with the committee retaining sole authority to direct the work and employ the firm. As part of its analysis, Radford collected and analyzed compensation information from a comparative group of biotechnology companies or peer group approved by the Compensation Committee. The Compensation Committee evaluates the criteria used in establishing the peer group at least annually, to ensure that it appropriately represents the companies competing with us to attract and retain human talent. The Committee seeks input from management in addition to the independent advisor to ensure the group is consistent with the Company's current business model. The list of companies in the peer group is approved based on various factors including size, market capitalization, stage of development, product

revenue, and product focus. During 2009, we used a peer group that included biotechnology companies with a market capitalization of between \$1-5 billion and expected revenues from product sales in 2009 of \$100-500 million. Based on these criteria, the peer group included in the 2009 analysis by Radford was composed of the following companies: Alexion Pharmaceuticals; Alkermes, Inc.; Amylin Pharmaceuticals, Inc.; Auxilium Pharmaceuticals; Cephalon Inc.; Cubist Pharmaceuticals; CV Therapeutics; Endo Pharmaceuticals; Genomic Health; Intermune; ISIS Pharmaceuticals; Myriad Genetics; Nektar Therapeutics; Onyx Pharmaceuticals; OSI Pharmaceuticals; Regeneron Pharmaceuticals; Sepracor; The Medicines Company; United Therapeutics; United Therapeutics; Vertex Pharmaceuticals; ViroPharma; Zymogenetics (the "2009 Peer Group"). The 2009 Peer Group was used when considering all of the recent compensation decisions.

### ***Elements of Compensation Package***

We generally provide three major categories of compensation: base salary, an annual cash bonus, and equity compensation. We believe that the combination of these three elements allow us to attract and retain employees in the very competitive San Francisco Bay Area and national market and to balance the motivation of all of our employees to execute on immediate goals and to remain conscious of our strategic imperatives and long-term goals.

The allocation of the individual components of compensation is based on a number of factors, including competitive market conditions and on classes of employees. Generally, the percentage of compensation at risk, either in the form of cash bonus or equity compensation, increases for more senior employees. Our executive officers have the highest percentage of their total compensation at risk and the highest percentage of total compensation allocated to equity compensation. We believe that this is appropriate as the more senior employees have more influence on whether or not we achieve our strategic imperatives and long-term goals.

The bonus program is an annual cash bonus, which is based on both meeting corporate and individual performance goals. The details of this program are discussed below.

Our equity compensation has historically been in the form of stock options. Our option grant practice is described below. Beginning in 2007, our Board and senior management began to receive a portion of their equity compensation in the form of restricted stock units. We believe that this is an appropriate adjustment to increase the share ownership of our management while limiting the total number of shares issued in our equity compensation program to minimize stockholder dilution.

Additionally, we provide a comprehensive benefits package, including health insurance, dental insurance, life insurance, disability insurance, a 401(k) matching program, and an Employee Stock Purchase Plan, which is intended to meet the requirements of Section 423 of the Code. These benefits are generally available to all employees on an equal basis, including our NEOs. The 401(k) matching program matches 100% of the employee's contribution up to the lesser of 2% of salary or \$4,000.

### ***Salary Adjustments***

We generally review our compensation practices on an annual basis in a process that takes several meetings. The first step in the process is that the Compensation Committee, with the support of management and our independent compensation consultant, reviews trends in the biotechnology compensation practices and reviews and approves the list of peer companies used in the later stages of the process.

Thereafter, management presents the Compensation Committee with recommendations regarding proposed adjustments to compensation elements and a variety of supporting data, including comparative compensation information from the approved peer group. This is presented individually for executive officers, including the NEOs, and based on classes of position for all other employees. Management includes significant supporting data with the presentation. These recommendations are discussed with and without management present and are discussed with the independent compensation consultant. The Compensation Committee then determines what, if any, adjustments to the compensation elements are appropriate for employees other than the CEO.

The Compensation Committee also reviews the market information provided by the independent compensation consultant, considers the CEO's performance and experience, and makes recommendations for adjustments to the CEO's compensation. These discussions are conducted in executive sessions without involvement by management. The Compensation Committee then presents the recommendations for the CEO to the Board for consideration and approval. All compensation decisions for the CEO must be approved by the Board. Prior to setting Mr. Bienaimé's salary increase for 2009, the Committee engaged Radford to perform an independent review of Mr. Bienaimé's compensation. In addition to the review, the Compensation Committee and the Board considered the Company's success in advancing its product pipeline, the acquisition of the product candidate for Duchenne muscular dystrophy, the revenue growth for Naglazyme and Kuvan, and the overall appreciation of the Company's share price and determined an increase at the upper end of the peer group range was appropriate. In December 2008, the Board approved a 6% increase to Mr. Bienaimé's salary.

In addition, each NEO is also individually evaluated based on their experience and tenure. For instance, Mr. Aselage and Dr. Baffi have very significant experience at their current positions. Accordingly, the Compensation Committee believes that it is appropriate to compensate them at the higher end of the peer group. In contrast, Mr. Cooper and certain other executive officers such as Mr. Davis and Mr. Wood have comparably less tenure in their current position or with BioMarin. Accordingly, in December 2008 for fiscal year 2009, the Compensation Committee approved increases to base salaries for each of the NEOs ranging from five to ten percent, which was generally consistent with the salary increases provided to the nonexecutive employees of the Company.

In setting Mr. Bienaimé's base salary increase for 2010, the Compensation Committee and the Board considered the Company's success in launching Kuvan and continuing to expand the Naglazyme revenue the initiation of the PEG-PAL trial, and the pre-IND work related to GALNS, and balanced this against the challenging macro economic environment. In December 2009, the Board approved a 5% increase to Mr. Bienaimé's base salary for 2010.

In December 2009, the Compensation Committee evaluated its continuing program to bring executive base salary, on average, to the median of the peer group. Each NEO was individually evaluated based on their experience and tenure. The Committee determined that, although the peer group targets continue to be the overall goal, because of the challenging macro economic conditions, it was appropriate to implement a more modest total salary increase and target accomplishing the overall compensation goal over a longer period of time. Accordingly, the Compensation Committee approved increases to base salaries, effective on March 8, 2010, for each of the NEOs ranging from 4% to 6%, which was generally consistent with the salary increases provided to the nonexecutive employees of the Company.

### ***Cash Bonus***

We maintain a company wide annual cash bonus program. The bonus program is generally based on corporate performance, with adjustments made within a range for individual performance. The corporate performance determines the size of the entire bonus pool and the individual performance determines the actual pay out to each employee. The bonus is paid in the first quarter of each year, based on the employee's performance in the prior year.

The bonus program, including specific objective and quantifiable corporate goals and target pay outs by level, are reviewed and approved by the full Board in December at the time the Board considers the budget for the following year. The goals are prepared in an interactive process in which the Compensation Committee works with the CEO and other members of management to develop corporate performance goals that are set at levels that the Compensation Committee believes management can reasonably achieve if the Company as a whole executes on its business plan. The corporate goals are designed to enhance long-term stockholder value by providing a foundation that will enable us to realize our long-term strategic plan. In setting these goals, the Compensation Committee seeks to provide appropriate short-term incentives to achieve near-term operational goals that directly support our longer-term goals of commercialization of current and new products. We have not



disclosed the specific corporate goals as they are based on various strategic elements, each of which is confidential and the Compensation Committee has determined that disclosure of the goals can result in competitive harm to us. The following table describes the general nature of the goals for 2009, each of which was assigned a percentage weight consistent with the following order:

<u>General Description</u>	<u>Total Funding Percentage</u>
Goals related to financial performance including product revenue and net income .....	50 %
Goals related to milestones for clinical programs .....	40 %
Goals related to milestones for preclinical programs .....	10 %
Total .....	100 %

The following table describes the general nature of the goals for 2010 as approved by the Compensation Committee and the Board:

<u>General Description</u>	<u>Total Funding Percentage</u>
Goals related to financial performance including product revenue and net income .....	50 %
Goals related to milestones for clinical programs .....	32.5 %
Goals related to milestones for preclinical programs .....	12.5 %
Goals related to manufacturing bulk drug product in our new facility .....	5 %
Total .....	100 %

In 2009, our performance against our goals resulted in a calculated bonus pool of 110% of the target bonus pool. As a comparison, in 2008 and 2007, our performance against our goals resulted in a pay out in February 2009 and February 2008 of 114% and 109%, respectively, of the target bonus pool. The 2009 target bonus for each NEO expressed as a percentage of base salary is determined by the employee's position at the Company. The target bonus amounts for the NEOs for 2009 bonuses (which were paid in February 2010) were: Mr. Bienaimé, 100% of base salary; Mr. Aselage and Dr. Fuchs, 40% of base salary; Drs. Baffi and Mr. Cooper, 35% of base salary. Mr. Bienaimé's target bonus is at the higher end of the 2009 Peer Group. The Board determined that this higher target is appropriate given Mr. Bienaimé's extensive experience as the chief executive of several biotechnology companies, and his demonstrated success in creating stockholder value and advancing our development as a company, and our target of establishing total compensation at the 75<sup>th</sup> percentile of the market. Because the bonus targets for several of the NEOs other than Mr. Bienaimé continue to be substantially below the 75<sup>th</sup> percentile of the market, for 2010, the Compensation Committee increased Mr. Aselage's target bonus to 45% of base salary and Dr. Baffi's target bonus to 40% of base salary. The Committee believes that these increases are appropriate due to Mr. Aselage's position as head of our commercial organization, and Dr. Baffi's tenure with the company, promotion to executive vice president and his position supervising all of our manufacturing operations, which accounts for approximately half of all of our employees. For 2010, no changes were made to target bonus amounts for Mr. Cooper or Dr. Fuchs. The Board meets near the end of each year to review our performance against the prior year's goals and approve the bonus pool pay out. At that time, the Board also approves the specific pay out to the CEO and the Compensation Committee approves the specific pay out to the other executive officers. In consultation with individual managers, our management then approves the individual pay outs to employees other than the executive officers. Individual pay outs from the bonus pool to employees other than executive officers continued to depend on the employee's position and individual performance. Consistent with prior years, and in recognition of the philosophy of the Compensation Committee and the CEO that the performance of the Company is determined in large part by the performance of the executive management acting collaboratively as a team, in December 2009, the Compensation Committee chose not to differentiate performance and approved a 2009 bonus for each executive equal to the executive's target bonus amounts expressed as a percentage of base salary multiplied by the 110% company wide funding level.

The purpose of this decision is to not only align the individual executive's performance with the Company's overall performance but to also minimize any personal or individual discretion that comes from setting individual objectives for executives. The specific amount paid to each NEO for 2009 is listed in the *Summary Compensation Table* below.

The bonus program has various payout levels depending on our performance against the goals. If the corporate goals relating to financial performance, i.e. net income and Naglazyme and Kuvan revenue goals, are achieved, the pay out is based on a sliding scale. If we achieve 75% of our financial goal, 75% of the amount attributable to the goal will be funded. The amount funded increases proportionally up to a maximum of 200% of the amount associated with the goal, upon reaching 200% of target. The Board has also set a minimum achievement of 75% of the financial goal in order to fund any bonus amount for the financial performance goal. For the goals related to clinical and preclinical programs, each goal has three levels of performance, threshold, target and maximum, based on whether the company has accomplished the minimum acceptable level of performance (threshold), accomplished the goal (target) or exceeded it (maximum). If we do not attain at least the threshold performance level, there will be no pay out attributable to that goal. If we achieve the threshold performance level, then 75% of the amount attributable to that goal will be funded. If we achieve the target goal, then 100% of the amount attributable to that goal will be funded and if we exceed the goal and achieve the maximum performance level is achieved, then 125% of the amount attributable to that goal would be funded. We believe that in order to achieve an overall competitive pay program, including salary plus incentives, we need to allow for the above target incentives for achieving our goals. We feel that this type of structure motivates executives to challenge their teams to not only meet but exceed goals that add value to our stockholders. In addition, as a commercial company, we are seeking to provide greater pay for performance elements to our plan tied to specific business outcomes that can increase stockholder value.

### ***Equity Compensation***

We grant stock options to virtually all newly hired employees. Additionally, we currently make annual stock option grants to almost all employees, the only general exception being employees who are performing below expectations or who have recently joined the Company. New hire grants for non-executives are approved by the CEO, subject to guidelines approved by the Compensation Committee. The guidelines are based primarily on competitive option grant practices in the market where we compete for employees. All other grants are approved by the Compensation Committee or the full Board.

The timing of the annual grant is the date of the annual meeting of stockholders. The Board elected to implement this process so that the options are granted on a predictable day each year and at a time that will tend to minimize the amount of material non-public information in the possession of the Board or the executive officers.

In order to manage total share dilution and to better align the interests of our executives with our stockholders, a portion of the equity awards granted to executive officers are made in the form of restricted stock units. Currently, approximately 25% of the total value of the equity award is made in restricted stock units. We expect that in the future we will continue to evaluate the appropriate employee population to receive restricted stock units.

The equity compensation granted to each employee, including the NEOs, in May 2009 was determined based upon a number of factors. The Compensation Committee gave particular consideration to the Company's performance, and also considered equity grants of the 2009 Peer Group based on a Black-Scholes valuation. For a discussion of assumptions used in calculating the Black-Scholes valuation see Note 3 to the Company's Financial Statements for the year ended December 31, 2009 included in the 2009 Annual Report. In determining the allocation of options and restricted stock units, the Compensation Committee considered a variety of factors, including the effect on the total number of shares to be issued under the 2006 Plan, peer group practices, and the comparative value of options and restricted stock units. Overall, the Compensation Committee sought to grant equity compensation at the 75<sup>th</sup> percentile of the 2009 Peer Group. This is consistent with the Compensation

Committee's overall goal of targeting total compensation at the 75<sup>th</sup> percentile. For the NEOs other than Mr. Bienaimé, the considerations in differentiating grants among the NEOs were principally tenure and experience, as discussed under *Salary Adjustments* above. For Mr. Bienaimé, the principal consideration was evaluating the practices of the 2009 Peer Group and considering our performance against the 2009 Peer Group.

We have reviewed our historical option grant practices to consider if the options were properly dated. Based on such review, we believe that all options were issued on the date approved by the Board or a properly authorized committee and that the exercise price for each option issued since the date of our initial public offering was the closing price of our common stock on the date of issuance, unless the option grant specifically approved a different price in accordance with the terms of the applicable option plan pursuant to which such option was granted.

### ***Perquisites***

We provide our NEOs, along with other officers, a limited number of perquisites. An item is not a perquisite if it is integrally and directly related to the performance of the executive's duties. An item is a perquisite if it confers a direct or indirect benefit that has a personal aspect, without regard to whether it may be provided for some business reason or for the convenience of the Company, unless it is generally available on a non-discriminatory basis to all employees.

We provide the following to our NEOs:

- **Reimbursement for Financial Planning and Tax Preparation.** We reimburse our executive officers, including our NEOs, for personal financial planning and tax preparation. The benefit is limited to \$3,500 annually for vice presidents and senior vice presidents who report directly to our CEO and \$2,500 annually for all other vice presidents, and is taxable to the executive. The perquisite is intended to encourage executives to engage knowledgeable experts to assist with financial and tax planning.
- **Life Insurance.** In accordance with the terms of our employment agreement with Mr. Bienaimé dated May 11, 2005 and amended and restated on January 1, 2009, in addition to the life insurance generally provided to all employees, we provide Mr. Bienaimé with a fully paid, whole life insurance policy with a stated death benefit of \$500,000 and a term life insurance policy with a death benefit of \$1,000,000.

During a portion of 2009, we provided Mr. Aselage with certain hotel reimbursements while he was required to work late in Novato, California. We determined that these amounts did not qualify as a business expense under Internal Revenue Service ("IRS") guidelines. Accordingly, we discontinued this benefit.

### ***Nonqualified Deferred Compensation***

Our NEOs, members of management, other highly compensated employees and members of the Board are eligible to enroll in our Deferred Compensation Plan under which participants may elect to defer all or a portion of their salary, annual cash bonus and restricted stock awards otherwise payable to them, and thereby defer taxation of these deferred amounts until actual payment of the deferral amounts in future years. This plan was implemented in 2006 as a financial planning tool for senior employees and allows them to save for retirement in a tax-effective way at minimal cost to us. The Board amended and restated the Deferred Compensation Plan on January 1, 2009 in order to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"), and related Treasury Regulations. See the *Nonqualified Deferred Compensation* table below for detailed information regarding the account balances for each NEO.

### ***Post-Employment Obligations***

We have employment agreements with each of our executive officers that include severance provisions. Under the terms of the employment contracts, with respect to each NEO other than Mr. Bienaimé, upon an involuntary termination by us without cause, or a termination by the executive under specific circumstances, such

as a relocation more than 50 miles from their previous job location, a substantial reduction in the officer's duties, status or reporting structure or a decrease in the officer's base salary, the employment agreements provide for a cash severance payment equal to year's base salary and target bonus. With respect to Mr. Bienaimé, except for a termination for cause, he is entitled to a cash severance payment equal to 200% of his base salary and continuation of medical insurance benefits for 30 months, depending on the nature of termination, acceleration of all unvested equity awards, and certain other benefits continuation and certain gross up payments to cover certain tax liabilities related to the severance payments.

In addition, pursuant to our Severance Plan, as amended and restated in March 2009 (the "Severance Plan"), immediately upon a change in control, all unvested options held by each of the NEOs, other than Mr. Bienaimé, will immediately vest. The accelerated vesting occurs upon a change in control, whether or not the employee is terminated.

We believe that these provisions enhance retention in the face of the disruptive impact of a pending change in control of the company. In addition, the program is intended to align executive and stockholder interests by enabling executives to consider corporate transactions that are in the best interests of our stockholders and other constituents without undue concern over whether the transactions may jeopardize the executives' own employment.

No benefits will be paid to Mr. Bienaimé under his employment agreement if the termination is for cause, for a voluntary resignation (other than as set forth above), or retirement. No benefits will be paid to the other executive officers under the employment agreements if the termination is for cause, for a voluntary resignation (other than as set forth above), retirement or due to death.

Please see *Potential Payments Upon Termination or Change in Control* below for a more detailed discussion of the severance and change in control provisions in our NEO's employment contracts.

#### ***Accounting and Tax Considerations.***

*Nonqualified Deferred Compensation*—On October 22, 2004, the American Jobs Creation Act of 2004 was signed into law, adding Section 409A of the Code which changed the tax rules applicable to nonqualified deferred compensation arrangements. While the final Treasury Regulations under Section 409A did not become effective until January 1, 2009, the Company believes it operated in good faith compliance with the provisions of Section 409A which became effective on January 1, 2005. A more detailed discussion of the Company's nonqualified deferred compensation arrangements is provided under the heading "Nonqualified Deferred Compensation" below.

*Accounting for Stock-Based Compensation*—Beginning on January 1, 2006, we adopted the provisions of SFAS 123R, now referred to as FASB ASC Topic 718, which require us to estimate and record an expense for each equity award over the vesting period of the award, and estimate prospective forfeitures. Generally, the Compensation Committee does not make compensation decisions based on the tax or accounting treatment of any particular form of compensation; however, it has considered and approved and may in the future consider the grant of alternative equity incentives to our NEOs in lieu of stock option grants in light of the accounting impact of FASB ASC Topic 718 with respect to stock option grants and other considerations.

*Section 162(m)*—Section 162(m) of the Code limits our deduction for federal income tax purposes to not more than \$1,000,000 of compensation paid to certain executive officers in a calendar year. Compensation above \$1,000,000 may be deducted if it is "performance-based compensation." The Board and the Compensation Committee regularly consider the impact of Section 162(m) of the Code, regarding the deductibility of compensation to certain executive officers in excess of \$1,000,000 but have not yet established a policy for determining which forms of incentive compensation awarded to our executive officers will be designed to qualify as "performance-based compensation." To maintain flexibility in compensating our executive officers in a manner designed to promote our goals, the Compensation Committee has not adopted a policy that allows all

executive compensation to be deductible. To date, exclusive of stock option exercises, there have been a very limited number of executives whose compensation, including salary, bonus and grants of restricted stock units, have exceeded this amount. The Committee and the Board will continue to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and may, in the future, consider qualifying the Company's equity compensation plans and/or bonus plans so that compensation payable under those arrangements is fully deductible under Section 162(m).

### **Director and Officer Stock Ownership Guidelines**

In order to preserve the linkage between the interests of executives and those of stockholders, the Compensation Committee and the Board established share retention guidelines for our executives. The guidelines recommend that our directors should hold shares equal to the lesser of 10,000 shares of common stock or three times the director's annual cash retainer amount, our chief executive officer should hold shares of the company with a value equal to at least three times his or her base salary and the senior vice presidents should hold shares of the company with a value equal to at least two times his or her base salary. All shares of restricted stock held by our officers and directors, whether or not vested, are included in the calculations. To give the officers time to comply with this recommendation, the Compensation Committee determined that our directors and officers should have until June 2013 to comply with these guidelines. As of December 31, 2009 Mr. Bienaimé beneficially held shares equal to 3.1 times his base salary, Drs. Fuchs and Baffi held shares equal to 0.9 and 4.3 times their base salary, respectively, and Messrs. Cooper and Aselage held shares equal to 2.0 and 4.1 times their base salary, respectively. In addition, as of December 31, 2009, all of our directors held shares equal to three times their respective annual cash retainer amounts. The Committee believes these retention requirements are an important tool in aligning the interests of the company's executives with the long-term interests of the Company's stockholders.

### **COMPENSATION COMMITTEE REPORT(2)**

The Compensation Committee is responsible for setting general compensation goals and operational guidelines for BioMarin personnel, for recommending the chief executive officer's and director's compensation for consideration by the full Board, for setting all elements of the compensation of the other executive officers of BioMarin, and for approving grants of stock options for executive officers of BioMarin. The Compensation Committee has reviewed and discussed the *Compensation Discussion and Analysis* with management, and based on such review and discussions, the Compensation Committee has recommended to the Board that the Compensation Discussion and Analysis be included in this proxy statement.

Respectfully submitted on March 22, 2010 by the members of the Compensation Committee of the Board of Directors:

Alan J. Lewis, Ph.D., Chairman  
Michael Grey  
V. Bryan Lawlis, Ph.D.

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(2) The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of BioMarin under the Securities Act, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

## Summary Compensation Table

The following table discloses compensation paid by us during 2009 to: (i) Jean-Jacques Bienaimé, our Chief Executive Officer; (ii) Jeffrey H. Cooper, our Chief Financial Officer; and (iii) Henry J. Fuchs, M.D., Ph.D., Robert A. Baffi, Ph.D. and Stephen A. Aselage, the three most highly-compensated officers other than the Chief Executive Officer and Chief Financial Officer who were serving as officers at the end of fiscal year 2009 and whose salary and bonus exceeded \$100,000. These individuals are referred to as the “Named Executive Officers.”

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u>	<u>Stock Awards(1)</u>	<u>Option Awards(2)</u>	<u>Non-Equity Incentive Plan Compensation(3)</u>	<u>All Other Compensation(4)</u>	<u>Total</u>
Jean-Jacques Bienaimé . . . . . Chief Executive Officer	2009	\$739,482	\$ 460,480	\$1,821,600	\$794,962	\$29,985(5)	\$ 3,846,509
	2008	\$673,439	\$1,157,700	\$7,891,080	\$769,500	\$29,037(5)	\$10,520,756
	2007	\$636,933	\$ 346,600	\$1,409,600	\$733,815	\$24,622(5)	\$ 3,151,570
Jeffrey H. Cooper . . . . . Senior Vice President, Chief Financial Officer	2009	\$351,408	\$ 115,120	\$ 455,400	\$133,405	\$ 7,598	\$ 1,062,931
	2008	\$314,714	\$ 308,720	\$1,182,240	\$123,690	\$ 5,999	\$ 1,935,363
	2007	\$279,519	\$ 138,640	\$ 528,600	\$ 96,773	\$ 8,684	\$ 1,052,216
Henry J. Fuchs, M.D., Ph.D. . . . . Executive Vice President & Chief Medical Officer(6)	2009	\$339,038	\$ 221,000	\$ 923,200	\$180,400	\$54,931(7)	\$ 1,718,569
	2008	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Robert A. Baffi, Ph.D. . . . . Executive Vice President, Technical Operations	2009	\$331,914	\$ 129,510	\$ 531,300	\$122,301	\$ 7,148	\$ 1,122,173
	2008	\$299,366	\$ 308,720	\$1,272,840	\$119,700	\$ 5,781	\$ 2,006,407
	2007	\$284,327	\$ 138,640	\$ 528,600	\$ 98,325	\$10,309	\$ 1,060,201
Stephen Aselage . . . . . Executive Vice President & Chief Business Officer	2009	\$361,525	\$ 172,680	\$ 683,100	\$155,459	\$13,685(8)	\$ 1,386,449
	2008	\$328,561	\$ 385,900	\$1,544,640	\$150,480	\$ 4,355	\$ 2,413,936
	2007	\$294,965	\$ 173,300	\$ 616,700	\$136,160	\$ 8,112	\$ 1,229,237

- (1) The amounts in this column reflect the full grant date fair values in accordance with FASB ASC Topic 718. For assumptions used in determining these values, see Note 3 the consolidated financial statements contained in the Company’s Form 10-K for the year ended December 31, 2009.
- (2) The amounts in this column reflect the full grant date fair values in accordance with FASB ASC Topic 718. For assumptions used in determining these values, see Note 3 the consolidated financial statements contained in the Company’s Form 10-K for the year ended December 31, 2009.
- (3) Amounts noted for 2009 represent amounts earned by Named Executive Officers during 2009, but paid in 2010. Amounts noted for 2008 represent amounts earned by Named Executive Officers during 2008, but paid in 2009. Amounts noted for 2007 represent amounts earned by the Named Executive Officers during 2007, but paid in 2008.
- (4) These amounts represent the premiums paid for life insurance benefits, personal tax preparation/financial planning consultation and vested 401(k) matching for each Named Executive Officer.
- (5) Includes payments of life insurance premiums of \$18,641, \$21,485 and \$22,433 and a reimbursement of personal tax preparation/financial planning services of \$3,325, \$3,552 and \$3,552 for 2007, 2008 and 2009, respectively.
- (6) Dr. Fuchs joined the company in March 2009, therefore, no amounts appear in the table for 2007 and 2008.
- (7) Includes \$50,000 sign-on bonus paid to Dr. Fuchs when he joined the company in March 2009.
- (8) Includes \$5,056 for hotel reimbursements that did not qualify as a business expense under IRS guidelines.

## Grants of Plan-Based Awards

The following table sets forth certain information for each plan-based award during fiscal year 2009 to each of the Named Executive Officers.

Name(a)	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			All Other Stock Awards: Number of Shares or Units(#)	All Other Option Awards: Number of Securities Underlying Options(#)	Exercise or Base Price of Option Awards (\$/Share)(2)	Grant Date Fair Value of Stock and Option Awards \$(3)
		Threshold (\$)	Target (\$)	Maximum (\$)				
Jean-Jacques Bienaimé ...	5/12/09	—	—	—	—	240,000	14.39	1,821,600
	5/12/09	—	—	—	32,000	—	—	460,480
	—	542,019	722,693	1,174,375	—	—	—	—
Jeffrey H. Cooper .....	5/12/09	—	—	—	—	60,000	14.39	455,400
	5/12/09	—	—	—	8,000	—	—	115,120
	—	259,879	346,505	563,071	—	—	—	—
Robert A. Baffi, Ph.D. ....	5/12/09	—	—	—	—	70,000	14.39	531,300
	5/12/09	—	—	—	9,000	—	—	129,510
	—	238,248	317,664	516,204	—	—	—	—
Henry J. Fuchs, M.D., Ph.D. ....	3/2/09	—	—	—	—	160,000	11.05	923,200
	3/2/09	—	—	—	20,000	—	—	287,800
	—	307,500	410,000	666,250	—	—	—	—
Stephen Aselage .....	5/12/09	—	—	—	—	90,000	14.39	683,100
	5/12/09	—	—	—	12,000	—	—	172,680
	—	264,987	353,316	574,139	—	—	—	—

- (1) Amounts represent potential payments under our 2009 bonus plan, which was paid in 2010. For further discussion on our bonus program, please see the *Compensation Discussion and Analysis* and see the *Summary Compensation Table* for amounts actually paid under the 2009 bonus plan.
- (2) Options were granted at an exercise price equal to the closing price of our common stock on NASDAQ on the date of the grant.
- (3) The amounts presented above represent the full grant date fair value of the restricted stock award or option grant in with FASB ASC Topic 718. For assumptions used in determining these values, see Note 3 the consolidated financial statements contained in the Company's Form 10-K for the year ended December 31, 2009.

The number of options and restricted stock units granted to the Chief Executive Officer are determined based on recommendations by the Compensation Committee and are approved by the Board and the number of options and restricted stock units granted to the other Named Executive Officers are determined by the Compensation Committee. Please see *Compensation Discussion and Analysis* for additional information regarding grant practices. Except as otherwise noted, options vest 6/48ths on the six month anniversary of the date of grant, and 1/48<sup>th</sup> per month thereafter for the next 3.5 years, and remain exercisable for ten years after the date of grant. Restricted stock units vest in four equal quarters on the anniversary of the date of the grants.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth the outstanding unexercised options granted pursuant to equity awards as of the end of fiscal year 2009 for each of the Named Executive Officers.

### Outstanding Equity Awards at 2009 Fiscal Year-End

Name(a)	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options Exercisable(#)	Number of Securities Underlying Unexercised Options Unexercisable(#)	Option Exercise Price \$(1)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested(#)	Market Value of Shares or Units of Stock That Have Not Vested \$(13)
Jean-Jacques Bienaimé	111,764	0	6.46	5/10/15	10,000(9)	188,100
	162,500	0	9.86	11/10/15	22,500(10)	423,225
	162,500	0	12.99	5/10/16	32,000(11)	601,920
	223,958	26,042(2)	12.99	5/10/16		
	168,229	256,771(3)	38.59	5/21/18		
	5,500	16,500(4)	17.86	12/16/18		
	192,708	57,292(5)	17.54	11/19/16		
	100,000	60,000(6)	17.33	6/7/17		
35,000	205,000(7)	14.39	5/11/19			
Jeffrey H. Cooper	1,459	0	5.15	8/18/14	4,000(9)	75,240
	13,750	0	6.13	1/6/15	6,000(10)	112,860
	27,500	1,250(8)	11.74	1/5/16	8,000(11)	150,480
	46,250	13,750(5)	17.54	11/19/16		
	37,500	22,500(6)	17.33	6/6/17		
	23,750	36,250(3)	38.59	5/21/18		
	2,750	8,250(4)	17.86	12/16/18		
8,750	51,250(7)	14.39	5/11/19			
Robert A. Baffi, Ph.D.	163,888	0	22.00	5/8/10	4,000(9)	75,240
	35,000	0	6.13	1/7/15	6,000(10)	112,860
	73,437	1,563(8)	11.74	1/5/2016	9,000(11)	169,290
	69,375	20,625(5)	17.54	11/19/16		
	37,500	22,500(6)	17.33	6/6/2017		
	25,729	39,271(3)	38.59	5/21/18		
	2,750	8,250(4)	17.86	12/16/18		
	10,208	59,792(7)	14.39	5/11/19		
Henry J. Fuchs, M.D., Ph.D.	30,000	130,000	11.05	3/1/19	20,000(12)	376,200
Stephen Aselage	24,090	0	7.16	6/30/15	5,000(9)	94,050
	33,437	1,563(8)	11.74	1/5/16	7,500(10)	141,075
	77,083	22,917(5)	17.54	11/19/16	12,000(11)	225,720
	43,750	26,250(6)	17.33	6/6/17		
	31,666	48,314(3)	38.59	5/21/18		
	13,125	76,875(7)	14.39	5/11/19		
2,750	8,250(4)	17.86	12/16/08			

- (1) Represents the closing market price of our common stock on the grant date.
- (2) Unexercisable portion vests 1/48<sup>th</sup> of total number of options granted on the 11<sup>th</sup> day of every month.
- (3) Unexercisable portion vests 1/48<sup>th</sup> of total number of options granted on the 22<sup>nd</sup> of every month.
- (4) Unexercisable portion vests 1/48<sup>th</sup> of the total number of options granted on the 17<sup>th</sup> of every month.
- (5) Unexercisable portion vests 1/48<sup>th</sup> of total number of options granted on the 20<sup>th</sup> of every month.



- (6) Unexercisable portion vests 1/48<sup>th</sup> of total number of options granted on the 7<sup>th</sup> of every month.
- (7) Unexercisable portion vests 1/48<sup>th</sup> of total number of options granted on the 12<sup>th</sup> of every month.
- (8) Unexercisable portion vests January 6, 2010.
- (9) Fifty percent (50%) of the unexercisable portion of restricted stock units awarded on June 7, 2007 vests on each of June 7, 2010 and June 7, 2011.
- (10) Thirty-three and one third percent (33.33%) of the unexercisable portion of restricted stock units awarded on May 22, 2008 vests on each of May 22, 2010, May 22, 2011 and May 22, 2012.
- (11) Twenty-five percent (25%) of the unexercisable portion of restricted stock units awarded on May 12, 2009 vests on each of May 12, 2010, May 12, 2011, May 12, 2012 and May 12, 2013.
- (12) The unexercisable portion of restricted stock units awarded on March 2, 2009 vests 5,000 shares on April 2, 2010, March 2, 2011, March 2, 2012 and March 2, 2013.
- (13) The value of restricted stock units shown in the table was calculated using the closing price of our common stock on December 31, 2009 (\$18.81).

### Options Exercises and Stock Vested

The following table sets forth the number and value of options exercised and share awards that vested in fiscal year 2009 for each of the Named Executive Officers.

#### Options Exercises and Stock Vested

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise(#)	Value Realized on Exercise (\$)	Number of Shares Acquired on Vesting(#)	Value Realized on Vesting (\$)(1)
Jean-Jacques Bienaimé . . . . .	—	—	5,000	67,650
	—	—	7,500	110,925
Jeffrey H. Cooper . . . . .	—	—	2,000	27,060
	—	—	2,000	29,580
Robert A. Baffi, Ph.D. . . . .	—	—	2,000	29,580
	—	—	2,000	27,060
Stephen Aselage . . . . .	—	—	2,500	36,975
	—	—	2,500	33,825

- (1) The value realized on vesting of restricted stock units was calculated as of the product of the closing price of a share of our common stock on the vesting date, multiplied by the number of shares vested.

### Pension Benefits

There is no retirement pension plan provided for the Named Executive Officers.

### Nonqualified Deferred Compensation

The following table sets forth certain information with respect to our Nonqualified Deferred Compensation Plan (the "Deferred Compensation Plan").

The Deferred Compensation Plan allows members of management, other highly compensated employees and members of the Board to make voluntary irrevocable deferrals of the compensation that they would otherwise be paid by us to specified future dates, employment termination, hardship events, disability, retirement or death. Participants are permitted to defer up to 100% of salary, annual cash bonus and restricted stock awards, subject to limitations to allow us to make necessary withholding payments. Plan participants' deferred compensation is 100% vested under the Deferred Compensation Plan. We may make additional direct

contributions to the Deferred Compensation Plan for the benefit of the participants, but any such contributions must be approved by the Board. Our contributions, if any, will become 100% vested after three years of service with us (or such other time as we designate at the time of the contribution), or upon a change in control, death or disability. Participants have an unsecured contractual commitment by us to pay the amounts that become due under the Deferred Compensation Plan. Deferred compensation may be held in trust and is deemed invested based on participant direction as allowed by the Deferred Compensation Plan. Participants' accounts are credited or debited with the increase or decrease in the realizable net asset value of the designated deemed investments in accordance with the ratio which the portion of the account of each participant which is deemed to be invested within that investment option bears to the aggregate of all amounts deemed to be invested within that investment option. Any funds held in a trust will be our sole property, subject to any claims of general creditors in the event of bankruptcy, and plan participants will have no vested interest with respect to such trust fund.

<u>Name</u>	<u>Executive Contributions in 2009 (\$)(1)</u>	<u>Registrant Contributions in 2009 (\$)</u>	<u>Aggregate Earnings in Last Fiscal Year (\$)</u>	<u>Aggregate Withdrawals/ Distributions (\$)</u>	<u>Aggregate Balance at 2009 (\$)(2)</u>
Jean-Jacques Bienaimé .....	178,575(3)	—	—	—	329,181
Jeffrey H. Cooper .....	174,157(3)	—	\$ 1,359(4)	—	310,006
Robert A. Baffi, Ph.D .....	56,640(3)	—	—	—	112,860
Stephen Aselage .....	264,962(3)	—	\$ 9,022(4)	—	576,593

- (1) Cash contributions made by Mr. Aselage and Mr. Cooper, during 2009 include \$197,329 and \$123,300, respectively, of compensation included in the "salary" column of the *Summary Compensation Table*. Also includes contributions of shares of common stock received.
- (2) Amounts include cash contributions of \$67,870, \$19,656, \$19,656, and \$118,762 for Mr. Bienaimé, Mr. Cooper, Mr. Baffi, and Mr. Aselage, respectively, which were previously reported in the Summary Compensation Table for 2007 and cash contributions of \$91,582 and \$131,470 for Mr. Cooper and Mr. Aselage, respectively, which were previously reported in the Summary Compensation Table for 2008.
- (3) Amounts include the value of shares of common stock received by Mr. Bienaimé, Mr. Cooper, Mr. Baffi and Mr. Aselage upon the vesting of restricted stock grants during 2009 of \$178,575, \$56,640, \$56,640 and \$70,800, respectively.
- (4) Aggregate earnings for Mr. Cooper, and Mr. Aselage during 2009 include \$1,359, and \$9,022, respectively, of dividends and interest.

#### **Potential Payments Upon Termination or Change-in-Control**

We entered into an employment agreement with Mr. Bienaimé at the time of his hire and with each of our other executive officers, including the NEOs, on April 9, 2007 or upon their date of hire. On January 1, 2009, to comply with the changes to Section 409A of the Code, we amended and restated the employment agreements with each of our executive officers, including Mr. Bienaimé. The following discussion is based on such agreements and for our NEOs other than Mr. Bienaimé, our Severance Plan. The amount and type of compensation payable to each NEO upon termination of employment under various circumstances and upon a change in control are described below.

##### *Payments on Termination*

The amount and type of compensation payable to each NEO upon termination of employment under various circumstances are described below. There are three general categories of terminations, which are:

- voluntary termination of employment by the NEO for reasons not constituting constructive termination, which we refer to as voluntary termination; retirement of the NEO; and termination of the NEO's employment by us for cause, as such term is defined in the employment agreements and in our stock plans, which we refer to as termination for cause;

- termination of the NEO's employment by us for reasons not constituting cause, such as due to a companywide or departmental reorganization, or a resignation by the NEO constituting constructive termination, such as a change in work location of more than a specified distance from the previous location, which we refer to as involuntary termination without cause; and
- termination of the NEO's employment in connection with a change in control.

*Compensation upon Voluntary Termination, Retirement or Termination for Cause*

A termination of employment due to voluntary termination, retirement, or termination for cause does not entitle the NEOs to any payments or benefits other than the accrued salary and vacation pay and vested benefits described above. Such compensation and benefits are available to salaried employees generally, except that any amounts payable to the NEOs upon termination under our Deferred Compensation Plan would not be applicable to certain employees as only employees with the title of vice president, senior director, and director are entitled to participate in our Deferred Compensation Plan. Stock awards held by our NEOs will not be subject to accelerated vesting or otherwise enhanced in the event of voluntary termination, retirement, or termination for cause.

*Compensation upon Involuntary Termination without Cause*

Each of the NEOs' employment agreements include specific benefits upon involuntary termination by us without cause. For each of the NEOs other than Mr. Bienaimé, these benefits consist of a lump sum payment equal to year's base salary and target bonus, payable within two weeks after separation of employment, conditioned on the NEO signing our standard severance and release agreement. These agreements do not provide for the accelerated vesting or other enhancement of equity awards upon an involuntary termination without cause.

With respect to Mr. Bienaimé, if we terminate Mr. Bienaimé's employment without cause or if Mr. Bienaimé resigns for good reason or becomes permanently disabled while employed by us or if we file for bankruptcy, Mr. Bienaimé will be entitled to receive the following "Termination Compensation": (i) cash severance payment in an amount equal to his then current annual base salary as of the date of termination for a period of 24 months; (ii) a cash bonus equal to 100% of his base salary for such year provided that our senior vice presidents are paid bonuses under our bonus plan for the year of his termination, and provided that certain performance goals are met; (iii) a continuation of all health benefits paid by us for a period of 24 months after the date of termination; (iv) a cash payment of \$18,000 for outplacement services (plus an amount for taxes payable on such cash payment); (v) the fully-paid whole life insurance policy with a stated death benefit of \$500,000 maintained for Mr. Bienaimé (plus an amount for taxes payable on imputed income and such amount for taxes); (vi) a cash payment of up to \$5,000 for tax preparation (plus an amount for taxes payable on such cash payment); (vii) our annual contribution to Mr. Bienaimé's 401k plan for the year of termination to the extent allowable; and (viii) automatic vesting of all options granted to Mr. Bienaimé that have not vested as of the date of termination, provided that Mr. Bienaimé remains in full compliance with his non-competition agreement and confidentiality agreement during the 24-month period. The Termination Compensation is payable in one lump sum within thirty days after termination.

*Compensation upon Termination of Employment in Connection with Change in Control*

Each of the Named NEOs who are involuntarily terminated without cause or constructively terminated within a designated period following a change in control are entitled to certain benefits. For each NEO other than Mr. Bienaimé, these benefits consist of a lump sum payment equal to one year's base salary and target bonus, payable within two weeks after separation of employment, conditioned on the NEO signing our standard severance and release agreement.

With respect to Mr. Bienaimé, if we terminate Mr. Bienaimé's employment without cause or if Mr. Bienaimé resigns for good reason or becomes permanently disabled while employed by us, in any such case following a change in control, Mr. Bienaimé will be entitled to receive the following "Enhanced Termination Compensation": (i) cash severance payment equal to 200% of the base salary that he would have collected over

the Enhanced Severance period of 30 months; (iii) a continuation of all health benefits paid by us for a period of 30 months after the date of termination; (iv) a cash payment of \$18,000 for outplacement services (plus an amount for taxes payable on such cash payment); (v) the fully-paid whole life insurance policy with a stated death benefit of \$500,000 maintained for Mr. Bienaimé (plus an amount for taxes payable on imputed income and such amount for taxes); (vi) a cash payment of up to \$5,000 for tax preparation (plus an amount for taxes payable on such cash payment); (vii) our annual contribution to Mr. Bienaimé's 401k plan for the year of termination to the extent allowable; and (viii) automatic vesting of all options granted to Mr. Bienaimé that have not vested as of the date of termination, provided that Mr. Bienaimé remains in full compliance with his non-competition agreement and confidentiality agreement during the 30-month period. The Enhanced Termination Compensation is payable in one lump sum within thirty days after termination.

If amounts payable to Mr. Bienaimé as the result of a change in control would result in a parachute payment under Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), which would be subject to an excise tax under Code Section 4999, or interest or penalties are incurred with respect to such excise tax, we will pay Mr. Bienaimé an additional payment such that, after payment by Mr. Bienaimé of all taxes imposed upon this payment and any interest or penalties imposed with respect to such taxes, Mr. Bienaimé retains an amount equal to the sum of: (i) the excise tax (including interest and penalties) imposed; and (ii) the product of any income tax deductions disallowed to Mr. Bienaimé because of the inclusion of the payment in his adjusted gross income, and the highest applicable marginal rate of federal income taxation for the calendar year in which the payment is to be made.

***Estimated Potential Payments on Termination or Change in Control***

The table below sets forth the estimated current value of payments and benefits to each of the NEOs upon a change of control as described above. The amounts shown assume that the triggering events occurred on December 31, 2009 and do not include (i) benefits earned during the term of the NEOs employment that are available to all salaried employees, such as accrued vacation; (ii) benefits paid by insurance providers under life and disability policies; and (iii) benefits previously accrued under the Nonqualified Deferred Compensation Plan. The actual amounts of payments and benefits that would be provided can only be determined at the time of the NEO's separation from the Company. With respect to each NEO other than Mr. Bienaimé, under the Company's Severance Plan, effective immediately upon a change of control, all unvested option and restricted stock awards automatically vest in full. Mr. Bienaimé's option awards only vest if he is terminated without cause or if Mr. Bienaimé resigns for good reason or becomes permanently disabled while employed by us, as described above. Per SEC rules, the value of accelerated options shown in the table below is the aggregate spread between \$18.81, the closing price of our common stock on December 31, 2009 and the exercise prices of the accelerated options, if less than \$18.81.

<u>Executive Benefits and Payments Upon Termination</u>	<u>Involuntary Termination Without Cause</u>	<u>Change of Control- Continued Employment</u>	<u>Change of Control- Terminated</u>
<b>Jean-Jacques Bienaimé(1):</b>			
Base Salary . . . . .	\$1,431,000	—	\$3,517,242
Short-term Incentive . . . . .	\$ 715,500	—	—
Stock award vesting acceleration . . . . .	—	\$1,846,225(2)	\$1,846,225(2)
Benefits and Perquisites . . . . .			
Benefit Continuation . . . . .	\$ 47,054	—	\$ 47,054
Life Insurance Proceeds . . . . .	—	—	\$ 215,563
Outplacement Services . . . . .	\$ 25,417	—	\$ 25,417
Financial Planning Services . . . . .	—	—	\$ 7,060
401K Match . . . . .	—	—	—
280G Tax Gross-up . . . . .	—	—	\$1,529,831(3)
Total . . . . .	<u>\$2,218,971</u>	<u>\$1,846,225</u>	<u>\$7,188,392</u>

<u>Executive Benefits and Payments Upon Termination</u>	<u>Involuntary Termination Without Cause</u>	<u>Change of Control- Continued Employment</u>	<u>Change of Control- Terminated</u>
<b>Jeffrey H. Cooper:</b>			
Base Salary .....	\$341,000	—	\$ 341,000
Short-term Incentive (based on % of base salary) .....	\$119,350	—	\$ 119,350
Stock award vesting acceleration .....	—	\$ 632,543(4)	\$ 632,543(4)
Benefits and Perquisites:			
Benefit Continuation .....	\$ 14,961	—	\$ 14,961
Total .....	<u>\$475,311</u>	<u>\$ 632,543</u>	<u>\$1,107,854</u>
<b>Henry J. Fuchs, M.D., Ph.D.:</b>			
Base Salary .....	\$410,000	—	\$ 410,000
Short-term Incentive (based on % of base salary) .....	\$164,000	—	\$ 164,000
Stock award vesting acceleration .....	—	\$1,385,008(5)	\$1,385,008(5)
Benefits and Perquisites:			
Benefit Continuation .....	\$ 13,063	—	\$ 13,063
Total .....	<u>\$587,063</u>	<u>\$1,385,008</u>	<u>\$1,972,071</u>
<b>Robert A. Baffi, Ph.D.:</b>			
Base Salary .....	\$315,000	—	\$ 315,000
Short-term Incentive (based on % of base salary) .....	\$126,000	—	\$ 126,000
Stock award vesting acceleration .....	—	\$ 700,052(6)	\$ 700,052(6)
Benefits and Perquisites:			
Benefit Continuation .....	\$ 17,079	—	\$ 17,079
Total .....	<u>\$458,079</u>	<u>\$ 700,052</u>	<u>\$1,158,131</u>
<b>Stephen Aselage:</b>			
Base Salary .....	\$349,800	—	\$ 349,800
Short-term Incentive (based on % of base salary) .....	\$157,410	—	\$ 157,410
Stock award vesting acceleration .....	—	\$ 929,808(7)	\$ 929,808(7)
Benefits and Perquisites:			
Benefit Continuation .....	\$ 18,822	—	\$ 18,822
Total .....	<u>\$526,032</u>	<u>\$ 929,808</u>	<u>\$1,455,840</u>

- (1) No incremental benefits are due should death of the employee occur, except for amounts due for services previously rendered, and those due under the life insurance policies.
- (2) Based on market price of \$18.81. Relates to 621,605 options and 32,000 RSUs that would accelerate upon vesting.
- (3) This item is payable pursuant to the terms of our employment agreement with Mr. Bienaime dated May 11, 2005 and amended and restated on January 1, 2009.
- (4) Based on market price of \$18.81. Relates to 133,250 options and 18,000 RSUs that would accelerate upon vesting.
- (5) Based on market price of \$18.81. Relates to 130,001 options and 20,000 RSUs that would accelerate upon vesting.
- (6) Based on market price of \$18.81. Relates to 152,001 options and 19,000 RSUs that would accelerate upon vesting.
- (7) Based on market price of \$18.81. Relates to 217,522 options and 24,500 RSUs that would accelerate upon vesting.

## **Compensation Risks**

We believe that risks arising from our compensation policies and practices for our employees are not reasonably likely to have a material adverse effect on the Company. In addition, the Compensation Committee believes that the mix and design of the elements of executive compensation do not encourage management to assume excessive risks.

The Compensation Committee, with assistance of its independent compensation consultant, extensively reviewed the elements of executive compensation to determine whether any portion of executive compensation encouraged excessive risk taking and concluded:

- significant weighting towards long-term incentive compensation discourages short-term risk taking;
- for most employees, base salary makes up a significant majority of compensation;
- goals are appropriately set to avoid targets that, if not achieved, result in a large percentage loss of compensation;
- equity ownership guidelines discourage excessive risk taking; and
- as a pharmaceutical company, the Company does not face the same level of risks associated with compensation for employees at financial services (traders and instruments with a high degree of risk) or technology companies (rapidly changing markets).

Furthermore, as described in our Compensation Discussion and Analysis, compensation decisions include subjective considerations, which restrain the influence of formulae or objective factors on excessive risk taking.

## **Transactions with Related Persons, Promoters, and Certain Control Persons**

Since January 1, 2009, there has not been nor is there currently proposed any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds \$120,000 and in which any Director, executive officer, holder of more than 5% of our common stock, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest other than:

- (i) compensation agreements and other arrangements, which are described elsewhere in this proxy statement; and
- (ii) the transactions described below.

Harbor-UCLA Research Educational Institute (REI) licenses certain intellectual property and provides other research services to us. We are also obligated to pay REI royalties on future sales of products covered by the license agreement. Our joint venture with Genzyme is subject to a second agreement with REI that requires the joint venture to pay REI a royalty on sales of Aldurazyme through November 2019, of which Emil D. Kakkis, M.D., Ph.D., our former Chief Medical Officer, is entitled to certain portions, per the terms of the agreement. The license agreement was effective before Dr. Kakkis was one of our officers. Pursuant to these agreements, REI was entitled to payments of \$7.4 million, \$9.1 million and \$9.3 million during 2007, 2008 and 2009, respectively, and from this amount, Dr. Kakkis was entitled to approximately \$1.4 million, \$1.8 million and \$1.8 million during 2007, 2008, and 2009 respectively.

## **Review, Approval, and Ratification of Related Party Transactions**

Our CGN Committee has primary responsibility for reviewing and approving in advance or ratifying all related party transactions. Additionally, on at least an annual basis, the Audit Committee also reviews all identified related party transactions. In conformance with SEC regulations, we define related persons to include our executive officers, our directors and nominees to become a director of our company, any person who is known to us to be the beneficial owner of more than 5% of any class of our voting securities, any immediate family member of any of the foregoing persons, and any firm, corporation or other entity in which any of the foregoing persons is employed, is a general partner or in which such person has a 5% or greater beneficial ownership interest.

We have several processes that we use to ensure that we identify and review all related party transactions. First, each executive officer is required to notify either our general counsel or chief financial officer of any potential transaction that could create a conflict of interest, and the general counsel or chief financial officer are required to notify the CGN Committee of the potential conflict. The directors, chief executive officer, chief financial officer and general counsel are required to notify the CGN Committee of any potential transaction that could create a conflict of interest. Second, each year, we submit and require our directors and executive officers to complete director and officer questionnaires identifying any transactions with us in which the executive officer or director or their family members have an interest.

The CGN Committee reviews related party transactions due to the potential for such transactions to create a conflict of interest. A conflict of interest occurs when an individual's private interest interferes, or appears to interfere, with our interests. It is our general policy to approve or ratify related person transactions only when our Board or a committee of our Board determines that the transaction is in, or is not inconsistent with, our and our stockholders' best interests, including situations where the Company may obtain products or services of a nature, quantity or quality, or on other terms, that are not readily available from alternative sources or when the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party.

These policies and procedures are included in our Corporate Governance Principles, which is available in the "Corporate Governance" section of the "Investors" section of our website at [www.bmrn.com](http://www.bmrn.com). Information on our website is not incorporated by reference into this proxy statement.

#### **Indebtedness of Directors and Executive Officers**

None of our directors or executive officers or associates of any Director or executive officer is or at any time since January 1, 2009 has been indebted to us.

## OTHER MATTERS

Except as otherwise indicated, information contained herein is given as of March 25, 2010. Our management and our Board know of no matters to come before the Annual Meeting other than the matters referred to in the Notice of Annual Meeting of Stockholders. The persons named in the enclosed proxy will vote the shares represented thereby in accordance with the recommendation of the Board as to any proposal properly presented at the Annual Meeting, or if no recommendation is made by the Board, then pursuant to the authority granted in the proxy or vote by Internet or telephone.

The matters to be considered at the Annual Meeting are of great importance to our stockholders. Accordingly, you are urged to read and carefully consider the information presented in this proxy statement, and to sign and date the enclosed Proxy Card and return it today in the enclosed pre-addressed postage-paid envelope.

## IMPORTANT NOTE

**YOUR VOTE IS IMPORTANT, NO MATTER HOW MANY OR HOW FEW SHARES YOU HOLD.** Please sign and date the enclosed Proxy Card and return it today in the enclosed pre-addressed postage-paid envelope or vote by Internet or telephone. Please do not complete any subsequently delivered proxy cards unless they are solicited by the Company. If your shares are held in street name, only your broker or bank can vote your shares and only upon receipt of your specific instructions. Please return the enclosed Proxy Card to your broker and contact the person responsible for your account to ensure that a Proxy Card is voted on your behalf. **IN ADDITION, TO ENSURE THAT THE PRESENCE OF A QUORUM AT THE ANNUAL MEETING MAY BE ASSURED, PLEASE SIGN AND DATE THE ENCLOSED PROXY CARD AND RETURN IT TODAY IN THE ENCLOSED PRE-ADDRESSED POSTAGE-PAID ENVELOPE OR VOTE BY INTERNET OR TELEPHONE AS SOON AS POSSIBLE.**

## CONTACT FOR QUESTIONS AND ASSISTANCE IN VOTING

If you have any questions or need assistance in voting your shares, please call the firm assisting us in the solicitation of proxies:

Morrow & Co., LLC  
470 West Avenue  
Stamford, CT 06902  
1-800-607-0088

If you need additional copies of this proxy statement or voting materials, you should contact Morrow & Co., LLC as described above.

## APPROVAL

The contents of this proxy statement and the sending thereof to the stockholders have been authorized by the Board of Directors of the Company.

DATED this 1<sup>st</sup> day of April, 2010 at Novato, California



G. Eric Davis  
Senior Vice President, General Counsel and Secretary



**BIOMARIN PHARMACEUTICAL INC.**  
**2006 SHARE INCENTIVE PLAN**  
(As amended and restated on March 22, 2010)

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**PLAN DOCUMENT**

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### 1. Establishment, Purpose, and Types of Awards

BioMarin Pharmaceutical Inc. (the “**Company**”) hereby establishes this equity-based incentive compensation plan to be known as the “BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan” (hereinafter referred to as the “**Plan**”), in order to provide incentives and awards to select employees, directors, consultants, and advisors of the Company and its Affiliates. The Plan permits grants of the following types of awards (“**Awards**”), according to the Sections of the Plan listed here:

<b>Section 6</b>	Options
<b>Section 7</b>	Restricted Shares, Restricted Share Units, and Unrestricted Shares
<b>Section 8</b>	Deferred Share Units
<b>Section 9</b>	Performance Awards

The Plan is not intended to affect and shall not affect any stock options, equity-based compensation, or other benefits that the Company or its Affiliates may have provided, or may separately provide in the future pursuant to any agreement, plan, or program that is independent of this Plan. Without limiting the foregoing, upon approval of the Plan by the stockholders of the Company, no further awards or grants shall be made under the Company’s 1997 Stock Plan or the Company’s 1998 Director Option Plan.

### 2. Defined Terms

Terms in the Plan that begin with an initial capital letter have the defined meaning set forth in *Appendix A*, unless defined elsewhere in this Plan or the context of their use clearly indicates a different meaning.

### 3. Shares Subject to the Plan

Subject to the provisions of **Section 12**, the maximum number of Shares that the Company may issue for all Awards (including ISOs) shall not exceed Twenty-Three Million (23,000,000) Shares, less one (1) Share for every one (1) Share that is subject to an Award granted prior to May 12, 2010, less one (1) Share for every one (1) Share that is subject to an Option granted on or after May 12, 2010 and less 1.62 Shares for every one (1) Share that is subject to any Award granted on or after May 12, 2010 other than an Option. For all Awards, the Shares issued pursuant to the Plan may be authorized but unissued Shares, or Shares that the Company has reacquired or otherwise holds in treasury.

Shares that are subject to an Award that for any reason expires, is forfeited, is cancelled, or becomes unexercisable, and Shares that are for any other reason not paid or delivered under the Plan shall again, except to the extent prohibited by Applicable Law, be available for subsequent Awards under the Plan to the extent provided in this paragraph. The following Shares shall not be added back to the Shares authorized for issuance: (i) Shares tendered by a Participant or withheld by the Company in payment of the exercise price of an Option or other obligation owed by the Participant to the Company in connection with the exercise or settlement of the

Award, (ii) Shares tendered by a Participant or withheld by the Company to satisfy any tax withholding obligation with respect to an Award, and (iii) Shares subject to an Award that settled for cash (in whole or in part). Any Shares that again become available for issuance pursuant to this paragraph shall be added back as one (1) Share for every one (1) Share that is subject to an Award granted prior to May 12, 2010, one (1) Share for every one (1) Share that is subject to an Option granted on or after May 12, 2010 and 1.62 Shares for every one (1) Share that is subject to any Award granted on or after May 12, 2010 other than an Option. Notwithstanding the foregoing, but subject to adjustments pursuant to **Section 12**, the number of Shares that are available for ISO Awards shall be determined, to the extent required under applicable tax laws, by reducing the number of Shares designated in the preceding paragraph by the number of Shares issued pursuant to Awards.

#### **4. Administration**

(a) *General.* The Committee shall administer the Plan in accordance with its terms, provided that the Board may act in lieu of the Committee on any matter. The Committee shall hold meetings at such times and places as it may determine and shall make such rules and regulations for the conduct of its business as it deems advisable. In the absence of a duly appointed Committee or if the Board otherwise chooses to act in lieu of the Committee, the Board shall function as the Committee for all purposes of the Plan.

(b) *Committee Composition.* The Board shall appoint the members of the Committee. If and to the extent permitted by Applicable Law, the Committee may authorize one or more Directors to make Awards to Eligible Persons who are not Reporting Persons. The Board may at any time appoint additional members to the Committee, remove and replace members of the Committee with or without Cause, and fill vacancies on the Committee however caused. Unless otherwise directed by the Board, the Committee shall be the Compensation Committee of the Board.

(c) *Powers of the Committee.* Subject to the provisions of the Plan, the Committee shall have the authority, in its sole discretion:

(i) to determine Eligible Persons to whom Awards shall be granted from time to time and the number of Shares or units to be covered by each Award;

(ii) to determine, from time to time, the Fair Market Value of Shares;

(iii) to determine, and to set forth in Award Agreements, the terms and conditions of all Awards, including any applicable exercise or purchase price, the installments and conditions under which an Award shall become vested (which may be based on performance), terminated, expired, cancelled, or replaced, and the circumstances for vesting acceleration or waiver of forfeiture restrictions, and other restrictions and limitations;

(iv) to approve the forms of Award Agreements and all other documents, notices and certificates in connection therewith which need not be identical either as to type of Award or among Participants;

(v) to construe and interpret the terms of the Plan and any Award Agreement, to determine the meaning of their terms, and to prescribe, amend, and rescind rules and procedures relating to the Plan and its administration;

(vi) in order to fulfill the purposes of the Plan and without amending the Plan, modify, cancel, or waive the Company's rights with respect to any Awards, to adjust or to modify Award Agreements for changes in Applicable Law, and to recognize differences in foreign law, tax policies, or customs; and

(vii) to make all other interpretations and to take all other actions that the Committee may consider necessary or advisable to administer the Plan or to effectuate its purposes.

Subject to Applicable Law and the restrictions set forth in the Plan, the Committee may delegate administrative functions to individuals who are Reporting Persons, officers, or Employees of the Company or its Affiliates.

(d) *Deference to Committee Determinations.* The Committee shall have the discretion to interpret or construe ambiguous, unclear, or implied (but omitted) terms in any fashion it deems to be appropriate in its sole discretion, and to make any findings of fact needed in the administration of the Plan or Award Agreements. The Committee's prior exercise of its discretionary authority shall not obligate it to exercise its authority in a like fashion thereafter. The Committee's interpretation and construction of any provision of the Plan, or of any Award or Award Agreement, shall be final, binding, and conclusive. The validity of any such interpretation, construction, decision or finding of fact shall not be given de novo review if challenged in court, by arbitration, or in any other forum, and shall be upheld unless clearly made in bad faith or materially affected by fraud.

(e) *Prohibition on Repricing.* Notwithstanding anything contained in this Plan to the contrary, unless the Company has obtained the consent of a majority of the Shareholders, in no event will the Committee or the Company authorize any amendment to the Plan, or to any Award under the Plan, that would effect a reduction in the price per Share of such Award, other than as a result of a stock split or other recapitalization as contemplated by **Section 12**. Furthermore, except as contemplated by **Section 12**, no Award shall be cancelled and replaced with a grant of an Award having a lesser price per Share without the consent of a majority of the Shareholders.

(f) *No Liability; Indemnification.* Neither the Board nor any Committee member, nor any Person acting at the direction of the Board or the Committee, shall be liable for any act, omission, interpretation, construction or determination made in good faith with respect to the Plan, any Award or any Award Agreement. The Company and its Affiliates shall pay or reimburse any member of the Committee, as well as any Director, Employee, or Consultant who takes action in connection with the Plan, for all expenses incurred with respect to the Plan, and to the full extent allowable under Applicable Law shall indemnify each and every one of them for any claims, liabilities, and costs (including reasonable attorney's fees) arising out of their good faith performance of duties under the Plan. The Company and its Affiliates may obtain liability insurance for this purpose.

## 5. Eligibility

(a) *General Rule.* The Committee may grant ISOs only to Employees (including officers who are Employees) of the Company or an Affiliate that is a "parent corporation" or "subsidiary corporation" within the meaning of Section 424 of the Code, and may grant all other Awards to any Eligible Person. A Participant who has been granted an Award may be granted an additional Award or Awards if the Committee shall so determine, if such person is otherwise an Eligible Person and if otherwise in accordance with the terms of the Plan.

(b) *Grant of Awards.* Subject to the express provisions of the Plan, the Committee shall determine from the class of Eligible Persons those individuals to whom Awards under the Plan may be granted, the number of Shares subject to each Award, the price (if any) to be paid for the Shares or the Award and, in the case of Performance Awards, in addition to the matters addressed in **Section 9**, the specific objectives, goals and performance criteria that further define the Performance Award. Each Award shall be evidenced by an Award Agreement signed by the Company and, if required by the Committee, by the Participant. The Award Agreement shall set forth the material terms and conditions of the Award established by the Committee, and each Award shall be subject to the terms and conditions set forth in **Sections 22, 23, and 24** unless otherwise specifically provided in an Award Agreement.

(c) *Replacement Awards.* Subject to Applicable Laws (including the last sentence of this section), the Committee may, in its sole discretion and upon such terms as it deems appropriate, require as a condition of the grant of an Award to a Participant that the Participant surrender for cancellation some or all of the Awards that have previously been granted to the Participant under this Plan or otherwise. An Award that is conditioned upon such surrender may or may not be the same type of Award, may cover the same (or a lesser or greater) number of Shares as such surrendered Award, may have other terms that are determined without regard to the terms or conditions of such surrendered Award, and may contain any other terms that the Committee deems appropriate. In the case of Options, these other terms may not involve an Exercise Price that is lower than the Exercise Price of the surrendered Option unless the Company's shareholders approve the grant itself or the program under which the grant is made pursuant to the Plan.

## 6. Option Awards

(a) *Types; Documentation.* Subject to **Section 5(a)**, the Committee may in its discretion grant Options pursuant to Award Agreements that are delivered to Participants. Each Option shall be designated in the Award Agreement as an ISO or a Non-ISO, and the same Award Agreement may grant both types of Options. At the sole discretion of the Committee, any Option may be exercisable, in whole or in part, immediately upon the grant thereof, or only after the occurrence of a specified event, or only in installments, which installments may vary. Options granted under the Plan may contain such terms and provisions not inconsistent with the Plan that the Committee shall deem advisable in its sole and absolute discretion.

(b) *ISO \$100,000 Limitation.* To the extent that the aggregate Fair Market Value of Shares with respect to which Options designated as ISOs first become exercisable by a Participant in any calendar year (under this Plan and any other plan of the Company or any Affiliate) exceeds \$100,000, such excess Options shall be treated as Non-ISOs. For purposes of determining whether the \$100,000 limit is exceeded, the Fair Market Value of the Shares subject to an ISO shall be determined as of the Grant Date. In reducing the number of Options treated as ISOs to meet the \$100,000 limit, the most recently granted Options shall be reduced first. In the event that Section 422 of the Code is amended to alter the limitation set forth therein, the limitation of this **Section 6(b)** shall be automatically adjusted accordingly.

(c) *Term of Options.* Each Award Agreement shall specify a term at the end of which the Option automatically expires, subject to earlier termination provisions contained in **Section 6(h)** hereof; provided, that, the term of any Option may not exceed ten years from the Grant Date. In the case of an ISO granted to an Employee who is a Ten Percent Holder on the Grant Date, the term of the ISO shall not exceed five years from the Grant Date.

(d) *Exercise Price.* The exercise price of an Option shall be determined by the Committee in its sole discretion and shall be set forth in the Award Agreement, provided that –

- (i) if an ISO is granted to an Employee who on the Grant Date is a Ten Percent Holder, the per Share exercise price shall not be less than 110% of the Fair Market Value per Share on the Grant Date, and
- (ii) for all other Options, such per Share exercise price shall not be less than 100% of the Fair Market Value per Share on the Grant Date.

(e) *Exercise of Option.* The times, circumstances and conditions under which an Option shall be exercisable shall be determined by the Committee in its sole discretion and set forth in the Award Agreement. The Committee shall have the discretion to determine whether and to what extent the vesting of Options shall be tolled during any unpaid leave of absence; provided, however, that in the absence of such determination, vesting of Options shall be tolled during any such leave approved by the Company.

(f) *Minimum Exercise Requirements.* An Option may not be exercised for a fraction of a Share. The Committee may require in an Award Agreement that an Option be exercised as to a minimum number of Shares, provided that such requirement shall not prevent a Participant from purchasing the full number of Shares as to which the Option is then exercisable.

(g) *Methods of Exercise.* Prior to its expiration pursuant to the terms of the applicable Award Agreement, and subject to the times, circumstances and conditions for exercise contained in the applicable Award Agreement, each Option may be exercised, in whole or in part (provided that the Company shall not be required to issue fractional shares), by delivery of written notice of exercise to the secretary of the Company accompanied by the full exercise price of the Shares being purchased. In the case of an ISO, the Committee shall determine the acceptable methods of payment on the Grant Date and it shall be included in the applicable Award Agreement. The methods of payment that the Committee may in its discretion accept or commit to accept in an Award Agreement include:

- (i) cash or check payable to the Company (in U.S. dollars);

(ii) other Shares that (A) are owned by the Participant who is purchasing Shares pursuant to an Option, (B) have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which the Option is being exercised, (C) were not acquired by such Participant pursuant to the exercise of an Option, unless such Shares have been owned by such Participant for at least six months or such other period as the Committee may determine, (D) are all, at the time of such surrender, free and clear of any and all claims, pledges, liens and encumbrances, or any restrictions which would in any manner restrict the transfer of such shares to or by the Company (other than such restrictions as may have existed prior to an issuance of such Shares by the Company to such Participant), and (E) are duly endorsed for transfer to the Company;

(iii) a cashless exercise program that the Committee may approve, from time to time in its discretion, pursuant to which a Participant may concurrently provide irrevocable instructions (A) to such Participant's broker or dealer to effect the immediate sale of the purchased Shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the exercise price of the Option plus all applicable taxes required to be withheld by the Company by reason of such exercise, and (B) to the Company to deliver the certificates for the purchased Shares directly to such broker or dealer in order to complete the sale; or

(iv) any combination of the foregoing methods of payment.

The Company shall not be required to deliver Shares pursuant to the exercise of an Option until payment of the full exercise price therefore is received by the Company.

(h) *Termination of Continuous Service.* The Committee may establish and set forth in the applicable Award Agreement the terms and conditions on which an Option shall remain exercisable, if at all, following termination of a Participant's Continuous Service. The Committee may waive or modify these provisions at any time. To the extent that a Participant is not entitled to exercise an Option at the date of his or her termination of Continuous Service, or if the Participant (or other person entitled to exercise the Option) does not exercise the Option to the extent so entitled within the time specified in the Award Agreement or below (as applicable), the Option shall terminate and the Shares underlying the unexercised portion of the Option shall revert to the Plan and become available for future Awards. In no event may any Option be exercised after the expiration of the Option term as set forth in the Award Agreement.

The following provisions shall apply to the extent an Award Agreement does not specify the terms and conditions upon which an Option shall terminate when there is a termination of a Participant's Continuous Service:

(i) Termination other than Upon Disability or Death or for Cause. In the event of termination of a Participant's Continuous Service (other than as a result of Participant's death, disability, retirement or termination for Cause), the Participant shall have the right to exercise an Option at any time within 90 days following such termination to the extent the Participant was entitled to exercise such Option at the date of such termination.

(ii) Disability. In the event of termination of a Participant's Continuous Service as a result of his or her being Disabled, the Participant shall have the right to exercise an Option at any time within one year following such termination to the extent the Participant was entitled to exercise such Option at the date of such termination.

(iii) Retirement. In the event of termination of a Participant's Continuous Service as a result of Participant's retirement, the Participant shall have the right to exercise the Option at any time within six months following such termination to the extent the Participant was entitled to exercise such Option at the date of such termination.

(iv) Death. In the event of the death of a Participant during the period of Continuous Service since the Grant Date of an Option, or within thirty days following termination of the Participant's Continuous

Service, the Option may be exercised, at any time within one year following the date of the Participant's death, by the Participant's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent the right to exercise the Option had vested at the date of death or, if earlier, the date the Participant's Continuous Service terminated.

(v) Cause. If the Committee determines that a Participant's Continuous Service terminated due to Cause, the Participant shall immediately forfeit the right to exercise any Option, and it shall be considered immediately null and void.

(i) *Reverse Vesting*. The Committee in its sole discretion may allow a Participant to exercise unvested Options, in which case the Shares then issued shall be Restricted Shares having analogous vesting restrictions to the unvested Options.

## **7. Restricted Shares, Restricted Share Units, and Unrestricted Shares**

(a) *Grants*. The Committee may in its sole discretion grant restricted shares ("**Restricted Shares**") to any Eligible Person and shall evidence such grant in an Award Agreement that is delivered to the Participant and that sets forth the number of Restricted Shares, the purchase price for such Restricted Shares (if any), and the terms upon which the Restricted Shares may become vested. In addition, the Company may in its discretion grant to any Eligible Person the right to receive Shares after certain vesting requirements are met ("**Restricted Share Units**"), and shall evidence such grant in an Award Agreement that is delivered to the Participant and that sets forth the number of Shares (or formula, that may be based on future performance or conditions, for determining the number of Shares) that the Participant shall be entitled to receive upon vesting and the terms upon which the Shares subject to a Restricted Share Unit may become vested and the delivery terms for such Shares. The Committee may condition any Award of Restricted Shares or Restricted Share Units to a Participant on receiving from the Participant such further assurances and documents as the Committee may require to enforce the restrictions. In addition, the Committee may grant Awards hereunder in the form of unrestricted shares ("**Unrestricted Shares**"), which shall vest in full upon the date of grant or such other date as the Committee may determine or which the Committee may issue pursuant to any program under which one or more Eligible Persons (selected by the Committee in its sole discretion) elect to pay for such Shares or to receive Unrestricted Shares in lieu of cash bonuses that would otherwise be paid.

(b) *Vesting and Forfeiture*. The Committee shall set forth in an Award Agreement granting Restricted Shares or Restricted Share Units, the terms and conditions under which the Participant's interest in the Restricted Shares or the Shares subject to Restricted Share Units will become vested and non-forfeitable. Except as set forth in the applicable Award Agreement or the Committee otherwise determines, upon termination of a Participant's Continuous Service for any other reason, the Participant shall forfeit his or her Restricted Shares and unvested Restricted Share Units; provided that if a Participant purchases the Restricted Shares and forfeits them for any reason, the Company shall return the purchase price to the Participant only if and to the extent set forth in an Award Agreement.

(c) *Issuance of Restricted Shares Prior to Vesting*. The Company shall issue stock certificates that evidence Restricted Shares pending the lapse of applicable restrictions, and that bear a legend making appropriate reference to such restrictions. Except as set forth in the applicable Award Agreement or the Committee otherwise determines, the Company or a third party that the Company designates shall hold such Restricted Shares and any dividends that accrue with respect to Restricted Shares pursuant to **Section 7(e)**.

(d) *Issuance of Shares upon Vesting*. As soon as practicable after vesting of a Participant's Restricted Shares (or Shares underlying Restricted Share Units) and the Participant's satisfaction of applicable tax withholding requirements, the Company shall release to the Participant, free from the vesting restrictions, one Share for each vested Restricted Share (or issue one Share free of the vesting restriction for each vested Restricted Share Unit), unless an Award Agreement provides otherwise. No fractional shares shall be distributed, and cash shall be paid in lieu thereof.

(e) *Dividends Payable on Vesting.* Whenever unrestricted Shares are issued to a Participant pursuant to **Section 7(d)**, the Participant shall also receive, with respect to each Share issued, (i) a number of Shares equal to the stock dividends which were declared and paid to the holders of Shares between the Grant Date and the date such Share is issued, and (ii) a number of Shares having a Fair Market Value equal to any cash dividends that were paid to the holders of Shares based on a record date between the Grant Date and the date such Share is issued.

(f) *Section 83(b) Elections.* A Participant may make an election under Section 83(b) of the Code (the “**Section 83(b) Election**”) with respect to Restricted Shares. If a Participant who has received Restricted Share Units provides the Committee with written notice of his or her intention to make a Section 83(b) Election with respect to the Shares subject to such Restricted Share Units, the Committee may in its discretion convert the Participant’s Restricted Share Units into Restricted Shares, on a one-for-one basis, in full satisfaction of the Participant’s Restricted Share Unit Award. The Participant may then make a Section 83(b) Election with respect to those Restricted Shares. Shares with respect to which a Participant makes a Section 83(b) Election shall not be eligible for deferral pursuant to **Section 8**.

(g) *Deferral Elections.* At any time within the thirty-day period (or other shorter or longer period that the Committee selects in its sole discretion) in which a Participant who is a member of a select group of management or highly compensated employees (within the meaning of the Code) receives an Award of either Restricted Shares or Restricted Share Units, the Committee may permit the Participant to irrevocably elect, on a form provided by and acceptable to the Committee, to defer the receipt of all or a percentage of the Shares that would otherwise be transferred to the Participant upon the vesting of such Award. If the Participant makes this election, the Shares subject to the election, and any associated dividends and interest, shall be credited to an account established pursuant to **Section 8** on the date such Shares would otherwise have been released or issued to the Participant pursuant to **Section 7(d)**.

## **8. Deferred Share Units**

(a) *Elections to Defer.* The Committee may permit any Eligible Person who is a Director, Consultant or member of a select group of management or highly compensated employees (within the meaning of the Code) to irrevocably elect, on a form provided by and acceptable to the Committee (the “**Election Form**”), to forego the receipt of cash or other compensation (including the Shares deliverable pursuant to any Award other than Restricted Shares for which a Section 83(b) Election has been made), and in lieu thereof to have the Company credit to an internal Plan account (the “**Account**”) a number of deferred share units (“**Deferred Share Units**”) having a Fair Market Value equal to the Shares and other compensation deferred. These credits will be made at the end of each calendar month during which compensation is deferred. Each Election Form shall take effect on the first day of the next calendar year (or on the first day of the next calendar month in the case of an initial election by a Participant who first becomes eligible to defer hereunder) after its delivery to the Company, subject to **Section 7(g)** regarding deferral of Restricted Shares and Restricted Share Units and to **Section 9(e)** regarding deferral of Performance Awards, unless the Company sends the Participant a written notice explaining why the Election Form is invalid within five business days after the Company receives it. Notwithstanding the foregoing sentence: (i) Election Forms shall be ineffective with respect to any compensation that a Participant earns before the date on which the Company receives the Election Form, and (ii) the Committee may unilaterally make awards in the form of Deferred Share Units, regardless of whether or not the Participant foregoes other compensation.

(b) *Vesting.* Unless an Award Agreement expressly provides otherwise, each Participant shall be 100% vested at all times in any Shares subject to Deferred Share Units.

(c) *Issuances of Shares.* The Company shall provide a Participant with one Share for each Deferred Share Unit in five substantially equal annual installments that are issued before the last day of each of the five calendar years that end after the date on which the Participant’s Continuous Service terminates, unless –

(i) the Participant has properly elected a different form of distribution, on a form approved by the Committee, that permits the Participant to select any combination of a lump sum and annual installments that are completed within ten years following termination of the Participant’s Continuous Service, and

(ii) the Company received the Participant's distribution election form at the time the Participant elects to defer the receipt of cash or other compensation pursuant to **Section 8(a)**, provided that such election may be changed through any subsequent election that (i) is delivered to the Company at least one year before the date on which distributions are otherwise scheduled to commence pursuant to the Participant's election, and (ii) defers the commencement of distributions by at least five years from the originally scheduled commencement date.

Fractional shares shall not be issued, and instead shall be paid out in cash.

(d) *Crediting of Dividends.* Whenever Shares are issued to a Participant pursuant to **Section 8(c)**, the Participant shall also receive, with respect to each Share issued, (i) a number of Shares equal to any stock dividends which were declared and paid to the holders of Shares between the Grant Date and the date such Share is issued, and (ii) a number of Shares having a Fair Market Value equal to any cash dividends that were paid to the holders of Shares based on a record date between the Grant Date and the date such Share is issued.

(e) *Emergency Withdrawals.* In the event a Participant suffers an unforeseeable emergency within the contemplation of this **Section 8(e)** and Section 409A of the Code, the Participant may apply to the Company for an immediate distribution of all or a portion of the Participant's Deferred Share Units. The unforeseeable emergency must result from a sudden and unexpected illness or accident of the Participant, the Participant's spouse, or a dependent (within the meaning of Section 152(a) of the Code) of the Participant, casualty loss of the Participant's property, or other similar extraordinary and unforeseeable conditions beyond the control of the Participant. Examples of purposes which are not considered unforeseeable emergencies include post-secondary school expenses or the desire to purchase a residence. In no event will a distribution be made to the extent the unforeseeable emergency could be relieved through reimbursement or compensation by insurance or otherwise, or by liquidation of the Participant's nonessential assets to the extent such liquidation would not itself cause a severe financial hardship. The amount of any distribution hereunder shall be limited to the amount necessary to relieve the Participant's unforeseeable emergency plus amounts necessary to pay taxes reasonably anticipated as a result of the distribution. The Committee shall determine whether a Participant has a qualifying unforeseeable emergency and the amount which qualifies for distribution, if any. The Committee may require evidence of the purpose and amount of the need, and may establish such application or other procedures as it deems appropriate.

(f) *Unsecured Rights to Deferred Compensation.* A Participant's right to Deferred Share Units shall at all times constitute an unsecured promise of the Company to pay benefits as they come due. The right of the Participant or the Participant's duly-authorized transferee to receive benefits hereunder shall be solely an unsecured claim against the general assets of the Company. Neither the Participant nor the Participant's duly-authorized transferee shall have any claim against or rights in any specific assets, shares, or other funds of the Company.

## **9. Performance Awards**

(a) *Performance Units.* The Committee may in its discretion grant Performance Units to any Eligible Person and shall evidence such grant in an Award Agreement that is delivered to the Participant which sets forth the terms and conditions of the Award.

(b) *Performance Compensation Awards.* The Committee may, at the time of grant of a Performance Unit, designate such Award as a "Performance Compensation Award" (payable in cash or Shares) in order that such Award constitutes "qualified performance-based compensation" under Code Section 162(m), in which event the Committee shall have the power to grant such Performance Compensation Award upon terms and conditions that qualify it as "qualified performance-based compensation" within the meaning of Code Section 162(m). With respect to each such Performance Compensation Award, the Committee shall establish, in writing within the time required under Code Section 162(m), a "Performance Period," "Performance Measure(s)," and "Performance Formula(e)" (each such term being hereinafter defined).



A Participant shall be eligible to receive payment in respect of a Performance Compensation Award only to the extent that the Performance Measure(s) for such Award is achieved and the Performance Formula(e) as applied against such Performance Measure(s) determines that all or some portion of such Participant's Award has been earned for the Performance Period. As soon as practicable after the close of each Performance Period, the Committee shall review and certify in writing whether, and to what extent, the Performance Measure(s) for the Performance Period have been achieved and, if so, determine and certify in writing the amount of the Performance Compensation Award to be paid to the Participant and, in so doing, may use negative discretion to decrease, but not increase, the amount of the Award otherwise payable to the Participant based upon such performance.

(c) *Definitions.*

(i) **"Performance Formula"** means, for a Performance Period, one or more objective formulas or standards established by the Committee for purposes of determining whether or the extent to which an Award has been earned based on the level of performance attained or to be attained with respect to one or more Performance Measure(s). Performance Formulae may vary from Performance Period to Performance Period and from Participant to Participant and may be established on a stand-alone basis, in tandem or in the alternative.

(ii) **"Performance Measure"** means one or more of the following selected by the Committee to measure Company, Affiliate, and/or business unit performance for a Performance Period, whether in absolute or relative terms (including, without limitation, terms relative to a peer group or index): basic, diluted, or adjusted earnings per share; sales or revenue; earnings before interest, taxes, and other adjustments (in total or on a per share basis); basic or adjusted net income; returns on equity, assets, capital, revenue or similar measure; economic value added; working capital; total shareholder return; and product development, product market share, research, licensing, litigation, human resources, information services, mergers, acquisitions, sales of assets of Affiliates or business units. Each such measure shall be, to the extent applicable, determined in accordance with generally accepted accounting principles as consistently applied by the Company (or such other standard applied by the Committee) and, if so determined by the Committee, and in the case of a Performance Compensation Award, to the extent permitted under Code Section 162(m), adjusted to omit the effects of extraordinary items, gain or loss on the disposal of a business segment, unusual or infrequently occurring events and transactions and cumulative effects of changes in accounting principles. Performance Measures may vary from Performance Period to Performance Period and from Participant to Participant, and may be established on a stand-alone basis, in tandem or in the alternative.

(iii) **"Performance Period"** means one or more periods of time (of not less than one fiscal year of the Company), as the Committee may designate, over which the attainment of one or more Performance Measure(s) will be measured for the purpose of determining a Participant's rights in respect of an Award.

(d) *Deferral Elections.* At any time prior to the date that is at least six months before the close of a Performance Period (or shorter or longer period that the Committee selects) with respect to an Award of either Performance Units or Performance Compensation, the Committee may permit a Participant who is a member of a select group of management or highly compensated employees (within the meaning of the Code) to irrevocably elect, on a form provided by and acceptable to the Committee, to defer the receipt of all or a percentage of the cash or Shares that would otherwise be transferred to the Participant upon the vesting of such Award. If the Participant makes this election, the cash or Shares subject to the election, and any associated interest and dividends, shall be credited to an account established pursuant to **Section 8** on the date such cash or Shares would otherwise have been released or issued to the Participant pursuant to **Section 9(a)** or **Section 9(b)**.

## 10. Taxes

(a) *General.* As a condition to the issuance or distribution of Shares pursuant to the Plan, the Participant (or in the case of the Participant's death, the person who succeeds to the Participant's rights) shall make such arrangements as the Company may require for the satisfaction of any applicable federal, state, local or foreign withholding tax obligations that may arise in connection with the Award and the issuance of Shares. The Company shall not be required to issue any Shares until such obligations are satisfied. If the Committee allows the withholding or surrender of Shares to satisfy a Participant's tax withholding obligations, the Committee shall not allow Shares to be withheld in an amount that exceeds the minimum statutory withholding rates for federal and state tax purposes, including payroll taxes.

(b) *Default Rule for Employees.* In the absence of any other arrangement, an Employee shall be deemed to have directed the Company to withhold or collect from his or her cash compensation an amount sufficient to satisfy such tax obligations from the next payroll payment otherwise payable after the date of the exercise of an Award.

(c) *Special Rules.* In the case of a Participant other than an Employee (or in the case of an Employee where the next payroll payment is not sufficient to satisfy such tax obligations, with respect to any remaining tax obligations), in the absence of any other arrangement and to the extent permitted under Applicable Law, the Participant shall be deemed to have elected to have the Company withhold from the Shares or cash to be issued pursuant to an Award that number of Shares having a Fair Market Value determined as of the applicable Tax Date (as defined below) or cash equal to the amount required to be withheld. For purposes of this Section 10, the Fair Market Value of the Shares to be withheld shall be determined on the date that the amount of tax to be withheld is to be determined under the Applicable Law (the "Tax Date").

(d) *Surrender of Shares.* If permitted by the Committee, in its discretion, a Participant may satisfy the minimum applicable tax withholding and employment tax obligations associated with an Award by surrendering Shares to the Company (including Shares that would otherwise be issued pursuant to the Award) that have a Fair Market Value determined as of the applicable Tax Date equal to the amount required to be withheld. In the case of Shares previously acquired from the Company that are surrendered under this Section 10, such Shares must have been owned by the Participant for more than six months on the date of surrender (or such longer period of time the Company may in its discretion require).

(e) *Income Taxes and Deferred Compensation.* Participants are solely responsible and liable for the satisfaction of all taxes and penalties that may arise in connection with Awards (including any taxes arising under Section 409A of the Code), and the Company shall not have any obligation to indemnify or otherwise hold any Participant harmless from any or all of such taxes. The Committee shall have the discretion to organize any deferral program, to require deferral election forms, and to grant or to unilaterally modify any Award in a manner that (i) conforms with the requirements of Section 409A of the Code with respect to compensation that is deferred and that vests after December 31, 2004, (ii) that voids any Participant election to the extent it would violate Section 409A of the Code, and (iii) for any distribution election that would violate Section 409A of the Code, to make distributions pursuant to the Award at the earliest to occur of a distribution event that is allowable under Section 409A of the Code or any distribution event that is both allowable under Section 409A of the Code and is elected by the Participant, subject to any valid second election to defer, provided that the Committee permits second elections to defer in accordance with Section 409A(a)(4)(C). The Committee shall have the sole discretion to interpret the requirements of the Code, including Section 409A, for purposes of the Plan and all Awards.

## 11. Non-Transferability of Awards

(a) *General.* Except as set forth in this Section 11, or as otherwise approved by the Committee, Awards may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by the laws of descent or distribution, or in the case of an option other than an ISO, pursuant to a domestic relations

order as defined under Rule 16a-12 under the Exchange Act. The designation of a beneficiary by a Participant will not constitute a transfer. An Award may be exercised, during the lifetime of the holder of an Award, only by such holder, the duly-authorized legal representative of a Participant who is Disabled, a transferee permitted by this **Section 11**, or except as would cause an ISO to lose such status, by a bankruptcy trustee.

(b) *Limited Transferability Rights.* Notwithstanding anything else in this **Section 11**, the Committee may in its discretion provide in an Award Agreement that an Award relating to non-ISOs, Restricted Shares, or Performance Shares may be transferred, on such terms and conditions as the Committee deems appropriate, either (i) by instrument to the Participant's "Immediate Family" (as defined below), (ii) by instrument to an inter vivos or testamentary trust (or other entity) in which the Award is to be passed to the Participant's designated beneficiaries, or (iii) by gift to charitable institutions. Each share of restricted stock shall be non-transferable until such share becomes non-forfeitable. Any transferee of the Participant's rights shall succeed and be subject to all of the terms of the applicable Award Agreement and the Plan. "Immediate Family" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, and shall include adoptive relationships.

## **12. Adjustments Upon Changes in Capitalization, Merger or Certain Other Transactions**

(a) *Changes in Capitalization.* The Committee shall equitably adjust the number of Shares covered by each outstanding Award, and the number of Shares that have been authorized for issuance under the Plan but as to which no Awards have yet been granted or that have been returned to the Plan upon cancellation, forfeiture, or expiration of an Award, as well as the price per Share covered by each such outstanding Award, to reflect any increase or decrease in the number of issued Shares resulting from a stock-split, reverse stock-split, stock dividend, combination, recapitalization or reclassification of the Shares, or any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company. In the event of any such transaction or event, the Committee may provide in substitution for any or all outstanding Options under the Plan such alternative consideration (including securities of any surviving entity) as it may in good faith determine to be equitable under the circumstances and may require in connection therewith the surrender of all Options so replaced. In any case, such substitution of securities shall not require the consent of any person who is granted Options pursuant to the Plan. Except as expressly provided herein, or in an Award Agreement, if the Company issues for consideration shares of stock of any class or securities convertible into shares of stock of any class, the issuance shall not affect, and no adjustment by reason thereof shall be required to be made with respect to the number or price of Shares subject to any Award.

(b) *Dissolution or Liquidation.* In the event of the dissolution or liquidation of the Company other than as part of a Change of Control, each Award will terminate immediately prior to the consummation of such action, subject to the ability of the Committee to exercise any discretion authorized in the case of a Change in Control.

(c) *Change in Control.* In the event of a Change in Control, the Committee may in its sole and absolute discretion and authority, without obtaining the approval or consent of the Company's shareholders or any Participant with respect to his or her outstanding Awards, take one or more of the following actions:

(i) arrange for or otherwise provide that each outstanding Award shall be assumed or a substantially similar award shall be substituted by a successor corporation or a parent or subsidiary of such successor corporation (the "Successor Corporation");

(ii) accelerate the vesting of Awards so that Awards shall vest (and, to the extent applicable, become exercisable) as to the Shares that otherwise would have been unvested and provide that repurchase rights of the Company with respect to Shares issued upon exercise of an Award shall lapse as to the Shares subject to such repurchase right;

(iii) arrange or otherwise provide for the payment of cash or other consideration to Participants in exchange for the satisfaction and cancellation of outstanding Awards;

(iv) terminate upon the consummation of the transaction, provided that the Committee may in its sole discretion provide for vesting of all or some outstanding Awards in full as of a date immediately prior to consummation of the Change of Control. To the extent that an Award is not exercised prior to consummation of a transaction in which the Award is not being assumed or substituted, such Award shall terminate upon such consummation; or

(v) make such other modifications, adjustments or amendments to outstanding Awards or this Plan as the Committee deems necessary or appropriate, subject however to the terms of **Section 14(a)**.

Notwithstanding the above, in the event a Participant holding an Award assumed or substituted by the Successor Corporation in a Change in Control is Involuntarily Terminated by the Successor Corporation in connection with, or within 12 months following consummation of, the Change in Control, then any assumed or substituted Award held by the terminated Participant at the time of termination shall accelerate and become fully vested (and exercisable in full in the case of Options), and any repurchase right applicable to any Shares shall lapse in full, unless an Award Agreement provides for a more restrictive acceleration or vesting schedule or more restrictive limitations on the lapse of repurchase rights or otherwise places additional restrictions, limitations and conditions on an Award. The acceleration of vesting and lapse of repurchase rights provided for in the previous sentence shall occur immediately prior to the effective date of the Participant's termination, unless an Award Agreement provides otherwise.

(d) *Certain Distributions.* In the event of any distribution to the Company's shareholders of securities of any other entity or other assets (other than dividends payable in cash or stock of the Company) without receipt of consideration by the Company, the Committee may, in its discretion, appropriately adjust the price per Share covered by each outstanding Award to reflect the effect of such distribution.

### **13. Time of Granting Awards.**

The date of grant ("**Grant Date**") of an Award shall be the date on which the Committee makes the determination granting such Award or such other date as is determined by the Committee and set forth in the Award Agreement, provided that in the case of an ISO, the Grant Date shall be the later of the date on which the Committee makes the determination granting such ISO or the date of commencement of the Participant's employment relationship with the Company.

### **14. Modification of Awards and Substitution of Options.**

(a) *Modification, Extension, and Renewal of Awards.* Within the limitations of the Plan, the Committee may modify an Award to accelerate the rate at which an Option may be exercised (including without limitation permitting an Option to be exercised in full without regard to the installment or vesting provisions of the applicable Award Agreement or whether the Option is at the time exercisable, to the extent it has not previously been exercised), to accelerate the vesting of any Award, to extend or renew outstanding Awards or to accept the cancellation of outstanding Awards to the extent not previously exercised. However, the Committee may not cancel an outstanding option that is underwater for the purpose of reissuing the option to the participant at a lower exercise price or granting a replacement award of a different type. Notwithstanding the foregoing provision, no modification of an outstanding Award shall materially and adversely affect such Participant's rights thereunder, thereunder (with such an affect being presumed to arise from a modification that would trigger a violation of Section 409A of the Code), unless either (i) the Participant provides written consent or (ii) before a Change in Control the Committee determines in good faith that the modification is not materially adverse to the Participant.

(b) *Substitution of Options.* Notwithstanding any inconsistent provisions or limits under the Plan, in the event the Company or an Affiliate acquires (whether by purchase, merger or otherwise) all or substantially all of outstanding capital stock or assets of another corporation or in the event of any reorganization or other transaction qualifying under Section 424 of the Code, the Committee may, in accordance with the provisions of

that Section, substitute Options for options under the plan of the acquired company provided (i) the excess of the aggregate fair market value of the shares subject to an option immediately after the substitution over the aggregate option price of such shares is not more than the similar excess immediately before such substitution and (ii) the new option does not give persons additional benefits, including any extension of the exercise period.

#### **15. Term of Plan.**

The Plan shall continue in effect for a term of ten (10) years from its effective date as determined under **Section 19**, unless the Plan is sooner terminated under **Section 16**.

#### **16. Amendment and Termination of the Plan.**

(a) *Authority to Amend or Terminate.* Subject to Applicable Laws, the Board may from time to time amend, alter, suspend, discontinue, or terminate the Plan; provided that any amendment to increase the annual restriction on the amount of Awards provided for in **Section 3** shall be subject to Shareholder approval.

(b) *Effect of Amendment or Termination.* No amendment, suspension, or termination of the Plan shall materially and adversely affect Awards already granted (with such an effect being presumed to arise from a modification that would trigger a violation of Section 409A of the Code) unless either it relates to an adjustment pursuant to Section 12, or modification pursuant to Section 14(a) above, or it is otherwise mutually agreed between the Participant and the Committee, which agreement must be in writing and signed by the Participant and the Company. Notwithstanding the foregoing, the Committee may amend the Plan to eliminate provisions which are no longer necessary as a result of changes in tax or securities laws or regulations, or in the interpretation thereof.

#### **17. Conditions Upon Issuance of Shares.**

Notwithstanding any other provision of the Plan or any agreement entered into by the Company pursuant to the Plan, the Company shall not be obligated, and shall have no liability for failure, to issue or deliver any Shares under the Plan unless such issuance or delivery would comply with Applicable Law, with such compliance determined by the Company in consultation with its legal counsel.

#### **18. Reservation of Shares.**

The Company, during the term of this Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.

#### **19. Effective Date.**

This Plan shall become effective on the date of its approval by the Board; provided that this Plan shall be submitted to the Company's stockholders for approval, and if not approved by the stockholders in accordance with Applicable Laws (as determined by the Committee in its sole discretion) within one year from the date of approval by the Board, this Plan and any Awards shall be null, void, and of no force and effect. Awards granted under this Plan before approval of this Plan by the shareholders shall be granted subject to such approval, and no Shares shall be distributed before such approval.

#### **20. Controlling Law.**

All disputes relating to or arising from the Plan shall be governed by the internal substantive laws (and not the laws of conflicts of laws) of the State of Delaware, to the extent not preempted by United States federal law. If any provision of this Plan is held by a court of competent jurisdiction to be invalid and unenforceable, the remaining provisions shall continue to be fully effective.

## 21. Laws And Regulations.

(a) *U.S. Securities Laws.* This Plan, the grant of Awards, and the exercise of Options under this Plan, and the obligation of the Company to sell or deliver any of its securities (including, without limitation, Options, Restricted Shares, Restricted Share Units, Deferred Share Units, and Shares) under this Plan shall be subject to all Applicable Law. In the event that the Shares are not registered under the Securities Act of 1933, as amended (the “Act”), or any applicable state securities laws prior to the delivery of such Shares, the Company may require, as a condition to the issuance thereof, that the persons to whom Shares are to be issued represent and warrant in writing to the Company that such Shares are being acquired by him or her for investment for his or her own account and not with a view to, for resale in connection with, or with an intent of participating directly or indirectly in, any distribution of such Shares within the meaning of the Act, and a legend to that effect may be placed on the certificates representing the Shares.

(b) *Other Jurisdictions.* To facilitate the making of any grant of an Award under this Plan, the Committee may provide for such special terms for Awards to Participants who are foreign nationals or who are employed by the Company or any Affiliate outside of the United States of America as the Committee may consider necessary or appropriate to accommodate differences in local law, tax policy or custom. The Company may adopt rules and procedures relating to the operation and administration of this Plan to accommodate the specific requirements of local laws and procedures of particular countries. Without limiting the foregoing, the Company is specifically authorized to adopt rules and procedures regarding the conversion of local currency, taxes, withholding procedures and handling of stock certificates which vary with the customs and requirements of particular countries. The Company may adopt sub-plans and establish escrow accounts and trusts as may be appropriate or applicable to particular locations and countries.

**22. No Shareholder Rights.** Neither a Participant nor any transferee of a Participant shall have any rights as a shareholder of the Company with respect to any Shares underlying any Award until the date of issuance of a share certificate to a Participant or a transferee of a Participant for such Shares in accordance with the Company’s governing instruments and Applicable Law. Prior to the issuance of Shares pursuant to an Award, a Participant shall not have the right to vote or to receive dividends or any other rights as a shareholder with respect to the Shares underlying the Award, notwithstanding its exercise in the case of Options. No adjustment will be made for a dividend or other right that is determined based on a record date prior to the date the stock certificate is issued, except as otherwise specifically provided for in this Plan.

**23. No Employment Rights.** The Plan shall not confer upon any Participant any right to continue an employment, service or consulting relationship with the Company, nor shall it affect in any way a Participant’s right or the Company’s right to terminate the Participant’s employment, service, or consulting relationship at any time, with or without Cause.

**24. Termination, Rescission and Recapture of Awards.** Notwithstanding any other provision of the Plan, but subject to any contrary terms set forth in any Award Agreement, this Section 24 shall only apply to a Participant who is, on the Award Date, an Employee of the Company or its Affiliates, and shall automatically cease to apply to any Participant from and after his or her termination of Continuous Service after a Change in Control.

(a) Each Award under the Plan is intended to align the Participant’s long-term interest with those of the Company. If the Participant engages in certain activities discussed below, either during employment or after employment with the Company terminates for any reason, the Participant is acting contrary to the long-term interests of the Company. Accordingly, except as otherwise expressly provided in the Award Agreement, the Company may terminate any outstanding, unexercised, unexpired, unpaid, or deferred Awards (“**Termination**”), rescind any exercise, payment or delivery pursuant to the Award (“**Rescission**”), or recapture any Common Stock (whether restricted or unrestricted) or proceeds from the Participant’s sale of Shares issued pursuant to the Award (“**Recapture**”), if the Participant does not comply with the conditions of subsections (b) and (c) hereof (collectively, the “**Conditions**”).

(b) A Participant shall not, without the Company's prior written authorization, disclose to anyone outside the Company, or use in other than the Company's business, any proprietary or confidential information or material, as those or other similar terms are used in any applicable patent, confidentiality, inventions, secrecy, or other agreement between the Participant and the Company with regard to any such proprietary or confidential information or material.

(c) Pursuant to any agreement between the Participant and the Company with regard to intellectual property (including but not limited to patents, trademarks, copyrights, trade secrets, inventions, developments, improvements, proprietary information, confidential business and personnel information), a Participant shall promptly disclose and assign to the Company or its designee all right, title, and interest in such intellectual property, and shall take all reasonable steps necessary to enable the Company to secure all right, title and interest in such intellectual property in the United States and in any foreign country.

(d) Upon exercise, payment, or delivery of cash or Common Stock pursuant to an Award, the Participant shall certify on a form acceptable to the Company that he or she is in compliance with the terms and conditions of the Plan and, if a severance of Continuous Service has occurred for any reason, shall state the name and address of the Participant's then-current employer or any entity for which the Participant performs business services and the Participant's title, and shall identify any organization or business in which the Participant owns a greater-than-five-percent equity interest.

(e) If the Company determines, in its sole and absolute discretion, that (i) a Participant has violated any of the Conditions or (ii) during his or her Continuous Service, or within 2 years after its termination for any reason, a Participant (a) has rendered services to or otherwise directly or indirectly engaged in or assisted, any organization or business that, in the judgment of the Company in its sole and absolute discretion, is or is working to become competitive with the Company; (b) has solicited any non-administrative employee of the Company to terminate employment with the Company; or (c) has engaged in activities which are materially prejudicial to or in conflict with the interests of the Company, including any breaches of fiduciary duty or the duty of loyalty, then the Company may, in its sole and absolute discretion, impose a Termination, Rescission, and/or Recapture with respect to any or all of the Participant's relevant Awards, Shares, and the proceeds thereof.

(f) Within ten days after receiving notice from the Company of any such activity, the Participant shall deliver to the Company the Shares acquired pursuant to the Award, or, if Participant has sold the Shares, the gain realized, or payment received as a result of the rescinded exercise, payment, or delivery; provided, that if the Participant returns Shares that the Participant purchased pursuant to the exercise of an Option (or the gains realized from the sale of such Common Stock), the Company shall promptly refund the exercise price, without earnings, that the Participant paid for the Shares. Any payment by the Participant to the Company pursuant to this **Section 24** shall be made either in cash or by returning to the Company the number of Shares that the Participant received in connection with the rescinded exercise, payment, or delivery. It shall not be a basis for Termination, Rescission or Recapture if after termination of a Participant's Continuous Service, the Participant purchases, as an investment or otherwise, stock or other securities of such an organization or business, so long as (i) such stock or other securities are listed upon a recognized securities exchange or traded over-the-counter, and (ii) such investment does not represent more than a five percent (5%) equity interest in the organization or business.

(g) Notwithstanding the foregoing provisions of this Section, the Company has sole and absolute discretion not to require Termination, Rescission and/or Recapture, and its determination not to require Termination, Rescission and/or Recapture with respect to any particular act by a particular Participant or Award shall not in any way reduce or eliminate the Company's authority to require Termination, Rescission and/or Recapture with respect to any other act or Participant or Award. Nothing in this Section shall be construed to impose obligations on the Participant to refrain from engaging in lawful competition with the Company after the termination of employment that does not violate subsections (b) or (c) of this Section, other than any obligations that are part of any separate agreement between the Company and the Participant or that arise under applicable law.

(h) All administrative and discretionary authority given to the Company under this Section shall be exercised by the most senior human resources executive of the Company or such other person or committee (including without limitation the Committee) as the Committee may designate from time to time.

(i) Notwithstanding any provision of this Section, if any provision of this Section is determined to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted by applicable law, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law. Furthermore, if any provision of this Section is illegal under any applicable law, such provision shall be null and void to the extent necessary to comply with applicable law.



**Biomarin Pharmaceutical Inc.**  
**SHARE INCENTIVE PLAN**

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**Appendix A: Definitions**

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As used in the Plan, the following definitions shall apply:

**“Affiliate”** means, with respect to any Person (as defined below), any other Person that directly or indirectly controls or is controlled by or under common control with such Person. For the purposes of this definition, “control,” when used with respect to any Person, means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of such Person or the power to elect directors, whether through the ownership of voting securities, by contract or otherwise; and the terms “affiliated,” “controlling” and “controlled” have meanings correlative to the foregoing.

**“Applicable Law”** means the legal requirements relating to the administration of options and share-based plans under applicable U.S. federal and state laws, the Code, any applicable stock exchange or automated quotation system rules or regulations, and the applicable laws of any other country or jurisdiction where Awards are granted, as such laws, rules, regulations and requirements shall be in place from time to time.

**“Award”** means any award made pursuant to the Plan, including awards made in the form of an Option, a Restricted Share, a Restricted Share Unit, an Unrestricted Share, a Deferred Share Unit, and a Performance Award, or any combination thereof, whether alternative or cumulative, authorized by and granted under this Plan.

**“Award Agreement”** means any written document setting forth the terms of an Award that has been authorized by the Committee. The Committee shall determine the form or forms of documents to be used, and may change them from time to time for any reason.

**“Board”** means the Board of Directors of the Company.

**“Cause”** for termination of a Participant’s Continuous Service will have the meaning set forth in any unexpired employment agreement between the Company and the Participant. In the absence of such an agreement, “Cause” will exist if the Participant is terminated from employment or other service with the Company or an Affiliate for any of the following reasons: (i) the Participant’s willful failure to substantially perform his or her duties and responsibilities to the Company or deliberate violation of a material Company policy; (ii) the Participant’s commission of any material act or acts of fraud, embezzlement, dishonesty, or other willful misconduct; (iii) the Participant’s material unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) Participant’s willful and material breach of any of his or her obligations under any written agreement or covenant with the Company.

The Committee shall in its discretion determine whether or not a Participant is being terminated for Cause. The Committee’s determination shall, unless arbitrary and capricious, be final and binding on the Participant, the Company, and all other affected persons. The foregoing definition does not in any way limit the Company’s ability to terminate a Participant’s employment or consulting relationship at any time, and the term “Company” will be interpreted herein to include any Affiliate or successor thereto, if appropriate.

**“Change in Control”** means any of the following:

(i) *Acquisition of Controlling Interest.* Any Person becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company’s then outstanding securities. In applying the preceding sentence, (i) securities acquired directly

from the Company or its Affiliates by or for the Person shall not be taken into account, and (ii) an agreement to vote securities shall be disregarded unless its ultimate purpose is to cause what would otherwise be Change of Control, as reasonably determined by the Board.

(ii) *Change in Board Control.* During a consecutive 2-year period commencing after the date of adoption of this Plan, individuals who constituted the Board at the beginning of the period (or their approved replacements, as defined in the next sentence) cease for any reason to constitute a majority of the Board. A new Director shall be considered an “approved replacement” Director if his or her election (or nomination for election) was approved by a vote of at least a majority of the Directors then still in office who either were Directors at the beginning of the period or were themselves approved replacement Directors, but in either case excluding any Director whose initial assumption of office occurred as a result of an actual or threatened solicitation of proxies or consents by or on behalf of any Person other than the Board.

(iii) *Merger.* The Company consummates a merger, or consolidation of the Company with any other corporation unless: (a) the voting securities of the Company outstanding immediately before the merger or consolidation would continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least 50% of the combined voting power of the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; and (b) no Person becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company’s then outstanding securities.

(iv) *Sale of Assets.* The stockholders of the Company approve an agreement for the sale or disposition by the Company of all, or substantially all, of the Company’s assets.

(v) *Liquidation or Dissolution.* The stockholders of the Company approve a plan or proposal for liquidation or dissolution of the Company.

Notwithstanding the foregoing, a “Change in Control” shall not be deemed to have occurred by virtue of the consummation of any transaction or series of integrated transactions immediately following which the record holders of the common stock of the Company immediately prior to such transaction or series of transactions continue to have substantially the same proportionate ownership in an entity which owns all or substantially all of the assets of the Company immediately following such transaction or series of transactions.

“**Code**” means the U.S. Internal Revenue Code of 1986, as amended.

“**Committee**” means one or more committees or subcommittees of the Board appointed by the Board to administer the Plan in accordance with **Section 4** above. With respect to any decision involving an Award intended to satisfy the requirements of Section 162(m) of the Code, the Committee shall consist of two or more Directors of the Company who are “outside directors” within the meaning of Section 162(m) of the Code. With respect to any decision relating to a Reporting Person, the Committee shall consist of two or more Directors who are disinterested within the meaning of Rule 16b-3.

“**Company**” means BioMarin Pharmaceutical Inc., a Delaware corporation; provided, however, that in the event the Company reincorporates to another jurisdiction, all references to the term “Company” shall refer to the Company in such new jurisdiction.

“**Consultant**” means any person, including an advisor, who is engaged by the Company or any Affiliate to render services and is compensated for such services.

“**Continuous Service**” means the absence of any interruption or termination of service as an Employee, Director, or Consultant. Continuous Service shall not be considered interrupted in the case of: (i) sick leave; (ii) military leave; (iii) any other leave of absence approved by the Committee, provided that such leave is for a period of not more than 90 days, unless reemployment upon the expiration of such leave is guaranteed by

contract or statute, or unless provided otherwise pursuant to Company policy adopted from time to time; (iv) changes in status from Director to advisory director or emeritus status; or (iv) in the case of transfers between locations of the Company or between the Company, its Affiliates or their respective successors. Changes in status between service as an Employee, Director, and a Consultant will not constitute an interruption of Continuous Service.

**“Deferred Share Units”** mean Awards pursuant to **Section 8**.

**“Director”** means a member of the Board, or a member of the board of directors of an Affiliate.

**“Disabled”** means a condition under which a Participant

(a) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, or

(b) is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, received income replacement benefits for a period of not less than 3 months under an accident or health plan covering employees of the Company.

**“Eligible Person”** means any Consultant, Director or Employee and includes non-Employees to whom an offer of employment has been extended.

**“Employee”** means any person whom the Company or any Affiliate classifies as an employee (including an officer) for employment tax purposes, whether or not that classification is correct. The payment by the Company of a director’s fee to a Director shall not be sufficient to constitute “employment” of such Director by the Company.

**“Exchange Act”** means the Securities Exchange Act of 1934, as amended.

**“Fair Market Value”** means, as of any date (the **“Determination Date”**) means: (i) the closing price of a Share on the New York Stock Exchange or the American Stock Exchange (collectively, the **“Exchange”**), on the Determination Date, or, if shares were not traded on the Determination Date, then on the nearest preceding trading day during which a sale occurred; or (ii) if such stock is not traded on the Exchange but is quoted on NASDAQ or a successor quotation system, (A) the last sales price (if the stock is then listed as a National Market Issue under The Nasdaq National Market System) or (B) the mean between the closing representative bid and asked prices (in all other cases) for the stock on the Determination Date as reported by NASDAQ or such successor quotation system; or (iii) if such stock is not traded on the Exchange or quoted on NASDAQ but is otherwise traded in the over-the-counter, the mean between the representative bid and asked prices on the Determination Date; or (iv) if subsections (i)-(iii) do not apply, the fair market value established in good faith by the Board.

**“Grant Date”** has the meaning set forth in **Section 13**.

**“Incentive Share Option or ISO”** hereinafter means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code, as designated in the applicable Award Agreement.

**“Involuntary Termination”** means termination of a Participant’s Continuous Service under the following circumstances occurring on or after a Change in Control: (i) termination without Cause by the Company or an Affiliate or successor thereto, as appropriate; or (ii) voluntary termination by the Participant within 60 days following (A) a material reduction in the Participant’s job responsibilities, provided that neither a mere change in title alone nor reassignment to a substantially similar position shall constitute a material reduction in job

responsibilities; (B) an involuntary relocation of the Participant's work site to a facility or location more than 50 miles from the Participant's principal work site at the time of the Change in Control; or (C) a material reduction in Participant's total compensation other than as part of a reduction by the same percentage amount in the compensation of all other similarly-situated Employees, Directors or Consultants.

**"Non-ISO"** means an Option not intended to qualify as an ISO, as designated in the applicable Award Agreement.

**"Option"** means any stock option granted pursuant to **Section 6**.

**"Participant"** means any holder of one or more Awards, or the Shares issuable or issued upon exercise of such Awards, under the Plan.

**"Performance Awards"** mean Performance Units and Performance Compensation Awards granted pursuant to **Section 9**.

**"Performance Compensation Awards"** mean Awards granted pursuant to **Section 9(b)**.

**"Performance Unit"** means Awards granted pursuant to **Section 9(a)**, which may be paid in cash, in Shares, or such combination of cash and Shares as the Committee in its sole discretion shall determine.

**"Person"** means any natural person, association, trust, business trust, cooperative, corporation, general partnership, joint venture, joint-stock company, limited partnership, limited liability company, real estate investment trust, regulatory body, governmental agency or instrumentality, unincorporated organization or organizational entity.

**"Plan"** means this BioMarin Pharmaceutical Inc. 2006 Share Incentive Plan.

**"Reporting Person"** means an officer, Director, or greater than ten percent shareholder of the Company within the meaning of Rule 16a-2 under the Exchange Act, who is required to file reports pursuant to Rule 16a-3 under the Exchange Act.

**"Restricted Shares"** mean Shares subject to restrictions imposed pursuant to **Section 7**.

**"Restricted Share Units"** mean Awards pursuant to **Section 7**.

**"Rule 16b-3"** means Rule 16b-3 promulgated under the Exchange Act, as amended from time to time, or any successor provision.

**"Separation from Service"** has the meaning set forth in Section 9 of the Plan.

**"Share"** means a share of common stock of the Company, as adjusted in accordance with **Section 12**.

**"Ten Percent Holder"** means a person who owns stock representing more than ten percent (10%) of the combined voting power of all classes of stock of the Company or any Affiliate.

**"Unrestricted Shares"** mean Shares awarded pursuant to **Section 7**.

**BIOMARIN PHARMACEUTICAL INC.  
2006 SHARE INCENTIVE PLAN**

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THE YEAR 2009 WILL BE REMEMBERED BY MANY AS ONE OF THE MOST TURBULENT ECONOMIC TIMES IN RECENT HISTORY. AT BIOMARIN, HOWEVER, WE HAD THE DISTINCT FORTUNE TO NOT ONLY WEATHER THE VOLATILE ECONOMIC STORMS, BUT TO THRIVE. INCREASED GLOBAL DEMAND FOR OUR THERAPIES AND AGGRESSIVE PIPELINE EXPANSION WILL BE THE HALLMARKS OF 2009.

The year was not without its challenges, but by leveraging the confidence and security that comes with having strong cash reserves, a solid financial footing and an unwavering focus on building long term value, we further solidified our position in the rare disease arena. Throughout the coming year, we will continue to enhance our product pipeline and maximize investment opportunities to fuel long term growth.

Highlights of the year include strong sales of our three commercialized products, the acquisition of Huxley Pharmaceuticals and several promising compounds, the advancement of several clinical and nonclinical programs, and the anticipated launch of our fourth and newly acquired product, Firdapse™ (amifampridine phosphate) for LEMS in Europe. The company's total net product revenues increased 25 percent over 2008, posting at \$315.7 million. Naglazyme sales in new and

existing markets exceeded our expectations with a 27 percent increase in net product sales over 2008, and third party sales of Aldurazyme showed modest gains as the number of patients on therapy continued to increase. Total annual net revenues for Kuvan were \$76.8 million, compared to \$46.7 million in 2008, and year end cash, cash equivalents and short and long term investments posted at \$470.5 million for the year. Another important achievement was the completion of construction of our new manufacturing facility in Novato, which will more than double our manufacturing capacity.

Encouraging early data from the GALNS Phase I/II program for MPS IVA leads us to anticipate a pivotal Phase III trial by the end of 2010. As for PEG-PAL, the Phase II study is progressing and we expect to report some results in the third quarter of 2010. We continue to build important data on Kuvan therapy outcomes and we have initiated an exciting new program to develop a real time blood Phe monitoring device that will enable patients to better track and manage their PKU. Our BMN-195 small molecule upregulator of utrophin for Duchenne Muscular Dystrophy has advanced from preclinical status to Phase I clinical trials. Soon we will begin

discussions with the FDA to establish development plans for Firdapse in the U.S. and we plan to submit an IND for the PARP inhibitor BMN-673 at the end of 2010.

We are pleased with our performance in 2009 and well positioned to meet our goals for 2010 as we look forward to an exciting year ahead. We are focused on carefully managing our pipeline and commercial products with the goal of continuing double-digit revenue growth in the coming years and to maximize long term value to BioMarin, patients and our shareholders.

I thank all of our employees for their expertise, passion and hard work throughout the year.

I would also like to thank patients and physicians for partnering with us to develop important therapeutics for rare diseases. I look forward to keeping you informed and sharing future developments with you as 2010 progresses.

Thank you for your support.

Sincerely,



Jean-Jacques Bienaimé  
Chief Executive Officer



BIOMARIN PHARMACEUTICAL DEVELOPS, MANUFACTURES AND COMMERCIALIZES INNOVATIVE BIOPHARMACEUTICALS FOR SERIOUS DISEASES AND MEDICAL CONDITIONS. THE COMPANY'S PRODUCT PORTFOLIO COMPRISES FOUR APPROVED THERAPIES AND MULTIPLE CLINICAL AND NONCLINICAL PRODUCT CANDIDATES.

2009 MILESTONES

FINANCIAL STRENGTH

Robust product sales fueled growth in 2009 and the company expects to be cash flow positive in 2010. To maximize long term value to patients and shareholders, management is focused on carefully managing the advancing pipeline portfolio with the goal to continue double-digit revenue growth in the coming years.

PIPELINE EXPANSION

BioMarin continues to make significant investments in research and development to ensure continued growth and innovation. The current pipeline includes a collection of promising clinical and nonclinical programs.

INVESTMENT IN THE FUTURE

BioMarin recently completed construction of its expanded manufacturing facility in Novato, California. This new site will accommodate a wide range of production systems to support future clinical and commercial manufacturing needs for Aldurazyme and Naglazyme and, if approved, GALNS and PEG-PAL.

INTERNATIONAL COMMERCIAL GROWTH

Sales of BioMarin's three commercial products continued to increase in 2009, driven by higher than expected international demand for Naglazyme. The company's fourth and newly acquired product, Firdapse™ for LEMS, will

soon be launched in Europe and the company is currently exploring development strategies for the U.S. market, along with additional indications for future development.

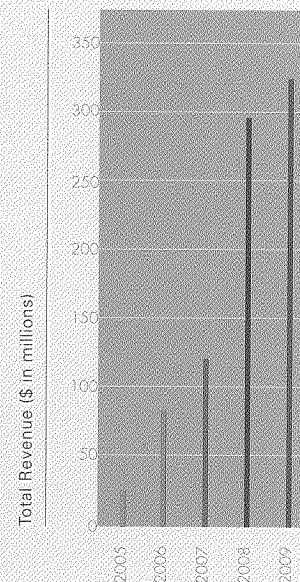
PEOPLE POWER

BioMarin continues to increase recruiting efforts to support the company's rapid growth. At the close of 2009 the employee roster contained a total of 714 people. In 2010, with even more attention focused on pipeline development and further global expansion, the company has plans to increase personnel by up to 15 percent in the next nine months.

BIOMARIN PIPELINE

NONCLINICAL TESTING	PHASE 1	PHASE 2	PHASE 3	BLA · NDA · MAA	COMMERCIALIZED
Naglazyme® for MPS VI					
Aldurazyme® for MPS I					
Kuvan® for PKU					
Firdapse™ for LEMS					
BMN-110 GALNS for MPS IVA					
PEG-PAL for PKU					
BMN-195 Utrophin upregulator for Duchenne Muscular Dystrophy					
BMN-103 α-glucosidase (GAA) for Pompe Disease					
BMN-168 6R-BH4 Prodrug					
BMN-185 IgA Protease for IgA Nephropathy					
BMN-673 PARP Inhibitor for Genetically Defined Cancers					
BMN-111					

5-YR REVENUE GROWTH



**FORWARD-LOOKING STATEMENT:** This Annual Report contains 'forward-looking statements' as defined under securities laws. These statements can generally be identified by the use of terminology such as 'believes', 'expects', 'anticipates', 'plans', 'intends', 'may', 'will', 'projects', 'continues', 'estimates', 'potential', 'opportunity', and so on. The company's actual results or experience may differ significantly from the forward-looking statement. Factors that could cause or contribute to these differences include the results of current clinical trials, the company's ability to obtain regulatory approval for product candidates, its ability to successfully market products and other factors discussed in the enclosed Form 10-K and the section entitled 'Risk Factors' therein.

One should not place undue influence on these forward-looking statements that 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 the company may issue in the future. BioMarin Pharmaceutical Inc. does not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the distribution of this Annual Report to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

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