

MEDICINES CO /DE  
Form 10-K  
February 29, 2012  
Table of Contents

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, 2011

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 000-31191

THE MEDICINES COMPANY

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

04-3324394

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

8 Sylvan Way

Parsippany, New Jersey

(Address of principal executive offices)

07054

(Zip Code)

Registrant's telephone number, including area code: (973) 290-6000

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

Title of Each Class

Common Stock, \$.001 Par Value Per Share

Name of Each Exchange on Which Registered

NASDAQ Global Select Market

Securities registered pursuant to 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 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  
Section 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 pursuant to Item 405 of Regulation S-K is not contained  
herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements  
incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,  
or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company” in Rule 12b-2 of the Exchange Act. (Check one):

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 ☒

The aggregate market value of voting Common Stock held by non-affiliates of the registrant on June 30, 2011 was approximately \$886,130,796 based on the last reported sale price of the Common Stock on The NASDAQ Global Select Market on June 30, 2011 of \$16.51 per share.

Number of shares of the registrant’s class of Common Stock outstanding as of February 23, 2012: 54,340,407.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2011. Portions of the proxy statement are incorporated herein by reference into the following parts of this Annual Report on Form 10-K:

Part III, Item 10. Directors, Executive Officers and Corporate Governance;

Part III, Item 11. Executive Compensation;

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Table of Contents

Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters;

Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence; and

Part III, Item 14. Principal Accountant Fees and Services.

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Table of Contents

THE MEDICINES COMPANY  
ANNUAL REPORT ON FORM 10-K  
For the Fiscal Year Ended December 31, 2011  
TABLE OF CONTENTS

	Page
<u>PART I</u>	
<u>ITEM 1</u> <u>BUSINESS</u>	<u>2</u>
<u>ITEM 1A</u> <u>RISK FACTORS</u>	<u>31</u>
<u>ITEM 1B</u> <u>UNRESOLVED STAFF COMMENTS</u>	<u>52</u>
<u>ITEM 2</u> <u>PROPERTIES</u>	<u>52</u>
<u>ITEM 3</u> <u>LEGAL PROCEEDINGS</u>	<u>52</u>
<u>ITEM 4</u> <u>MINE SAFETY DISCLOSURES</u>	<u>56</u>
<u>PART II</u>	
<u>ITEM 5</u> <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER</u> <u>MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>56</u>
<u>ITEM 6</u> <u>SELECTED FINANCIAL DATA</u>	<u>58</u>
<u>ITEM 7</u> <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND</u> <u>RESULTS OF OPERATIONS</u>	<u>59</u>
<u>ITEM 7A</u> <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>84</u>
<u>ITEM 8</u> <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>84</u>
<u>ITEM 9</u> <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING</u> <u>AND FINANCIAL DISCLOSURE</u>	<u>84</u>
<u>ITEM 9A</u> <u>CONTROLS AND PROCEDURES</u>	<u>84</u>
<u>ITEM 9B</u> <u>OTHER INFORMATION</u>	<u>85</u>
<u>PART III</u>	
<u>ITEM 10</u> <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	<u>85</u>
<u>ITEM 11</u> <u>EXECUTIVE COMPENSATION</u>	<u>85</u>
<u>ITEM 12</u> <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</u> <u>AND RELATED STOCKHOLDER MATTERS</u>	<u>85</u>
<u>ITEM 13</u> <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR</u> <u>INDEPENDENCE</u>	<u>85</u>
<u>ITEM 14</u> <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	<u>85</u>
<u>PART IV</u>	
<u>ITEM 15</u> <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	<u>86</u>
EX-21	
EX-23	
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	
EX-101 INSTANCE DOCUMENT	
EX-101 SCHEMA DOCUMENT	
EX-101 CALCULATION LINKBASE DOCUMENT	
EX-101 LABELS LINKBASE DOCUMENT	
EX-101 PRESENTATION LINKBASE DOCUMENT	

EX-101 DEFINITION LINKBASE DOCUMENT

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Table of Contents

The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® are either registered trademarks or trademarks of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this annual report on Form 10-K are the property of their respective owners. Except where otherwise indicated, or where the context may otherwise require, references to “Angiomax” in this annual report on Form 10-K mean Angiomax and Angiox, collectively. References to the “Company,” “we,” “us” or “our” mean The Medicines Company, a Delaware corporation, and its subsidiaries.

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our “critical accounting estimates” described in Item 7 in Part II of this annual report and the factors set forth under the caption “Risk Factors” in Item 1A in Part I of this annual report. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on our forward-looking statements as representing our views as of any date subsequent to the date of this annual report.

Table of Contents

## PART I

## Item 1. Business

## Our Company

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have three marketed products, Angiomax<sup>®</sup>(bivalirudin), Cleviprex<sup>®</sup> (clevidipine butyrate) injectable emulsion and our ready-to-use formulation of Argatroban. We also have a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and two early stage development product candidates, MDCO-2010 and MDCO-216. We believe that our marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of our products in development, have the potential to offer, improved performance to hospital businesses. In addition, in January 2012 we acquired from APP Pharmaceuticals, LLC, or APP, non-exclusive rights to market in the United States a portfolio of ten generic drugs, which we refer to as our acute care generic products.

The following chart identifies each of our marketed products and our products in development, their stage of development, their mechanism of action and the indications for which they have been approved for use or which they are intended to address. The following chart also identifies each of our acute care generic products and the therapeutic areas which they are intended to address. All of our marketed products and products in development are administered intravenously. All of our acute care generic products are injectable products.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Angiomax	Marketed	Direct thrombin inhibitor	U.S. - for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA, and for use in patients undergoing percutaneous coronary intervention, or PCI, including patients with or at risk of heparin induced thrombocytopenia and thrombosis syndrome, or HIT/HITS Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or

			STEMI, undergoing primary PCI
Cleviprex	Marketed in the United States; Approved in the United Kingdom, the Netherlands, Sweden, Switzerland, Australia and New Zealand; Marketing Authorization Application, or MAA, submitted in certain European Union countries	Calcium channel blocker	U.S. - Blood pressure reduction when oral therapy is not feasible or not desirable Ex-U.S. - with indications for blood pressure control in perioperative settings
Cangrelor	Phase 3	Antiplatelet agent	Prevention of platelet activation and aggregation when oral therapy is not feasible or not desirable Treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI, and including infections that are resistant to conventional treatment
Oritavancin	Phase 3	Antibiotic	



Table of Contents

MDCO-157 (IV clopidogrel)	Pre-registration stage	Platelet inhibitor	Platelet inhibition in patients suffering from ACS or patients recently experiencing myocardial infarction, stroke, or peripheral arterial disease when oral therapy is not feasible or not desirable
MDCO-2010	Phase 2	Serine protease inhibitor	Reduction of blood loss during surgery
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	Reversal cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events
Ready-to-Use Argatroban	Marketed in the United States	Direct thrombin inhibitor	Approved for prophylaxis or treatment of thrombosis in adult patients with HIT and for use as an anticoagulant in adult patients with or at risk for HIT undergoing PCI.
Acute care generic products: Adenosine, Amiodarone, Esmolol and Milrinone	Approved in the United States	Various	Cardiovascular
Acute care generic products: Azithromycin and Clindamycin	Approved in the United States	Various	Serious infection
Acute care generic products: Haloperidol, Ondansetron, Midazolam and Rocuronium	Approved in the United States	Various	Neurocritical care

## Angiomax

## Overview

We licensed Angiomax, an intravenous direct thrombin inhibitor that is a peptide compound, from Biogen Idec, Inc., or Biogen Idec, in 1997 and have exclusive license rights to develop, market, and sell Angiomax worldwide. We received our first marketing approval for Angiomax from the U.S. Food and Drug Administration, or the FDA, in December 2000 and our first marketing approval for the European Union in September 2004. We market Angiomax in the United States for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing PTCA and for use in patients undergoing PCI, including patients with or at risk of HIT/HITS.

In Europe, we market Angiox for use as an anticoagulant in patients undergoing PCI, for use in adult patients with ACS, and for the treatment of STEMI patients undergoing primary PCI. Our approval for ACS in Europe also includes specifically patients with unstable angina or non-STEMI planned for urgent or early intervention when used with aspirin and clopidogrel. Angiomax is also approved for sale in Australia, Canada and a number of countries in Central America, South America and the Middle East for PCI indications similar to those approved by the FDA. In addition, Angiomax is approved in Canada for the treatment of patients with HIT/HITS undergoing cardiac surgery.

We continue to develop Angiomax for use in additional patient populations, including patients with structural heart disease, patients undergoing peripheral angioplasty, carotid angioplasty and cardiovascular surgery and patients with or at risk of HIT/HITTS.

We market Angiomax to hospital systems, individual hospitals and health care providers, including interventional cardiologists in cardiac catheterization laboratories. In evaluating our operating performance, we focus on use of Angiomax by existing hospital customers and penetration into new hospitals. Both of these efforts are critical elements of our ability to increase market share and revenue. In 2011, our net sales of Angiomax totaled approximately \$483.9 million, including approximately \$452.3 million of net sales in the United States.

To support the commercialization and distribution efforts of Angiomax, we have developed, and continue to develop, our business infrastructure outside the United States, including forming subsidiaries, obtaining licenses and authorizations necessary to distribute Angiomax, hiring personnel and entering into arrangements for services from third parties, such as importation, packaging, quality control and distribution. We currently have operations in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, India, Italy, the Netherlands, New Zealand, Norway, Poland, Russia, Spain, Sweden, Switzerland and the United Kingdom and are developing our business infrastructure and capabilities in Brazil, China, Eastern Europe and Turkey. We believe that by establishing operations outside the United States for Angiomax, we will be positioned

## Table of Contents

to commercialize Cleviprex and our products in development, if and when they are approved outside the United States.

### Angiomax Patent Litigation

The principal U.S. patent covering Angiomax, U.S. patent No. 5,196,404, or the '404 patent, was set to expire in March 2010, but was extended under the Hatch-Waxman Act on an interim basis to August 13, 2012 following our litigation against the U.S. Patent and Trademark Office, or PTO, the FDA and the U.S. Department of Health and Human Services, or HHS. We had applied, under the Hatch-Waxman Act, for an extension of the term of the '404 patent. However, the PTO rejected our application because in its view the application was not timely filed. As a result, we filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our application to extend the term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP appealed the denial of its motion, as well as the federal district court's August 3, 2010 order. On January 22, 2012, we entered into a legal settlement with APP in which APP agreed to dismiss its appeal. Upon dismissal of APP's appeal, all pending litigation regarding the '404 patent was resolved. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. If the term of the '404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015.

In the second half of 2009, the PTO issued to us U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva Pharmaceuticals USA, Inc. and its affiliates, which we refer to collectively as Teva. In connection with the Teva settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers as described in Part 1, Item 3, Legal Proceedings. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, then Angiomax could be subject to generic competition earlier than May 1, 2019.

Our litigation with the PTO, the FDA and HHS, APP's past efforts to appeal the August 3, 2010 decision, the patent infringement suits and our settlements with Teva and APP are described in more detail in Part 1, Item 3 of this annual report.

### Medical Need

Arterial thrombosis is a condition involving the formation of blood clots in arteries that is associated with life-threatening conditions, such as ischemic heart disease, peripheral vascular disease and stroke. Anticoagulation therapy is used for the treatment and prevention of arterial thrombosis. Anticoagulation therapy attempts to modify actions of the components in the blood system that lead to the formation of blood clots and is usually started immediately after a diagnosis of blood clots, or after risk factors for clotting are identified. Anticoagulation therapy typically involves the use of drugs to inhibit one or more components of the clotting process and reduces the risk of clot formation. There are three main areas of the hospital where anticoagulants are used for acute treatment of arterial thrombosis:

- the cardiac catheterization laboratory, where coronary angioplasties are performed;
- the emergency department, where patients with ACS, including chest pain and heart attacks, also known as myocardial infarctions or MIs, are initially treated; and
- the operating room, where valve replacement and repair surgery and CABG surgery are performed.

Table of Contents

Coronary angioplasty procedures inherently increase the risk of clots forming in the coronary arteries or in other arteries of the body. Clots form as the body reacts to the manipulation of the artery as a result of, for example, the use of catheters and other devices in connection with the angioplasty procedure. Accordingly, anticoagulation therapy is routinely administered to patients undergoing angioplasty to slow the clotting process and avoid unwanted clotting in the coronary artery and the potential growth of clots or the movement of a clot or portions of a clot downstream in the blood vessels to new sites.

ACS patients are subject to chest pain that results from a range of conditions, from unstable angina to acute myocardial infarction, or AMI. Unstable angina is caused most often by a rupture of plaque on an arterial wall that results in clot formation and ultimately decreases coronary blood flow but does not cause complete blockage of the artery. Unstable angina is often medically managed in the emergency department with anticoagulation therapy. AMI occurs when coronary arteries, which supply blood to the heart, become completely blocked by a clot. AMI patients are routinely treated with anticoagulants and are increasingly undergoing angioplasty as a primary treatment to unblock clogged arteries.

Many of the most severe ACS patients undergo CABG surgery. A high level of anticoagulation is necessary in on-pump cardiac surgery during the period of cardiopulmonary bypass in order to prevent clots from forming in the machine used in such surgery or in the patient's cardiovascular system. Anticoagulation is also necessary in off-pump cardiac surgery to prevent clots from forming in the patient's cardiovascular system as a result of the manipulation of coronary arteries and the heart.

Heparin has historically been used in the United States as an anticoagulant in the treatment of arterial thrombosis. However, heparin can precipitate the immune response HIT/HITTS and its pharmacokinetics are non-linear, making it less predictable and making standardized dosing difficult. In some patients, especially higher risk ACS patients, either higher doses of heparin or adjunct therapy, such as glycoprotein IIb/IIIa receptor inhibitors, or GP IIb/IIIa inhibitors, are needed, which can result in higher rates of bleeding. These shortcomings are significant because when anticoagulation is insufficient in patients being treated for ischemic heart disease, the consequences can include death, AMI or revascularization. Revascularization occurs when a treated artery is blocked again and requires re-opening. In addition, because anticoagulation therapy reduces clotting, it also may cause excessive bleeding.

#### Clinical Development

We have invested significantly in the development of clinical data on the mode of action and clinical effects of Angiomax in procedures including coronary angioplasty and stenting. In our investigations, we have compared Angiomax to various competitive products, including heparin and enoxaparin, a low-molecular weight heparin, which until relatively recently were the only injectable anticoagulants for use in coronary angioplasty and combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors or oral inhibitors of the P2Y<sub>12</sub> receptor, which is a receptor involved in platelet aggregation. In total, we have tested Angiomax against heparin or enoxaparin or combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors or oral P2Y<sub>12</sub> inhibitors in 12 comparative PCI and ACS trials. In these trials, Angiomax use resulted in rates of complications, such as MI, that were comparable to the comparator drugs in the trials while resulting in fewer bleeding events, including a reduction in the need for blood transfusion, as compared to the comparator drugs in the trials. In addition, in these trials, the therapeutic effects of Angiomax were shown to be more predictable than the therapeutic effects of heparin.

REPLACE-2. We conducted the REPLACE-2 clinical trial in 2001 and 2002 to evaluate Angiomax as the foundation anticoagulant for angioplasty within the context of modern therapeutic products and technologies, including coronary stents. We designed the trial, which involved 6,002 patients in 233 clinical sites, to evaluate whether the use of Angiomax with provisional use of GP IIb/IIIa inhibitors provides clinical outcomes relating to rates of ischemic and bleeding events that are the same as, or non-inferior to, low-dose weight-adjusted heparin plus GP IIb/IIIa inhibitors. The primary objective of REPLACE-2 was to demonstrate non-inferiority to heparin plus a GP IIb/IIIa inhibitor for the quadruple composite effectiveness criteria, or endpoint, of death, MI, urgent revascularization and major bleeding. The secondary objectives of REPLACE-2 included non-inferiority to heparin plus a GP IIb/IIIa inhibitor for a triple composite endpoint of death, MI and urgent revascularization. We assessed these outcomes, using formal statistical tests for non-inferiority. Based on 30-day, 6-month and 12-month patient follow-up results, Angiomax met all primary and secondary objectives for the study. In addition, major hemorrhage was reported significantly less frequently in the

Angiomax with provisional GP IIb/IIIa inhibitor arm compared to the heparin plus a GP IIb/IIIa inhibitor arm. ACUITY. In 2004 and 2005, we conducted a 13,819 patient Phase 3 trial, called ACUITY, which involved Angiomax's use in patients presenting to the emergency department with ACS. In ACUITY, we tested the safety and effectiveness of Angiomax, as compared to heparin plus a GP IIb/IIIa inhibitor, at a lower dose than that which was then used in PCI patients. If an ACS patient treated with Angiomax in the emergency department subsequently underwent PCI, the dose was increased to provide the level of anticoagulation needed to perform the PCI. Outcomes were also measured among ACS patients that did not undergo PCI, namely those patients who were medically managed or who underwent CABG surgery. All of these emergency department ACS patients were randomized into one of three arms:

- a control arm, Arm A, providing for the administration of heparin or enoxaparin with GP IIb/IIIa inhibitors;

## Table of Contents

a second arm, Arm B, providing for the administration of Angiomax with planned use of GP IIb/IIIa inhibitors; and a third arm, Arm C, providing for the administration of Angiomax alone and permitting use of GP IIb/IIIa inhibitors only in selected cases involving ischemic events during PCI.

The 30-day patient results from the ACUITY trial, which were published in the New England Journal of Medicine in November 2006 by the principal investigators, showed that Angiomax met all pre-specified primary and secondary objectives for the ACUITY study. Specifically, in Arm C, the Angiomax monotherapy arm, Angiomax was effective and reduced the risk of major bleeding by 47% compared to the control arm, Arm A. In the Angiomax combination arm, Arm B, the Angiomax and GP IIb/IIIa combination was as effective, with similar reductions in bleeding, as the control arm. In December 2007, the one-year ACUITY results, which confirmed the ACUITY 30-day results, were published in the Journal of the American Medical Association. A subgroup analysis of the ACUITY trial, which was reported in the Journal of the American College of Cardiology in May 2008, revealed that in the trial switching to Angiomax after pre-treatment with heparin resulted in comparable ischemic outcomes and an approximately 50% reduction in major bleeding compared to consistent heparin therapy plus routine GP IIb/IIIa inhibitor for ACS patients undergoing early invasive treatment.

Based on the results of our Phase 3 ACUITY trial, in December 2006 we submitted an application to the European Agency for Evaluation of Medical Products, or EMEA, now the European Medicines Agency, or EMA, seeking approval of an additional indication for Angiomax for the treatment of patients with ACS. In addition, in July 2007 we submitted a supplemental new drug application, or sNDA, to the FDA seeking approval of an additional indication for Angiomax for an additional dosing regimen in the treatment of ACS initiated in the emergency department. In January 2008, the EMEA approved our application and authorized the use of Angiox in adult patients with ACS, when used with aspirin and clopidogrel, including specifically patients with unstable angina or non-ST segment elevation myocardial infarction planned for urgent or early intervention. In May 2008, we received a non-approvable letter from the FDA with respect to the Angiomax sNDA. In its letter, the FDA indicated that the basis of its decision involved the appropriate use and interpretation of the non-inferiority trials we relied upon in support of our sNDA, including the ACUITY trial. We disagree with the FDA on these issues and continue to evaluate how to respond to the FDA's views on the ACUITY trial.

**HORIZONS AMI.** We supported an investigator-initiated trial called HORIZONS AMI that was conducted from 2005 to 2007 to study Angiomax use in patients with STEMI undergoing PCI. The trial involved more than 3,600 patients presenting with STEMI undergoing a primary PCI strategy in hospitals in 11 countries and was designed to evaluate whether Angiomax with provisional use of GP IIb/IIIa inhibitors was as safe and effective as heparin with planned use of GPIIb/IIIa inhibitors in PCI patients. The two primary endpoints of the trial were major bleeding and net adverse clinical events, a composite of major bleeding and major adverse cardiovascular events, including death, reinfarction, stroke or ischemic target vessel revascularization. The principal secondary endpoint was major adverse cardiovascular events. The results of HORIZONS AMI, which were reported in the New England Journal of Medicine in May 2008, showed that treatment with Angiomax in the trial, as compared with the heparin arm of the trial, resulted in a statistically significant reduction in the incidence of net adverse clinical events by 24%, major bleeding by 40% and cardiac-related mortality by 38%. In addition, treatment with Angiomax demonstrated comparable rates of major adverse cardiac events. In the one-year follow-up data from the HORIZONS AMI trial, Angiomax showed a statistically significant reduction in the incidence of cardiac-related mortality by 43%; all-cause mortality by 29%; major bleeding by 39%; and net adverse clinical events by 17%. In this data, there was no difference in rates of major adverse cardiac events between Angiomax and the comparator drug therapies. We obtained approval in the European Union for the use of Angiox for the treatment of STEMI patients undergoing primary PCI on the basis of the HORIZONS AMI trial results.

### **Additional Development**

We continue to develop Angiomax for use in additional patient populations, including patients with structural heart disease, patients undergoing peripheral angioplasty, carotid angioplasty and cardiovascular surgery and patients with or at risk of HIT/HITS.

**EUROMAX.** We are currently conducting a Phase 4 clinical trial of Angiomax, which we refer to as the EUROMAX trial, to assess whether the early administration of Angiox in STEMI patients intended for primary PCI presenting

either via ambulance or to referral centers where PCI is not performed improves 30-day outcomes when compared to the current standard of care, heparin plus an optional GP IIb/IIIa inhibitor. We are conducting the EUROMAX trial at sites in six European countries. We commenced enrollment in our EUROMAX clinical trial in March 2010. We expect to enroll approximately 3,680 patients in the EUROMAX trial and to complete enrollment in 2012.

EUROVISION. In 2009, we initiated a registry in Europe called EUROVISION, which we designed to study utilization patterns of patients receiving Angiox and collect descriptive outcome and safety data of patients. We conducted the study at 70 sites in six European countries. This study was a required post marketing commitment with the EMA to better understand adherence to labeled dosing. In October 2010, we completed enrollment of the study with 2,022 patients. We are currently



## Table of Contents

discussing the data from this study with the EMA and expect to publish the results in 2012.

**HIT/HITTS Patients.** In December 2005, we submitted an application to the FDA for approval to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery after completing four studies in our Phase 3 clinical development program in cardiac surgery. In October 2006, we received a non-approvable letter from the FDA in connection with this application. In the letter, the FDA stated that it did not consider the data that we submitted in support of the application adequate to support approval for this indication because the FDA did not consider the evidence used to qualify patients for inclusion in the trials that formed the basis for our application as a persuasive indicator for the risk of HIT/HITTS. We are evaluating potential next steps. In July 2007, Canadian health authorities approved the use of Angiomax in Canada for the treatment of patients with HIT/HITTS undergoing cardiac surgery.

**BRAVO.** In 2011, we supported a pilot study of the use of Angiomax in catheter-based procedures in patients with severely defective aortic heart valves in whom surgery is not possible. These procedures are either transcatheter aortic valve implantations, or TAVI, where a new valve is implanted using a percutaneous approach, or balloon aortic valvuloplasty procedures, or BAV, where a balloon is used to repair the damaged aortic valve. In the pilot study, 428 patients with severe aortic stenosis undergoing BAV received either Angiomax or heparin. The study met its two objectives, demonstrating that patients treated with Angiomax experienced a 60% reduction in major bleeding events and a 44% reduction of net adverse clinical events (major bleeding, all-cause mortality, MI or stroke) compared to patients treated with heparin. We expect the BRAVO program to be continued in additional patients undergoing TAVI in 2012.

**ISAR-REACT-4.** Commencing in 2004, we supported the ISAR-REACT-4 clinical trial which studied whether the combination of unfractionated heparin and abciximab, a GP IIb/IIIa inhibitor which is marketed under the brand name ReoPro® by Eli Lilly and Company, or Eli Lilly, is more effective than Angiomax in preventing thrombotic and bleeding complications in patients with high risk non-STEMI undergoing PCI. The ISAR-REACT-4 trial was a 1,721-patient randomized, double-blind, active-controlled, multicenter clinical trial, which tested how many patients in each treatment group died, had another major heart attack, required another procedure to unblock the same artery or suffered major bleeding within 30 days of treatment. In November 2011, the results of ISAR REACT-4 were simultaneously presented at the American Heart Association Scientific Sessions 2011 and published in The New England Journal of Medicine. In the study, the combination of heparin and abciximab failed to reduce the rate of thrombotic complications and increased the risk of bleeding as compared to Angiomax.

## Cleviprex

### Overview

Cleviprex is an intravenous small molecule calcium channel blocker for the reduction of blood pressure when oral therapy is not feasible or not desirable. We licensed Cleviprex in March 2003 from AstraZeneca AB, or AstraZeneca. Under the terms of the agreement, we have exclusive license rights to develop, market, and sell Cleviprex worldwide. We received marketing approval for Cleviprex from the FDA in August 2008 for the reduction of blood pressure when oral therapy is not feasible or not desirable. During the first quarter of 2009, we submitted MAAs for Cleviprex to member states of the European Union, pursuant to the European Union's decentralized procedure. In addition to the United States, Cleviprex is also approved for sale in the United Kingdom, the Netherlands, Australia, New Zealand, Sweden and Switzerland with indications for blood pressure control in perioperative settings. We do not currently sell Cleviprex outside the United States. We are developing a global commercialization strategy for Cleviprex for the countries outside the United States in which Cleviprex has been approved for sale and in anticipation of its approval in further countries outside the United States.

Following approval in the United States, we began marketing Cleviprex to anesthesiology/surgery, acute and intensive care and emergency department practitioners in the United States, primarily for use in cardiovascular surgery. In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex and sell Cleviprex from the first quarter of 2010 through the first quarter of 2011. We cooperated with the FDA and our contract manufacturer to remedy the problem at the manufacturing site that resulted in the recalls. Our contract manufacturer made manufacturing process improvements, including enhanced filtration and equipment maintenance, to assure product quality. We began to resupply existing customers with Cleviprex in April 2011.

In June 2011, the FDA approved an sNDA that we submitted for an improved formulation of Cleviprex. The new formulation triples the maximum allowable infusion time per vial, commonly referred to in hospitals as "hang time", to 12 hours compared to the original 4-hour hang time vial approved by the FDA in 2008. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection. We believe Cleviprex offers the rapid and precise control necessary to treat neurocritical care and cardiac surgery patients.

## Table of Contents

We market Cleviprex with the same sales force that we use to market Angiomax in the United States.

### Medical Need

Increases in blood pressure, which are sometimes rapid and acute, often occur in patients treated in the acute and intensive care setting. Hospital physicians administer intravenous antihypertensive drugs to control high blood pressure, or acute hypertension, because prolonged severe hypertension is known to cause irreversible damage to the brain, heart, kidneys and blood vessels. Similarly, blood pressure that is too low is also known to cause organ dysfunction and potential damage, particularly ischemia of the heart and brain. As a result, physicians strive to control blood pressure within a range to ensure safe treatment of the patient.

During the twelve-month period ending October 31, 2008, patients made an estimated 3.3 million hospital visits in the United States for conditions requiring treatment with an intravenous antihypertensive. These numbers include patients presenting to the emergency department and patients undergoing surgery. Of these patients, approximately:

• 1.7 million medically managed patients were administered intravenous antihypertensives;

• 1.1 million surgical intervention patients were administered intravenous antihypertensives in connection with surgical procedures, and of these, approximately 475,000 patients were treated with intravenous antihypertensives in cardiac and vascular surgery; and

• 556,000 “all other” patients were administered intravenous antihypertensives.

In 2007, we surveyed 259 cardiologists, neurologists, surgeons and other acute and intensive care specialists to describe the features of an intravenous antihypertensive that they would value, along with the benefits they would expect to achieve. Approximately 90% of these physicians identified rapid onset, efficacy, few side effects and easy titration as important features that guide their selection of an intravenous antihypertensive medication.

Cleviprex belongs to a well-known class of drugs, called intravenous calcium channel blockers, which are used to control acute high blood pressure. Cleviprex acts by selectively relaxing the smooth muscle cells that line small arteries, resulting in widening of the artery and reduction of blood pressure. However, unlike most other calcium channel blockers, Cleviprex is metabolized in the blood and tissue, does not accumulate in the body and has an ultra-short half-life. We believe that Cleviprex is well suited for lowering blood pressure in the acute and intensive care setting because its rapid onset and offset of effect, its selective activity on arteries and its ability to be cleared from the body independent of organ function. These features contribute to Cleviprex's rapid, reliable and predictable blood pressure control, ease of use and favorable safety profile. In addition, due to its mode of metabolism, we believe that Cleviprex is suitable for a wide range of patients.

We believe that Cleviprex is particularly useful in the treatment of hypertensive patients suffering from stroke. In 2010, we conducted research to understand physicians' needs regarding the treatment of acute ischemic stroke and intracranial bleeding patients. The research indicated that improved speed and control of blood pressure control were the principal areas of treatment that required improvement.

### Clinical Development

We developed Cleviprex in a clinical trial program comprised of six Phase 3 clinical trials. The results of these trials formed the basis of our applications for marketing approval.

**ESCAPE.** We conducted two Phase 3 efficacy clinical trials of Cleviprex in 2003 to 2004, which we refer to as the ESCAPE trials, to evaluate the effectiveness of Cleviprex in approximately 152 patients in controlling blood pressure before and after cardiac surgery compared to a placebo control. The protocol-defined objective for both trials, as measured by rates of treatment success was defined as at least a 15% reduction in blood pressure within 30 minutes without the need to use an alternate drug. Cleviprex met this objective in both trials.

**ECLIPSE.** We conducted three Phase 3 safety clinical trials, which we refer to as the ECLIPSE trials, from 2003 to 2006 to evaluate the safety of Cleviprex in approximately 1,500 patients in comparison to sodium nitroprusside, nicardipine and nitroglycerine, three leading marketed blood pressure-reducing agents, before, during and following cardiac surgery. The protocol-defined safety objectives for all three trials included primary endpoints measured by the incidences of death, stroke, myocardial infarction and renal dysfunction, and secondary objectives measuring blood pressure control. Cleviprex met these safety objectives in all three trials.

**VELOCITY.** We conducted our sixth Phase 3 clinical trial of Cleviprex, which we refer to as the VELOCITY trial, from 2006 to 2007 to evaluate Cleviprex in over 100 patients with acute severe hypertension in the emergency room

and acute and intensive care unit. The primary efficacy endpoint was the percentage of patients in whom blood pressure was successfully reduced to the target blood pressure range within 30 minutes of initiating therapy. Cleviprex met the primary efficacy endpoint

## Table of Contents

of this study, demonstrating a rapid reduction in blood pressure, to the specified blood pressure range, in over 90% of patients within 30 minutes with a very low incidence of overshoot. Subset analyses, which were presented at the annual meeting of the Society of Clinical Care Medicine, or SCCM, in February 2008, further demonstrated Cleviprex's safety and efficacy in high risk patients, such as those with heart and renal failure. According to such subset analyses, in this study, Cleviprex rapidly achieved and maintained blood pressure control in patients with renal dysfunction and patients with acute heart failure.

We have also conducted the following Phase 4 trials of Cleviprex.

**ACCELERATE.** Our ACCELERATE trial, which we conducted from 2008 to 2010, evaluated the efficacy and safety of intravenous infusion of Cleviprex for the treatment of acute hypertension in patients with intracerebral hemorrhage. The final data from this trial were presented in February 2011 at the AHA International Stroke Conference, and showed that:

- target blood pressure was achieved in a median of 5.5 minutes;
- changes in hematoma volume in patients with intracerebral hemorrhage after blood pressure reduction and stroke scores in the time period studied were minimal;
- no meaningful increases or other clinically meaningful changes were observed in intracranial pressure;
- 100% of patients achieved target blood pressure within 30 minutes of Cleviprex initiation;
- 97% of patients did not need additional or alternative intravenous antihypertensives during the initial 30-minute period of Cleviprex therapy to reach the target blood pressure; and
- there was no need for supplemental therapy to raise blood pressure in the initial 30-minute period of Cleviprex therapy.

**SPRINT.** Our SPRINT trial, which we conducted from 2008 to 2009, evaluated the pharmacokinetics and pharmacodynamics of a bolus dosing regimen of Cleviprex for the management of blood pressure in cardiac surgery patients. Data from this trial demonstrated that the administration of Cleviprex as an intravenous bolus dose effectively decreased arterial blood pressure in cardiac surgery patients in a dose-proportional manner.

**PRONTO.** Our PRONTO trial, which we commenced in 2009, is evaluating the efficacy and safety of an intravenous infusion of Cleviprex as compared with standard-of-care intravenous antihypertensives for blood pressure lowering in patients with acute heart failure and elevated blood pressure. We expect to enroll approximately 120 to 140 patients in this clinical trial and to complete enrollment in the first quarter of 2012.

**Additional Development.** We are supporting numerous clinical studies of Cleviprex being conducted by hospitals and third-party researchers in areas such as intracranial bleeding, major cardiovascular surgery and neurocritical care, along with health economics analyses.

## Cangrelor

### Overview

Cangrelor is an intravenous small molecule antiplatelet agent that we are developing to prevent platelet activation and aggregation that leads to thrombosis in the acute care setting of the cardiac catheterization laboratory to address unmet medical needs in patients undergoing PCI. We exclusively licensed cangrelor in December 2003 from AstraZeneca.

Under the terms of our agreement with AstraZeneca, we have exclusive license rights to develop, market, and sell cangrelor worldwide, excluding Japan, China, Korea, Taiwan and Thailand.

### Medical Need

In patients undergoing PCI, the use of antiplatelet agents to block platelet activation at the time of the PCI and reduce the risk of clot formation is considered important therapy based on several studies of oral platelet inhibitors that have demonstrated better patient outcomes in coronary angioplasty.

There is currently no intravenous drug that primarily inhibits platelet activation. One of the leading oral platelet inhibitors is clopidogrel, which, like cangrelor, acts by blocking the P2Y<sub>12</sub> receptor. Clopidogrel is marketed under the brand name Plavix® by Bristol-Myers Squibb Co./Sanofi Pharmaceuticals Partnership. Clopidogrel is commonly administered at a high dose by giving patients four to eight oral tablets at the time of PCI. This practice is known as pre-loading. Although clopidogrel pre-loading has been shown to improve ischemic outcomes in coronary angioplasty, there are several efficacy and safety issues with the use of this agent in acute and intensive care practice. These issues include:

that the effect of clopidogrel can be delayed and variable because clopidogrel requires liver metabolism to form the active agent and such metabolism can be influenced by other medications; and

## Table of Contents

that there does not appear to be a consistent relationship between increased dosage of clopidogrel and intended effect across different patient groups.

In addition, oral agents like clopidogrel are difficult to administer in the acute and intensive care setting because they need to be swallowed by patients who may have received pre-procedural sedatives. This is especially true when there is a need for patients to swallow multiple tablets in a restricted period of time.

There are no short-acting platelet inhibitors available that allow maintenance of platelet inhibition before surgery without increasing bleeding complications at the time of surgery. In order to minimize bleeding complications, patients undergoing surgery, including CABG, are taken off antiplatelet therapy five to 10 days prior to surgery because the inhibition of platelet function is irreversible. Due to their irreversible nature, antiplatelet agents remain bound to receptors for the life of the platelet. This may impede patient management and treatment flexibility, as surgical procedures need to be delayed for days awaiting the generation and release of new platelets from the bone marrow. In addition, discontinuation of antiplatelet therapy five to 10 days prior to surgery increases the potential for stent thrombosis during the period prior to or during the surgical procedure. Currently, physicians face the difficult choice of discontinuing antiplatelet therapy prior to surgery and risking a potential ischemic event in the unprotected perioperative period or delaying surgery until the time at which the antiplatelet therapy is no longer required. We believe that an ultra short-acting reversible platelet inhibitor would maintain platelet inhibition at target levels and allow rapid restoration of platelet function after discontinuation, which would allow patients to undergo surgical procedures without increasing the risk of bleeding complications while maintaining ischemic protection. Based on input from our hospital users in the cardiac catheterization laboratory, we believe that the combination of the reduction in ischemic events, including stent thrombosis, through platelet inhibition and the acute and intensive care limitations of current oral therapy have created a need for an injectable platelet inhibitor that acts quickly and is cleared from the bloodstream rapidly. We are developing cangrelor to address this market.

### Clinical Development

**CHAMPION Program.** In May 2009, we discontinued enrollment in our Phase 3 clinical trial program for cangrelor. This program consisted of two trials, CHAMPION-PCI and CHAMPION PLATFORM, which we designed to evaluate cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI. In these trials, cangrelor was compared to the use of eight 75 mg clopidogrel tablets (600 mg). The primary composite endpoint of the CHAMPION-PCI trial measured death, MI, or urgent revascularization at 48 hours after the procedure and the CHAMPION-PLATFORM trial measured the composite endpoint of death, MI, or urgent revascularization of patients requiring PCI. Approximately 14,000 patients in the aggregate, reflecting approximately 98% of targeted patients in CHAMPION PCI and 84% of targeted patients in CHAMPION PLATFORM, had been enrolled in these trials when we discontinued enrollment after the independent Interim Analysis Review Committee for the program reported to us that the efficacy endpoints of the trial program would not be achieved.

In November 2009, the results of the CHAMPION trials were, in parallel, published in the New England Journal of Medicine and presented at the American Heart Association Scientific Sessions 2009. Cangrelor did not show superiority to clopidogrel in the pre-specified primary endpoints comprising death, MI or urgent revascularization, at 48 hours. However, in a report published in the American Heart Journal in February 2012, a pooled analysis of the data from the two CHAMPION clinical trials using the universal definition of MI showed cangrelor was associated with a significant reduction in early ischemic events when compared with clopidogrel in patients with non-STEMI ACS undergoing PCI.

**CHAMPION PHOENIX.** Following discussions with the FDA, leading experts in ischemic heart disease and AstraZeneca, in October 2010 we commenced the CHAMPION PHOENIX Phase 3 clinical trial of cangrelor to evaluate the use of cangrelor in patients undergoing PCI. We initially expect to enroll approximately 10,900 patients and may enroll additional patients in this trial depending on the results of an interim analysis of the trial. The trial is a double-blind parallel group randomized study, which compares cangrelor to a clopidogrel loading dose administered as soon as possible after it is determined that the patient will undergo PCI. In the trial, cangrelor will be infused for at least two hours or until the conclusion of the PCI, whichever is longer. The loading dose of 300mg or 600mg of clopidogrel is considered the current standard of care for patients undergoing PCI. The primary endpoint of the trial is measured by the composite incidence of death, MI, ischemic-driven revascularization or stent thrombosis.

In this study, as compared to the CHAMPION-PCI and CHAMPION PLATFORM clinical trials, we changed the process of endpoint evaluation to ensure that only the MIs which occur after randomization are counted for the purpose of the endpoints, which is consistent with the universal definition of MI. In addition, we excluded from the CHAMPION PHOENIX trial patients who had already received clopidogrel. If results of the CHAMPION PHOENIX trial are positive, we intend to file an NDA in the United States and an MAA in the European Union for the use of cangrelor in patients undergoing PCI.

BRIDGE. In the fourth quarter of 2008, we commenced a clinical trial, which we refer to as the BRIDGE trial, to assess



## Table of Contents

the use of prolonged cangrelor infusion as a platelet inhibiting bridge for patients who need to discontinue clopidogrel before cardiac surgery. The BRIDGE trial enrolled 210 patients with ACS or treated with a coronary stent on clopidogrel or other thienopyridine awaiting CABG surgery with the object to establish the dosage of cangrelor that achieves 60% or greater inhibition of platelet aggregation for up to seven days. In November 2011, we reported that in the BRIDGE trial, 99% of cangrelor-treated patients maintained target levels of platelet inhibition for all time points measured over the bridging period compared to 19% percent of placebo-treated patients. In addition, the primary safety measure demonstrated no significant excess in surgical bleeding complications between cangrelor-treated patients and placebo-treated patients.

### Oritavancin

#### Overview

Oritavancin is an investigational intravenous antibiotic that we are developing for the treatment of ABSSSI (which we formerly referred to as complicated skin and skin structure infections, or cSSSI), including infections caused by methicillin-resistant *Staphylococcus aureus*, or MRSA. Oritavancin is synthetically modified from a naturally occurring compound. Oritavancin was originally discovered and developed by Eli Lilly to combat antibiotic-resistant Gram-positive pathogens, including MRSA and pathogens resistant to vancomycin, the most commonly prescribed antibiotic for resistant Gram-positive infections. We obtained rights to oritavancin as a result of our acquisition of Targanta Therapeutics Corporation, or Targanta, in February 2009. We have exclusive rights to develop, market, and sell oritavancin worldwide under a license agreement with Eli Lilly.

In February 2008, Targanta submitted a new drug application, or NDA, to the FDA seeking to commercialize oritavancin for the treatment of ABSSSI, including infections caused by MRSA. In December 2008, the FDA issued a complete response letter to Targanta indicating that the NDA could not be approved in its present form. In its letter, the FDA stated that the NDA did not contain sufficient evidence to demonstrate the safety and efficacy of oritavancin for treatment of ABSSSI. In particular, the FDA stated that while one of the two Phase 3 trials on which Targanta's submission was based provided evidence of activity of oritavancin, it did not provide substantial evidence alone or in combination with the second, smaller Phase 3 clinical trial, to support the efficacy and safety of oritavancin. In addition, the FDA stated that in the larger trial called ARRI, oritavancin did not appear to perform well in patients with MRSA and that in the smaller trial called ARRD, the number of patients with MRSA was insufficient to address the performance of oritavancin in treating those patients. The FDA also referenced several safety findings from the trials in its letter, including the higher rate of study discontinuations for lack of efficacy among oritavancin-treated patients, the greater number of oritavancin-treated patients who died or had a serious adverse event of sepsis, septic shock and related events, and the greater number of oritavancin-treated patients who experienced adverse events of osteomyelitis and sepsis, in each case as compared to the patients treated with vancomycin and the oral antibiotic cephalexin in the trial. The FDA indicated that it would be necessary to perform additional adequate, well-controlled studies to demonstrate the safety and efficacy of oritavancin in patients with ABSSSI as a basis for regulatory approval.

In June 2008, Targanta submitted an MAA to the EMA seeking approval of oritavancin for the treatment of complicated skin and soft tissue infections, or cSSTI, caused by methicillin susceptible and resistant Gram-positive pathogens. We withdrew this MAA in August 2009 after the EMA expressed concerns similar to those raised by the FDA in its complete response letter.

Following our acquisition of Targanta, we worked with the FDA to design a clinical trial responsive to the issues raised in the FDA's complete response letter. In the fourth quarter of 2010, the FDA notified us under the Special Protocol Assessment, or SPA, process that the design and planned analysis of the Phase 3 clinical trials we proposed to conduct for oritavancin in patients with ABSSSI adequately addressed the objectives necessary to support regulatory submission. Based on that notification, in the fourth quarter of 2010, we commenced the SOLO I and SOLO II Phase 3 clinical trials of oritavancin to evaluate the efficacy and safety of a single-dose oritavancin as compared to multiple doses of vancomycin for the treatment of patients with ABSSSI. The ARRI and ARRD trial evaluated multiple dose administration of oritavancin.

#### Medical Need

Although there are a number of approved antibiotics for the treatment of Gram-positive infections, these antibiotics have important shortcomings, including:

- bacteria are increasingly becoming resistant to one or more of these existing antibiotics;

- some of these antibiotics, referred to as bacteriostatic drugs, solely inhibit the growth of pathogens and rely on the immune system to actually kill the bacteria. In contrast, bactericidal antibiotics that kill bacteria independent of the immune system, like oritavancin, offer a more effective treatment for patients with compromised immune systems that cannot rid their bodies of the pathogens;

- many of these antibiotics have a narrow therapeutic spectrum, which is the range of bacteria treated by a drug, and,

## Table of Contents

as a result, are only effective against some serious pathogens but not others; many of the antibiotics used to treat serious infections are difficult or inconvenient to administer, as they must be administered once or twice daily for seven to 14 days, or longer, with the patients being hospitalized for much or all of this period; and many of these antibiotics may cause serious side effects in some patients, sometimes requiring discontinuation of therapy. Due to these side effects, health care providers are required to engage in costly and time-consuming monitoring of blood levels and other parameters.

As a result, there is a significant need for new antibiotics that address the limitations of currently available products. We believe that infectious disease physicians desire new antibiotics with greater efficacy, fewer side effects, fewer administration issues and better hospital economics. We believe, if approved, oritavancin would address many of the shortcomings of approved antibiotics. There currently is no approved antibiotic given as a single intravenous infusion for treatment of ABSSSI. We believe that a single dose regimen would minimize the risk of intravenous line infections and reduces treatment discontinuations due to tolerability issues. In addition, because oritavancin has three distinct mechanisms of action, we expect that there would be a significantly lower risk of resistance developing to oritavancin. Oritavancin has rapid, potent bactericidal activity against all Gram-positive bacteria responsible for causing ABSSSI, including MRSA, as well as Staphylococcus aureus and enterococci resistant to the other antibiotics used to treat ABSSSI.

### Clinical Development

ARRI and ARRD. Eli Lilly and InterMune, Inc., which transferred their rights for oritavancin to Targanta in 2005, conducted two Phase 3 trials of oritavancin, called ARRI and ARRD, in 1,617 patients with ABSSSI. In the clinical trials, oritavancin was administered once-daily for three to seven days. Both of these Phase 3 clinical trials compared treatment with oritavancin to a control arm of vancomycin followed by an oral antibiotic, cephalexin, using a non-inferiority trial design. In both of the trials, oritavancin met the primary endpoint. In both trials, oritavancin was found to be effective in an average of 5.3 days compared to an average of 10.9 days for the vancomycin / cephalexin control arm.

SIMPLIFI. In September 2008, Targanta completed its SIMPLIFI Phase 2 clinical study of oritavancin. In the trial, Targanta evaluated the efficacy and safety of different dosing regimens of oritavancin in 300 patients with ABSSI. In Arm A of the trial, patients received a single 1,200 mg dose of oritavancin, in Arm B, patients received a 800 mg dose of oritavancin on day 1 followed by an optional 400 mg dose of oritavancin on day 5, and in Arm C, patients received a 200 mg dose of oritavancin given daily for three to seven days, which was the dose used in the ARRD and ARRI trials. The results showed comparable efficacy and safety across all three treatment arms. In addition, electrocardiography data collected in patients receiving the single 1,200 mg dose supported the cardiac safety of oritavancin administered in a single dose.

QT Study. In September 2007, Targanta completed a QT study to evaluate the cardiac safety of oritavancin. In this study, Targanta examined the effects of a single 200 mg intravenous dose of oritavancin, a single 800 mg intravenous dose of oritavancin, a single 400 mg oral dose of moxifloxacin in a control arm and an intravenous placebo. In this study, oritavancin at the doses examined did not demonstrate an undesirable effect on the cardiac QT interval.

SOLO. The SOLO I and SOLO II trials are identical multicenter, double-blind, randomized clinical studies in which a single 1,200 mg intravenous dose of oritavancin is compared with seven to 10 days of intravenous vancomycin treatment. We plan to enroll approximately 1,000 patients in each trial and to evaluate oritavancin's non-inferiority to vancomycin using a primary efficacy endpoint that is a composite of resolution of fever and cessation of spread of visible infection without the use of rescue antibiotics at 48 to 72 hours following initiation of treatment. Under the protocols for the trials, if the non-inferiority primary endpoints of both trials are met, we will also assess the superiority of oritavancin to vancomycin with respect to the primary efficacy endpoint. As of February 22, 2012, we have enrolled approximately 700 patients in the SOLO I and SOLO II clinical trials. We have decided to focus on accelerating enrollment in the SOLO I trial and expect to complete enrollment in such trial in the third quarter of 2012. If the SOLO I trial results are positive, we plan to accelerate enrollment in the SOLO II trial. Under the accelerated timeline, if the results of the trials warrant it, we would expect to file an NDA in the first half of 2013.

Additional development. We are exploring the development of oritavancin for other indications, including for the treatment of *Clostridium difficile*, anthrax and other Gram-positive bacterial infections.

**MDCO-157**

In May 2011, we entered into a licensing agreement with Ligand Pharmaceuticals Incorporated, or Ligand, through its subsidiary CyDex Pharmaceuticals, Inc., under which we acquired an exclusive, worldwide license to patents claiming a Captisol®-enabled intravenous formulation of clopidogrel bisulfate, which we refer to as MDCO-157, and to related know-how.

## Table of Contents

We expect to seek FDA marketing approval for MDCO-157 pursuant to the Section 505(b)(2) NDA process. This process would enable us to rely, in part, on the safety and efficacy data of oral clopidogrel, or published literature, in support of an application for marketing approval. In connection with the Section 505(b)(2) NDA process, we plan to conduct a pharmacodynamic equivalence study of MDCO-157 with oral clopidogrel. We are finalizing the protocol for the equivalence study and expect to commence the study in the second quarter of 2012. In addition, we are conducting commercial assessments of the market for MDCO-157, including the market size, dynamics and decision making on formulary access and pricing.

### **MDCO-2010**

MDCO-2010 is a small molecule serine protease inhibitor that we are developing as an intravenous antifibrinolytic for the reduction of blood loss during surgery. We acquired MDCO-2010 in August 2008 as a result of our acquisition of Curacyte Discovery GmbH, or Curacyte Discovery. Since Bayer Healthcare Pharmaceuticals withdrew Trasylol (aprotinin) from the market in 2008, there has been a significant unmet medical need for a product that reduces blood loss during surgery. The FDA had approved Trasylol for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of CABG surgery who are at an increased risk for blood loss and blood transfusion. In preclinical studies in animal models, MDCO-2010 has demonstrated a favorable pharmacokinetic profile for the surgical setting with a rapid onset and offset of effect. From 2009 to 2010, we conducted a Phase 1 clinical trial of MDCO-2010 in Switzerland in healthy volunteers that demonstrated safety and tolerability at low doses. Following that trial, in November 2010, we commenced our Phase 2 clinical trial program of MDCO-2010 with a Phase 2a clinical trial conducted in Switzerland to study the safety, tolerability, pharmacokinetics and pharmacodynamics of MDCO-2010. This trial was a randomized, double blind, placebo-controlled trial in 32 patients undergoing elective CABG surgery. We completed this trial in the third quarter of 2011 and presented the data at the American Society of Anesthesiologists conference in October 2011. In this Phase 2a clinical trial, MDCO-2010 was safely administered in periprocedural infusions at escalating doses. In addition, in the trial, MDCO-2010 demonstrated linear, predictable plasma pharmacokinetics and was associated with reduced 12-hour chest tube drainage and less transfusion requirements as compared to placebo.

Based on the Phase 2a results, we plan to commence a Phase 2b clinical trial of MDCO-2010 in the first quarter of 2012. We initially plan to conduct this trial in Germany, Canada and Switzerland, to determine dose response relationship regarding blood loss, pharmacokinetics and pharmacodynamics, and clinical outcomes of MDCO-2010 versus placebo and tranexamic acid in patients undergoing primary CABG surgery or combined primary CABG and aortic valve replacement. In February 2012, we submitted an investigational new drug application, or IND, for MDCO-2010 to the FDA and subject to the IND becoming effective, we plan to conduct the Phase 2b clinical trial of MDCO-2010 in the United States as well.

### **MDCO-216**

MDCO-216, a novel biologic, is a naturally occurring variant of a protein found in human high-density lipoprotein, or HDL, that has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with ACS. We licensed exclusive worldwide rights to MDCO-216, from Pfizer Inc., or Pfizer, in December 2009. In multiple non-clinical studies, conducted by Pfizer and its predecessors in animal models, MDCO-216 rapidly removed excess cholesterol from artery walls, thereby stabilizing and regressing atherosclerotic plaque. In a Phase 1/2 study conducted by Pfizer from 2001 through 2003 in 36 patients, MDCO-216 demonstrated statistically significant reductions in coronary plaque volume by 4.2% in six weeks. These findings were published in the Journal of the American Medical Association in 2003. In 2010, we completed a technology transfer program with Pfizer related to improved manufacturing methodologies developed by Pfizer since the Phase 1/2 trial of MDCO-216 conducted by Pfizer. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in preclinical studies of MDCO-216 in 2010. In November 2011, at The American Heart Association Scientific Sessions 2011, we presented the results of preclinical studies in which MDCO-216 showed a dose dependent ability in an animal model to cause cholesterol efflux, the first step in reverse cholesterol transport. In addition, in these studies, the treatment was well tolerated up to the highest dose tested. We plan to commence a Phase 1 study of MDCO-216 in the second half of 2012 to investigate the safety and tolerability of escalating single doses of MDCO-216 in subjects presenting stable angina and angiographic evidence of coronary disease and to characterize the single dose pharmacokinetics of

MDCO-216 in subjects presenting stable angina and angiographic evidence of coronary disease. We expect to use in this Phase 1 study the same new methodologies to produce product for this Phase 1 study as the methodologies we used to produce product for the 2010 preclinical studies.

Ready-to-Use Formulation Argatroban

In the third quarter of 2009, we licensed from Eagle Pharmaceuticals, Inc., or Eagle, marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle. Argatroban, which is currently marketed by

## Table of Contents

GlaxoSmithKline in a concentrated formulation and by Sandoz, a Novartis company, in a ready-to-use formulation, is approved as an anticoagulant in the United States for prophylaxis or the treatment of thrombosis in patients with or at risk for HIT and for patients with or at risk for HIT undergoing PCI. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market a second generic version of ready-to-use Argatroban with the same size specifications as our ready-to-use formulation prior to the expiration of the patents we license from Eagle. We believe that the ready-to-use formulation of Argatroban provides advantages to the other currently marketed formulations of Argatroban.

In June 2011, the FDA approved ready-to-use Argatroban for prophylaxis or treatment of thrombosis in adult patients with HIT and for use as an anticoagulant in adult patients with or at risk for HIT undergoing PCI. We began selling ready-to-use Argatroban in September 2011. In December 2011 Eagle conducted a voluntary recall of the product due to the presence of particulate matter in some vials. As a result, we have not been able to sell Argatroban since December 2011.

### Acute Care Generic Products

On January 22, 2012, we entered into a license and supply agreement with APP in connection with the settlement of our patent litigations with APP. Under the license and supply agreement, APP granted to us a non-exclusive license under APP's marketing authorizations and intellectual property to sell ten generic products to hospitals and integrated delivery networks in the United States. The generic products are adenosine, amiodarone, azithromycin, clindamycin, esmolol, haloperidol, ondansetron, midazolam, milrinone and rocuronium. These acute care generic products are used in the therapeutic areas in which we focus or plan to focus, including cardiovascular, neurocritical care and serious infection, and we believe complement Angiomax, Cleviprex and ready-to-use Argatroban. We expect to commence selling the acute care generic products in the second half of 2012.

### Sales and Distribution

We market and sell Angiomax and Cleviprex in the United States with a sales force that, as of February 15, 2012, consisted of 106 representatives, who we refer to as engagement partners and engagement managers, experienced in selling to hospital customers. Prior to the December 2011 recall, we used the same sales force to sell our ready-to-use Argatroban. We expect to use the same sales force to sell the acute care generic products for which we acquired the non-exclusive rights to sell and distribute from APP. In support of our sales efforts, we focus our Angiomax marketing in the United States and in Europe on hospital systems, individual hospitals, and health care providers, including interventional cardiologists in cardiac catheterization laboratories and we focus the marketing of Cleviprex on neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection. We believe our ability to deliver relevant, advanced and reliable service and information to our concentrated customer base provides us with significant market advantage in the United States, and will provide us with such advantage outside the United States, even in highly competitive sub-segments of the hospital market such as cardiology and neurocritical care.

We distribute Angiomax, Cleviprex and, prior to the December 2011 recall, distributed ready-to-use Argatroban, in the United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax and Cleviprex and, when and if available for sale, ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax and Cleviprex, and, when and if available for sale, would sell ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products for which we acquired the non-exclusive rights to sell and distribute from APP through the same sole source distribution model.

Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this

fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on our customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and other specified conditions.

In Europe, we market and sell Angiox with a sales force that, as of February 15, 2012, consisted of 41 engagement partners and engagement managers experienced in selling to hospital customers. Our European sales force targets hospitals



## Table of Contents

with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. In October 2011, we entered into a local sales support agreement with Daiichi Sankyo, Inc., or Daiichi Sankyo, under which Daiichi Sankyo agreed to provide supplemental sales force coverage to approximately 480 hospitals in Germany treating ACS patients and call upon most interventional cardiologists in Germany. We also market and sell Angiomax outside the United States through distributors, including Sunovion Pharmaceuticals Inc., which distributes Angiomax in Canada, affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America, and through a joint venture with our partner, Windlas Healthcare Private Limited, in India. We also have agreements with other third parties for other countries outside of the United States, including Israel and Russia. In January 2012, we reacquired our rights to sell Angiomax from a distributor in Australia and New Zealand and have two engagement partners and one engagement manager selling the product in those countries. We are developing a global commercialization strategy for Cleviprex in anticipation of its further approval outside of the United States.

### Manufacturing

We do not have a manufacturing infrastructure and do not intend to develop one. We are a party to agreements with contract manufacturers for the supply of bulk drug substance for our products and with other third parties for the formulation, packaging and distribution of our products. Our product manufacturing operation is comprised of professionals with expertise in pharmaceutical manufacturing, product development, logistics and supply chain management and quality management and supply chain compliance. These professionals oversee the manufacturing and distribution of our products by third-party companies.

### Angiomax

#### Bulk Drug Substance:

In December 1999, we entered into a commercial development and supply agreement with Lonza Braine, S.A., which was formerly known as UCB Bioproducts S.A., for the development and supply of Angiomax bulk drug substance. Together with Lonza Braine, we developed a second generation chemical synthesis process to improve the economics of manufacturing Angiomax bulk drug substance. This process, which was approved by the FDA in May 2003 and is used in the manufacture of Angiomax bulk drug substance today, is known as the Chemilog process. We have agreed that, during the term of the agreement, we will purchase a substantial portion of our Angiomax bulk drug substance manufactured using the Chemilog process from Lonza Braine at agreed upon prices. Following the expiration of the agreement or if we terminate the agreement prior to its expiration, Lonza Braine has agreed to transfer the development technology to us. If we engage a third party to manufacture Angiomax for us using the Chemilog process prior to bivalirudin becoming a generic drug in the United States, we will be obligated to pay Lonza Braine a royalty based on the amount paid by us to the third-party manufacturer. Our agreement with Lonza Braine expires in September 2013, subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal within one year prior to the expiration of the initial term or any renewal term. We may only terminate the agreement prior to its expiration in the event of a material breach by Lonza Braine, if such breach is not cured within 30 days.

In September 2011, we entered into a supply agreement with Teva API, Inc., or Teva API, which was formerly known as Plantex USA Inc., under which we agreed to purchase from Teva API certain minimum quantities of Angiomax bulk drug substance for our commercial supply at agreed upon specified prices. The initial term of the supply agreement ends December 31, 2015 and will automatically be renewed for up to two successive three-year periods unless terminated by us with at least six-month written notice or by Teva API with at least 24-months written notice prior to the expiration of the initial term or either renewal term. We have the right to terminate the supply agreement, effectively immediately, if a generic form of bivalirudin is launched after January 1, 2013. We and Teva API may terminate the supply agreement in the event of a material breach by the other party, unless the material breach is cured within 30 days of a written notice, and we may terminate the supply agreement upon breach of the settlement agreement and certain breaches of the license agreement.

### Drug Product:

In October 1997, we entered into a master agreement with Ben Venue Laboratories, Inc., or Ben Venue, for the manufacture of Angiomax drug product. Ben Venue conducts the fill-finish of Angiomax drug product for us through

purchase order arrangements agreed upon by the parties at the time of the order and governed by the master agreement. Ben Venue has no obligation under the master agreement to accept purchase orders from us. In 2011, Ben Venue announced its decision to exit the third-party manufacturing business. As a result, we are phasing down our production of Angiomax at Ben Venue. We expect to rely on Patheon International A.G., or Patheon, and APP to supply Angiomax drug product to us in the future.

In March 2011, we entered into a master agreement with Patheon for the manufacture of Angiomax drug product. Pursuant to the agreement, Patheon conducts the fill-finish of Angiomax drug product for our commercial sale supply in accordance

## Table of Contents

with binding yearly commitments provided by us. Our agreement with Patheon expires in December 2016, subject to automatic renewals for successive terms of two years each unless either party gives written notice to the other Party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 60 days after written notice, unless the breach by its nature is not curable. In such case, the non-breaching party has the right to terminate the agreement immediately upon providing written notice as long as the written notice is provided within 30 days of the terminating party receiving notice of the breach. We have the right to terminate the agreement upon 30 days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling Angiomax. Patheon may terminate the agreement upon six months' prior written notice if we assign any of our rights under the agreement to an assignee that, in the opinion of Patheon acting reasonably, is not a credit worthy substitute for us, is a competitor of Patheon, or an entity with whom Patheon has had prior unsatisfactory business relations.

In January 2012, we entered into a contract manufacturing agreement with APP. Under the contract manufacturing agreement, we agreed to purchase from APP a specified minimum percentage of our requirements for Angiomax finished product for the sale of the Angiomax product in the United States. We agreed to pay APP a fixed price per vial supplied and to reimburse APP for specified development costs and capital expenditures made by APP. The term of the contract manufacturing agreement ends on May 1, 2019, but may be extended, at our sole option, for an additional term of two years. If a generic form of bivalirudin for injection is marketed by APP or another third party during the term of the contract manufacturing agreement, we have the right to renegotiate the price and minimum quantity terms of the contract manufacturing agreement and, if such terms cannot be agreed to by the parties, we will have the right to terminate the contract manufacturing agreement upon 90 days prior written notice. Either party may terminate the contract manufacturing agreement in the event of a material breach by the other party, effective immediately in the case of a non-curable breach and effective upon 60 days prior written notice in the case of a curable breach if such breach is not cured within such 60-day period. Either party may also terminate the contract manufacturing agreement if the other party undergoes bankruptcy events. We may terminate the contract manufacturing agreement upon at least 12 months prior written notice if we decide to discontinue marketing the Angiomax product in the United States or upon 30 days prior written notice in the event that any government or regulatory authority prevents us from purchasing or selling the Angiomax product in the United States. We are currently completing a technology transfer with APP and making some required capital expenditures at APP's facility.

### Cleviprex

#### Bulk Drug Substance:

In October 2002, we entered into a master research and manufacturing agreement with Johnson Matthey Pharma Services, or Johnson Matthey, for the manufacture of Cleviprex bulk drug substance for use for our clinical trials of Cleviprex and for our commercial requirements. Johnson Matthey manufactures the bulk drug substance under project work orders agreed upon by the parties at the time of the order and governed by the master research and manufacturing agreement. Johnson Matthey has no obligation under the master agreement to accept project work orders from us.

#### Drug Product:

In December 2003, we entered into a contract manufacturing agreement with Fresenius Kabi Clayton, L.P., which was subsequently assigned to Hospira, Inc., or Hospira. Pursuant to the agreement, Hospira is the exclusive supplier for all finished drug product of Cleviprex for the intravenous treatment of primarily peri-operative hypertension using its proprietary formulation technology. The agreement continues until August 2018 and thereafter unless either party provides three years' prior written notice of termination which may be given any time after August 2015. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 60 days after written notice. In addition, upon 90 days' prior written notice either party may terminate the agreement if we permanently stop selling the Cleviprex. Upon expiration or termination of the agreement, Hospira is required to grant us a non-exclusive, world-wide, perpetual license to Hospira's proprietary technology for the manufacture of Cleviprex, subject to a low single digit royalty in specified circumstances.

In May 2011, we entered into a master contract manufacturing agreement with Fresenius Kabi Austria GmbH, L.P., or Fresenius, for the manufacture of the new formulation of Cleviprex drug product. Fresenius conducts the fill-finish of Cleviprex drug product for us through purchase order arrangements agreed upon by the parties at the time of the order and governed by the master agreement. Under the agreement, we have annual minimum purchase order requirements. The initial term of the agreement ends in May 2016 and will automatically be renewed for subsequent periods of 12 months unless either party provides written notice at least 12-months prior to the expiration of the initial term or a renewal term. Either party may terminate the agreement upon a material, curable breach by the other party if such breach is not cured in 30 days after notice of the breach, or immediately in the event of a material, noncurable breach or if either party ceases or threaten to cease to carry on the business to which the agreement relates. Fresenius may terminate the agreement with 12-months prior notice in the event

Table of Contents

of a change of control of us.

Cangrelor

Bulk Drug Substance:

Johnson Matthey manufactures cangrelor bulk drug substance for us for our clinical trial needs under the terms of the same master research and manufacturing agreement we entered into for Cleviprex in October 2002. Johnson Matthey manufactures the bulk drug substance under project work orders agreed upon by the parties and governed by the master research and manufacturing agreement with Johnson Matthey. Johnson Matthey has no obligation under the master agreement to accept project work orders from us.

Drug Product:

In October 2004, we entered into a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC, or Baxter, a division of Baxter Healthcare Corporation, for the manufacture of cangrelor finished drug product for our cangrelor clinical trials and to carry out release testing. The agreement expires when the development plan for cangrelor established under the agreement is completed. Either party may terminate the agreement for breach by the other party, if the breach is not cured after receipt of written notice of the breach within 10 days for monetary defaults and within 30 days for non-monetary defaults. Ben Venue also supplies cangrelor finished drug product to us under purchase order arrangements agreed upon by the parties and governed by our 1997 master agreement with them. In 2011, Ben Venue announced its decision to exit the third-party manufacturing business. As a result, in October 2011, we entered into an agreement with Patheon UK for the commercial scale up and validation of our commercial manufacturing process. We expect to enter into a manufacturing agreement with Patheon UK for the commercial supply of cangrelor.

Oritavancin

Bulk Drug Substance:

Prior to our acquisition of oritavancin, in December 2001, Targanta entered into a development and supply agreement with Abbott Laboratories, or Abbott, for the supply of oritavancin bulk drug substance for clinical use in clinical trials. Under the Abbott agreement, which we acquired with our acquisition of Targanta, we are required to purchase oritavancin bulk drug substance exclusively from Abbott, unless Abbott fails to deliver sufficient oritavancin bulk drug substance to meet our needs. In such event, we may use another manufacturer to supply oritavancin bulk drug substance for as long as Abbott is unable to supply sufficient oritavancin bulk drug substance. We are also required to purchase a minimum amount of oritavancin bulk drug substance from Abbott. The agreement expires on December 31, 2014, subject to automatic two-year renewal periods unless either party gives at least 24 months written notice of termination prior to the expiration of the initial term or 12 months written notice prior to the expiration of any renewal term. Either party may terminate the agreement upon two-years notice if the party determines that the launch of the product is not technically, clinically or commercially feasible or economically justifiable. Abbott has the right to terminate the agreement at any time upon 30 months written notice. Either party may terminate the agreement for breach by the other party, if the breach is not cured within 60 days after receipt of written notice or for breaches of a type that cannot be remedied within 60 days, if a remedy is not promptly commenced and diligently pursued until complete remediation. Upon termination, Abbott is required to assist us with a technology transfer to us or our designee.

In July 2011, we entered into an agreement with DSM BioSolutions B.V., or DSM, under which DSM is implementing the process at its facility to produce bulk drug substance of oritavancin. We expect to use DSM as our supplier of oritavancin bulk substance for commercial use if the product is approved for sale.

Drug Product:

We obtain oritavancin finished drug product from Ben Venue under a manufacturing and services agreement Targanta entered into in August 2008. Under the agreement, we have minimum purchase obligations commencing the first full year after the commercial launch of the product. The agreement expires on August 22, 2013. Either party may terminate the agreement for any reason with 24 months prior written notice or for material breach by the other party, if the material breach is not cured within three months after written notice of the breach. We can terminate the agreement with 90 days written notice in the event oritavancin is withdrawn from the market. Upon termination of the agreement, Ben Venue has agreed to conduct a manufacturing services and technology transfer to a third party

designated by us. In 2011, Ben Venue announced its decision to exit the third-party manufacturing business. As a result, in October 2011, we entered into an agreement with Patheon UK for the commercial scale up and validation of our commercial manufacturing process. We expect to enter into a manufacturing agreement with Patheon UK for the commercial supply of oritavancin.

MDCO-157

## Table of Contents

We currently obtain our supply of MDCO-157 bulk drug substance and drug product for our clinical trials from third-party manufacturers in Canada and Israel on a purchase order basis. In connection with our license of MDCO-157 from Ligand, Ligand has agreed to supply us with Captisol, an excipient in MDCO-157, for the MDCO-157 development program under a separate supply agreement entered in May 2011. If the intravenous formulation is approved for commercialization, we have agreed that Ligand will be the exclusive supplier of Captisol for the product. This agreement will expire or automatically terminate simultaneously with the expiration or termination, respectively, of the licensing agreement, and either party may terminate it for the other's material breach on the same terms as those of the licensing agreement.

### MDCO-2010

We currently obtain our supply of MDCO-2010 bulk drug substance and drug product for our early stage clinical trials from third-party manufacturers in Germany on a purchase order basis.

### MDCO-216

In connection with the license of MDCO-216 from Pfizer we acquired sufficient protein to carry out preclinical and early phase clinical studies. In 2010, we completed a technology transfer program with Pfizer related to improved manufacturing methodologies developed by Pfizer, primarily to reduce the cost to manufacture the drug product to make it commercially viable. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in preclinical studies of MDCO-216. We expect to use these methodologies to manufacture MDCO-216 for our currently planned Phase 1 clinical trial, but we believe additional work will be needed to scale up the manufacturing process in order to have drug product available for use in further clinical trials.

### Ready-to-Use Argatroban

In connection with our license of marketing rights to Eagle's formulation of Argatroban, Eagle has agreed to supply us with the ready-to-use product for a price equal to Eagle's costs, under a supply agreement we entered into with Eagle in September 2009. The supply agreement expires at the earlier of the termination of our license agreement with Eagle or September 24, 2019. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured after receipt of written notice within 30 days or up to 60 days if the breaching party gives notice that it is in good faith attempting to cure the breach.

In December 2011, Eagle conducted a voluntary recall of manufactured lots of ready-to-use Argatroban due to the presence of particulate matter in some vials. As a result, we have not been able to sell ready-to-use Argatroban since December 2011. We are cooperating with Eagle, Eagle's contract manufacturer and the FDA to remedy the problem at the manufacturing site that resulted in the recalls.

### Acute Care Generic Products

APP has agreed to supply and we have agreed to purchase our entire requirements for the acute care generic products from APP under the license and supply agreement we entered into with APP in January 2012. Under the terms of this agreement, we made a one-time, upfront payment of \$30 million to APP and a need to pay APP's cost of goods for the supply of products on an ongoing basis. The term of the license and supply agreement ends January 22, 2022. Each party may terminate the agreement in the event of a material breach by the other party, unless the material breach is cured within 90 days of written notice or within 120 days of written notice if the breach is incapable of being cured within the 90-day period. APP may terminate this agreement upon 60 days prior written notice if we fail to pay in full any invoice that is past due unless such payment is the subject of a dispute set forth in writing by us. We may terminate the agreement if, with respect to two purchase orders in a calendar year, APP has failed to supply at least the aggregate quantity of conforming product specified in the purchase order or failed to deliver the product prior to the applicable delivery date specified in the purchase order and APP has failed to cure these breaches in the manner specified in the agreement. In addition, either party may terminate the agreement on a product-by-product basis, effective immediately, upon written notice to the other party in the event the FDA takes any action the result of which is to permanently prohibit the manufacture of the product in the United States. APP may also terminate the agreement on a product-by-product basis upon 180 days prior written notice if APP has determined that it will discontinue the marketing authorization for the product in the United States. We may terminate the agreement on a product-by-product basis upon 180 days prior written notice if the total market value of a product falls below a specified percentage of the total market value of the product as of the effective date of the agreement. In the event that

the agreement is terminated with respect to a product, the parties shall agree upon a substitute product.

Business Development Strategy

18

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## Table of Contents

We intend to continue building our acute and intensive care portfolio of hospital products by selectively licensing or acquiring and then developing clinical compound candidates or products approved for marketing. We believe that we have proven capabilities in developing and commercializing in-licensed or acquired acute and intensive care drug candidates. We believe that products may be acquired from pharmaceutical companies which are in the process of refining their own product portfolios and from companies seeking specialist development or commercial collaborations.

We are continuously reviewing opportunities to acquire products through licenses, product acquisitions and company acquisitions. In evaluating product acquisition candidates, we plan to continue to focus on acquisition candidates that are either approved products or late stage products in development that offer improved solutions to our customers and leverage our current business infrastructure. In addition, our acquisition strategy is to acquire global rights for development compounds wherever possible. We may acquire approved products that can be marketed in hospitals by our commercial organization.

### Competition

The development and commercialization of new drugs is highly competitive. We face competition from pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors are substantially larger than we are and have substantially greater capital resources, research and development capabilities and experience, and financial, technical, manufacturing, marketing and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors.

Our business strategy is based on us selectively licensing or acquiring and then developing clinical compound candidates or products approved for marketing. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. However, the acquisition and licensing of pharmaceutical products is a competitive area, and a number of more established companies, which have acknowledged strategies to license and acquire products, may have competitive advantages, as may emerging companies taking similar or different approaches to product acquisition. Established companies pursuing this strategy may have a competitive advantage over us due to their size, cash flows and institutional experience.

In addition, our competitors may develop, market or license products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. We compete, in the case of our marketed products, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed.

### Angiomax

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant therapies currently on the market, awaiting regulatory approval or in development for the indications for which Angiomax is approved.

Angiomax competes primarily with heparin and enoxaparin, GP IIb/IIIa inhibitors, and combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors. Heparin is widely used in patients with ischemic heart disease. Heparin is manufactured and distributed by a number of companies as a generic product and is sold at a price that is significantly less than the price for Angiomax. GP IIb/IIIa inhibitors with which Angiomax competes include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin from Schering-Plough Corporation, and Aggrastat from Iroko Pharmaceuticals, LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy in high risk patients as compared to Angiomax.

Although in some cases GP IIb/IIIa inhibitors may be complementary to Angiomax, Angiomax may compete with GP IIb/IIIa inhibitors for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or a GP IIb/IIIa inhibitor but not necessarily more than one of these drugs.

We have agreed that APP may sell a generic version of Angiomax beginning May 1, 2019 or earlier under certain conditions and that Teva may sell a generic version of Angiomax beginning June 30, 2019, or earlier under certain conditions. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

Cleviprex

## Table of Contents

Cleviprex competes with a variety of antihypertensive agents in the acute and intensive care setting, many of which are generic and inexpensive. The FDA has approved nine intravenous drugs for the treatment of hypertension in the acute and intensive care setting. Physician selection of these agents depends upon patient diagnosis, how quickly they need to control blood pressure, relevant surgeries or procedures that may be planned in the near future, co-morbidities and end organ damage. Cleviprex therefore, competes with all of these agents.

### Cangrelor

We expect that cangrelor, if approved, will compete with oral platelet inhibitors that are well known and widely used in acute and intensive care settings, such as Plavix from Bristol Meyers Squibb/Sanofi Pharmaceuticals Partnership, Effient (prasugrel), an anti-platelet agent from Eli Lilly and Daiichi Sankyo, and Brilinta (ticagrelor), an anti-platelet agent from AstraZeneca. We believe that the combination of the reduction in ischemic events through platelet inhibition and the acute and intensive care limitations of current oral therapy have created a need for an injectable platelet inhibitor that acts quickly and is cleared from the bloodstream rapidly.

### Oritavancin

We expect that oritavancin, if approved, will compete with a number of drugs that target serious gram-positive infections acquired in the community or hospital and treated in an outpatient setting or hospital. These drugs include vancomycin, a generic drug that is manufactured by a variety of companies, daptomycin from Cubist Pharmaceuticals, Inc., linezolid from Pfizer, quinupristin/dalfopristin from Sanofi-Aventis and Monarch Pharmaceuticals Inc., telavancin, from Theravance, Inc. and Astellas Pharma Inc., teicoplanin from Sanofi-Aventis, ceftaroline from Forest/AstraZeneca/Dainippon Sumitomo and tigecycline from Pfizer. Each of these drugs is already established in the market, which will make market penetration for oritavancin more difficult. We believe that oritavancin, if approved as a single dose formulation, would provide advantages over other drug therapies by providing a full regimen of treatment in a single dose, which would eliminate the need for daily infusions and potentially reduce the need for patient hospitalization, outpatient infusion services or central intravenous access.

### Ready-to-Use Argatroban

Prior to its recall, the ready-to-use formulation of Argatroban that we licensed from Eagle competed with currently marketed versions of Argatroban promoted by GlaxoSmithKline and by Sandoz. In addition, we expect our ready-to-use Argatroban to compete with other potential direct generic copies or other innovative forms of the product. We believe that the ready-to-use formulation of Argatroban provides advantages to the other currently marketed formulations of Argatroban. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market a second generic version of ready-to-use Argatroban with the same size specifications as our ready-to-use formulation prior to the expiration of the patents we license from Eagle.

### MDCO-157

We expect that MDCO-157, if approved, will compete with oral platelet inhibitors that are well known and widely used in acute and intensive care settings, such as Plavix from Bristol Meyers Squibb/Sanofi Pharmaceuticals Partnership, Effient (prasugrel), an anti-platelet agent from Eli Lilly and Daiichi Sankyo, and Brilinta (ticagrelor), an anti-platelet agent from AstraZeneca. We believe that the acute and intensive care limitations of current oral therapy have created a need for an injectable platelet inhibitor.

### Acute Care Generic Products

The acute care generic products will compete with their respective brand name reference products and other equivalent generic products that may be sold by APP and other third parties.

### Patents, Proprietary Rights and Licenses

Our success will depend in part on our ability to protect the products we acquire or license by obtaining and maintaining patent protection both in the United States and in other countries. We rely upon trade secrets, know-how, continuing technological innovations, contractual restrictions and licensing opportunities to develop and maintain our competitive position. We plan to prosecute and defend patents or patent applications we file, acquire or license.

Angiomax. We have exclusively licensed from Biogen Idec and Health Research Inc., or HRI, patents and patent applications covering Angiomax and Angiomax analogs and other novel anticoagulants as compositions of matter, and processes for using Angiomax and Angiomax analogs and other novel anticoagulants. We also own two U.S. patents covering a more consistent and improved Angiomax drug product and the processes by which it is made. We have

also filed and are currently prosecuting a number of patent applications relating to Angiomax in the United States and Europe.

Table of Contents

The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent was set to expire in March 2010, but was extended on an interim basis to August 13, 2012 under the Hatch-Waxman Act following our litigation against the PTO, the FDA and HHS. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. If the term of the '404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015. In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva. In connection with the settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers as described in Part 1, Item 3, Legal Proceedings. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than May 1, 2019.

Our patent infringement suits and our settlements with Teva and APP are described in more detail in Item 3 of this annual report.

In Europe, the principal patent covering Angiomax expires in 2015.

**Cleviprex.** We have exclusively licensed from AstraZeneca rights to patents and patent applications covering Cleviprex as a composition of matter and covering formulations and uses of Cleviprex. Under the license, AstraZeneca is responsible for prosecuting and maintaining the patents and patent applications relating to Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which is set to expire in January 2016. Following receipt of marketing approval from the FDA, we submitted an application under the Hatch-Waxman Act to extend the term of the '346 patent. This application is currently pending. In addition, we have filed and are currently prosecuting a number of patent applications relating to Cleviprex covering compositions of matter and uses in the United States, Europe and other foreign countries. In Europe, the principal patent covering Cleviprex expires in November 2014 if no patent term extension is obtained. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we received regulatory approval and plan to file for supplementary protection certificates in other European countries when we receive approvals. In Europe, we expect to obtain data and market exclusivity for Cleviprex for at least ten years following regulatory approval of the drug.

**Cangrelor.** We have exclusively licensed from AstraZeneca rights to patent and patent applications covering cangrelor as a composition of matter and covering formulations and uses of cangrelor. Under the license, AstraZeneca is responsible for prosecuting and maintaining the patents and patent applications relating to cangrelor. The principal U.S. and European patents for cangrelor are set to expire in February 2014 if no patent term extension is obtained. In addition, we have also filed and are currently prosecuting a number of patent applications related to cangrelor.

Oritavancin. As a result of our acquisition of Targanta, we obtained an exclusive license from Eli Lilly to patents and patent applications covering oritavancin, its uses, formulations and analogs. Under this license, we are responsible for prosecuting and maintaining these patents and patent applications. The principal patent for oritavancin in both the United States and Europe is set to expire in November 2015 if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

MDCO-157. The principal patent application for MDCO-157 in both the United States and Europe, if issued, would expire in April 2028. The applications claim specific formulations of clopidogrel.

MDCO-2010. In connection with our acquisition of Curacyte Discovery, we acquired a portfolio of patents and patent

## Table of Contents

applications covering MDCO-2010, its analogs or other similar protease inhibitors. We are currently prosecuting and maintaining these patents and patent applications. In February 2012, the principal patent application for MDCO-2010 was allowed by the PTO, and, when issued, the resulting patent will be set to expire in September 2028 in the United States. The principal patent application in Europe is still pending and, if issued, would expire in October 2027.

MDCO-216. In connection with our acquisition of MDCO-216, we obtained an exclusive license from Pfizer to patents and patent applications covering MDCO-216 as a composition of matter, and processes for using MDCO-216 and making MDCO-216. We are maintaining a number of U.S. patents with respect to MDCO-216, including patents that claim the use of MDCO-216 in certain disease indications. One of these U.S. patents is directed to the use of MDCO-216 for the treatment of ACS and is set to expire in October 2024. We have also filed and are prosecuting a number of patent applications related to the use and production of MDCO-216 in the United States, Europe and other foreign countries. In addition, as a biologic, we expect MDCO-216 to receive 12 years of regulatory exclusivity in the United States and 10 years of regulatory exclusivity in Europe from the date, if any, of the initial marketing approval of MDCO-216.

Ready-to-Use Argatroban. We exclusively licensed from Eagle rights to two U.S. patents covering certain formulations of Argatroban. Our exclusive license is limited to the United States and Canada. The patents are set to expire in September 2027. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. We are in the process of reviewing this correspondence and determining what further action we may take.

The patent positions of pharmaceutical and biotechnology firms like us can be uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the patent applications we acquire, license or file will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications filed prior to November 29, 2000 and patent applications filed within the last 18 months are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the PTO to determine priority of invention, or in opposition proceedings in a foreign patent office. Participation in these proceedings could result in substantial cost to us, even if the eventual outcome is favorable to us. Even issued patents may not be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

The development of acute and intensive care hospital products is intensely competitive. A number of pharmaceutical companies, biotechnology companies, universities and research institutions have filed patent applications or received patents in this field. Some of these patent applications could be competitive with applications we have acquired or licensed, or could conflict in certain respects with claims made under our applications. Such conflict could result in a significant reduction of the coverage of the patents we have acquired or licensed, if issued, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if patents are issued to other companies that contain competitive or conflicting claims with claims of our patents and such claims are ultimately determined to be valid, we may not be able to obtain licenses to these patents at a reasonable cost, or develop or obtain alternative technology.

We also rely on trade secret protection for our confidential and proprietary information. However, others may independently develop substantially equivalent proprietary information and techniques. Others may also otherwise gain access to our trade secrets or disclose such technology. We may not be able to meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements provide that all

inventions conceived by the individual shall be our exclusive property. These agreements may not provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

We have a number of trademarks that we consider important to our business. The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® names and logos are either our registered trademarks or our trademarks in the United States and other countries. We have also registered some of these marks in a number of foreign countries. Although we have a foreign trademark registration program for selected marks, we may not be able to register or use such marks in each foreign country in which we seek registration. We believe that our products are identified by our trademarks and, thus, our trademarks are of significant value. Each registered trademark has a duration of 10 to 15 years, depending on the date it was registered and the country in which it is registered, and is subject to an infinite number of renewals for a like period upon continued use and appropriate application. We intend to continue the use of our trademarks and to renew our registered trademarks based



## Table of Contents

upon each trademark's continued value to us.

### License Agreements

A summary of our licenses for our products and products in development is set forth below.

**Angiomax.** In March 1997, we entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, for the license of the anticoagulant pharmaceutical bivalirudin, which we have developed and market as Angiomax. Under the terms of the agreement, we acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, we paid \$2.0 million on the closing date and are obligated to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of AMI in the United States and Europe. In addition, we are obligated to pay royalties on sales of Angiomax and on any sublicense royalties on a country-by-country basis earned until the later of the date 12 years after the date of the first commercial sales of the product in a country and the date on which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. The royalty rate due to Biogen Idec on sales increases as annual sales of Angiomax increase. Under the agreement, we are obligated to use commercially reasonable efforts to develop and commercialize Angiomax in the United States and specified European markets, including for PTCA and AMI indications. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 90 days' after written notice. In addition, we may terminate the agreement for any reason upon 90 days' prior written notice. During 2011, we incurred approximately \$107.9 million in royalties related to Angiomax under our agreement with Biogen Idec.

In March 1997, in connection with entering into the Biogen Idec license, Biogen Idec assigned to us a license agreement with HRI under which Biogen Idec had licensed HRI's right to a specified patent application held jointly with Biogen Idec which resulted in a series of U.S. patents including the '404 patent. Under the terms of the agreement, we have exclusive worldwide rights to HRI's rights to the licensed patent application and patents arising from the licensed patent application, other than rights for noncommercial research and educational purposes, which HRI retained. We are obligated to pay royalties on sales of Angiomax and on any sublicense income we earn. The royalty rate due to HRI on sales increases as annual sales of Angiomax increase. Under the agreement, we are obligated to use commercially reasonable efforts to research and develop, obtain regulatory approval and commercialize Angiomax. The license and rights under the agreement remain in force until the expiration of the last remaining patent granted under the licensed patent application. HRI may terminate the agreement for a material breach by us, if the material breach is not cured within 90 days after written notice or, in the event of bankruptcy, liquidation or insolvency, immediately on written notice. In addition, we may terminate the agreement for any reason upon 90 days' prior written notice upon payment of a termination fee equal to the minimum royalty fee payable under the license agreement.

**Cleviprex.** In March 2003, we licensed from AstraZeneca exclusive worldwide rights to Cleviprex for all countries other than Japan. In May 2006, we amended our license agreement with AstraZeneca to provide us with exclusive license rights in Japan in exchange for an upfront payment. Under the terms of the agreement, we have the rights to the patents, trademarks, inventories and know-how related to Cleviprex. We paid AstraZeneca \$1.0 million in 2003 upon entering into the license and agreed to pay up to an additional \$5.0 million upon reaching agreed upon regulatory milestones, of which we paid \$1.5 million in September 2007 as a result of the FDA's acceptance to file of our NDA for Cleviprex for the treatment of acute hypertension and \$1.5 million in the third quarter of 2008 as a result of Cleviprex's approval for sale by the FDA. We are obligated to pay royalties on a country-by-country basis on annual sales of Cleviprex, and on any sublicense income earned, until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell Cleviprex in a country and the date ten years from our first commercial sale of Cleviprex in such country. Under the agreement, we are obligated to use commercially reasonable efforts to develop, market and sell Cleviprex.

The licenses and rights under the agreement remain in force on a country-by-country basis until we cease selling Cleviprex in such country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress our concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three

months of the commencement of such discussions, we may then terminate the agreement upon 90 days' written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice if the breach is not cured within such 60 days. During 2011, we incurred \$0.8 million in royalties related to Cleviprex under our agreement with AstraZeneca.

Cangrelor. In December 2003, we licensed from AstraZeneca exclusive rights to cangrelor for all countries other than Japan, China, Korea, Taiwan and Thailand. Under the terms of the agreement, we have the rights to the patents, trademarks, inventories and know-how related to cangrelor. In June 2010, we entered into an amendment to our license agreement with AstraZeneca. The amendment requires us to commence certain clinical studies of cangrelor, eliminates the specific development time lines set forth in the license agreement and terminates certain regulatory assistance obligations of AstraZeneca. We paid

## Table of Contents

an upfront payment of \$1.5 million upon entering into the license and \$3.0 million upon entering the amendment to the license. We also agreed to make additional milestone payments of up to \$54.5 million in the aggregate upon reaching agreed upon regulatory and commercial milestones. We also paid AstraZeneca \$0.2 million for the transfer of technology in 2004. We are obligated to pay royalties on a country-by-country basis on annual sales of cangrelor, and on any sublicense income earned, until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell cangrelor in a country ten years from our first commercial sale of cangrelor in such country. Under the agreement we are obligated to use commercially reasonable efforts to diligently and expeditiously file NDAs in the United States and in other agreed upon major markets. The licenses and rights under the agreement remain in force on a country-by-country basis until we cease selling cangrelor in such country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress our concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days' written notice. In the event that a change of control of our company occurs in which we are acquired by a specified company at a time when that company is developing or commercializing a specified competitor product, AstraZeneca may terminate the agreement upon 120 days' written notice. Either party may terminate the agreement for material breach upon 60 days' prior written notice if the breach is not cured within such 60 days.

**Oritavancin.** As a result of our acquisition of Targanta, we are a party to a license agreement with Eli Lilly through our Targanta subsidiary. Under the terms of the agreement, we have exclusive worldwide rights to patents and other intellectual property related to oritavancin and other compounds claimed in the licensed patent rights. We are required to make payments to Eli Lilly upon reaching specified regulatory and sales milestones. In addition, we are obligated to pay royalties based on net sales of products containing oritavancin or the other compounds in any jurisdiction in which we hold license rights to a valid patent. The royalty rate due to Eli Lilly on sales increases as annual sales of these products increase.

We are obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for oritavancin in the United States and to commercialize oritavancin in the United States. If we breach that obligation, Eli Lilly may terminate our license in the United States, license rights to oritavancin could revert to Eli Lilly and we would lose our rights to develop and commercialize oritavancin. The license rights under the agreement remain in force, on a country-by-country basis, until there is no valid patent in such country and our obligation to pay royalties ceases in that country. Either party may terminate the agreement upon an uncured material breach by the other party. In addition, either party may terminate the agreement upon the other party's insolvency or bankruptcy.

**MDCO-157.** In May 2011, we entered into a licensing agreement with Ligand, through its subsidiary CyDex Pharmaceuticals, Inc., under which we acquired an exclusive, worldwide license to patents claiming a Captisol®-enabled intravenous formulation of clopidogrel bisulfate, which we refer to as MDCO-157, and to related know-how. Under the license agreement, we paid Ligand an upfront payment of approximately \$1.8 million in June 2011 and agreed to make additional payments of up to \$22 million upon the achievement of certain clinical, regulatory and commercial milestones. We also agreed to pay to Ligand tiered royalties from high single digits up to low double digits on annual worldwide net sales. The license obligates us to use commercially reasonable efforts to develop a licensed product, and to make \$2.5 million per year in development expenditures until we submit a NDA. The licenses and rights under the agreement remain in force on a country-by-country basis until the expiration of our obligations to pay royalties under the license agreement or the license agreement is otherwise terminated. Either party may terminate the agreement for material breach upon 30 days' prior written notice for breaches involving non-payment of amounts due under the license agreement or 120 days for all other material breaches (which can be extended for up to 90 days if the breaching party submits a reasonable plan to cure the breach), if the breach is not cured within the applicable period. We may terminate the agreement for any reason upon specified written notice. Ligand may terminate the agreement if we do not meet certain timelines or fulfill certain obligations under the license agreement. Finally, the license agreement will terminate if we terminate the supply agreement (described above) without cause or Ligand terminates it due to our material breach.

MDCO-216. In December 2009, we licensed exclusive worldwide rights to MDCO-216 from Pfizer. Under the terms of the agreement, we have rights under specified Pfizer patents, patent applications and know-how to develop, manufacture and commercialize products containing MDCO-216 and improvements to the compound. We paid Pfizer \$10 million upon entering into the agreement and agreed to pay up to an aggregate of \$410 million upon the achievement of specified clinical, regulatory and sales milestones. We are obligated to make royalty payments, which are payable on a product-by-product and country-by-country basis, until the latest of the expiration of the last patent or patent application covering MDCO-216, the expiration of any market exclusivity and a specified period of time after the first commercial sale of MDCO-216. In addition, we agreed to pay Pfizer a portion of the consideration received by us or our affiliates in connection with sublicenses. Under the agreement, we may sublicense the intellectual property to third parties, provided that we have complied with Pfizer's right of first negotiation and, in the case of sublicenses to unaffiliated third parties in certain countries, provided that we first obtain Pfizer's consent. We, either directly or through our affiliates or sublicensees, have also agreed to use commercially reasonable

## Table of Contents

efforts to develop at least one product with MDCO-216 and to commercialize any approved products related thereto. The agreement expires upon the expiration of our obligation to pay royalties under the agreement. Either party may terminate the agreement upon an uncured material breach by the other party. In addition, either party may terminate the agreement upon the other party's insolvency or bankruptcy or if the other party is subject to a force majeure event. We may terminate this agreement in its entirety, or on a product-by-product basis, at any time and for any reason upon prior written notice. Pfizer may terminate this agreement if we notify them that we intend to permanently abandon the development, manufacture and commercialization of the products or if we otherwise cease, for a specified period of time, to use commercially reasonable efforts to develop, manufacture and commercialize, as applicable, at least one product.

We also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments on sales of MDCO-216.

**Ready-to-Use Argatroban.** In September 2009, we licensed marketing rights in the United States and Canada to an intravenous, ready-to-use formulation of Argatroban from Eagle. Under the license agreement, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties on net sales of the ready-to-use formulation. The license agreement expires at the later of the termination of the development plan under the agreement or upon us ceasing to exploit the products under the agreement. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured after receipt of written notice within 30 days or up to 60 days if the breaching party gives notice that it is in good faith attempting to cure the breach. In addition, we have the right to terminate the agreement at any time upon 60 days' notice.

**Acute Care Generic Products.** In January 2012, we entered into a license agreement with APP under which APP granted us a non-exclusive license under APP's marketing authorizations and intellectual property to sell the acute care generic products to hospitals and integrated delivery networks in the United States. Under the license and supply agreement, we made a one-time, upfront payment of \$30 million to APP. We also agreed to purchase our entire requirements for these products from APP for a price equal to APP's cost of goods. The term of the license and supply agreement ends January 22, 2022. We and APP may terminate the agreement in the event of a material breach by the other party, unless the material breach is cured within 90 days of written notice or within 120 days of written notice if the breach is incapable of being cured within the 90-day period. APP may terminate this agreement upon 60 days written notice if we fail to pay in full any invoice that is past due unless such payment is the subject of a dispute set forth in writing by us. We may terminate the agreement if, with respect to two purchase orders in a calendar year, APP has failed to supply at least the aggregate quantity of conforming product specified in the purchase order or failed to deliver the product prior to the applicable delivery date specified in the purchase order and APP has failed to cure these breaches in the manner specified in the agreement. In addition, either party may terminate the license and supply agreement on a product-by-product basis, effective immediately, upon written notice to the other party in the event the FDA takes any action the result of which is to permanently prohibit the manufacture of the product in the United States. APP may also terminate the license and supply agreement on a product-by-product basis upon 180 days written notice if APP has determined that it will discontinue the marketing authorization for the product in the United States. We may terminate the agreement on a product-by-product basis upon 180 days written notice if the total market value of a product falls below a specified percentage of the total market value of the product as of the effective date of the agreement. In the event that this agreement is terminated with respect to a product, the parties shall agree upon a substitute product.

### Customers

Since March 2007, we have sold Angiomax in the United States to our sole source distributor, ICS. We began selling Cleviprex to ICS in September 2008. ICS accounted for 96% of our net revenue in 2011, 94% of our net revenue in 2010 and 96% of our net revenue in 2009. At December 31, 2011, amounts due from ICS represented approximately \$85.1 million, or 92%, of gross accounts receivable. At December 31, 2010, amounts due from ICS represented approximately \$55.2 million, or 90%, of gross accounts receivable. At December 31, 2009, amounts due from ICS represented approximately \$33.8 million, or 94%, of gross accounts receivable.

#### Government Regulation

Government authorities in the United States and other countries extensively regulate the research, testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products and product candidates. In the United States, the FDA regulates drugs, including biologic drugs, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and their implementing regulations. We cannot market or commercially distribute a drug until we have submitted an application for marketing authorization to the FDA, and the FDA has approved it. Both before and after approval is obtained, violations of regulatory requirements may result in various adverse consequences, including, among other things, untitled letters, warning letters, fines and other monetary penalties, the FDA's

## Table of Contents

delay in approving or refusal to approve a product, product recall or seizure, suspension or withdrawal of an approved product from the market, interruption of production, operating restrictions, injunctions and the imposition of civil or criminal penalties. The steps required before a drug may be approved by the FDA and marketed in the United States include:

• pre-clinical laboratory tests, animal studies and formulation studies;

• submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

• adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

• submission to the FDA of an NDA or biologics license application, or BLA;

• satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMP; and

• FDA review and approval of the NDA or BLA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information, analytical data, study protocols, and other information, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA puts the trial on clinical hold because of concerns or questions about issues such as the design of the trials or the safety of the drug for administration to humans. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not necessarily result in the FDA allowing clinical trials to commence. In addition, the FDA may impose a clinical hold on an ongoing clinical trial if, for example, safety concerns arise, in which case the trial cannot recommence without the FDA's authorization.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring subject safety, and the effectiveness criteria, or endpoints, to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and the FDA may or may not allow that trial to proceed. Each trial also must be reviewed and approved by an independent Institutional Review Board, or IRB, at each proposed study site before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its safety, dosage tolerance, pharmacokinetics, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to:

• evaluate dosage tolerance and appropriate dosage;

• identify possible adverse effects and safety risks; and

• evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials typically involve administration of the drug to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. We cannot guarantee that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB,

or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Sponsors are required to publicly disseminate information about ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil money penalties and other civil and criminal sanctions for failing to meet these obligations.

Sponsors of drugs may apply for an SPA from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the primary basis for determining a drug product's efficacy. Even if the FDA agrees on the design, execution and analyses proposed in protocols reviewed under an SPA, the FDA may revoke or alter its agreement if, among other reasons, new public health



## Table of Contents

concerns emerge or the relevant assumptions change or are determined to be inaccurate. Moreover, an SPA does not guarantee approval, which depends on the results of the trials, the adverse event profile, and an evaluation of the benefit/risk profile of the drug product.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. The FDA also often inspects one or more sites at which the pivotal clinical trial or trials were conducted to ensure the integrity of the data and compliance with Good Clinical Practice, or GCP, requirements. If the FDA determines the application, data or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. As a condition of approval of an application, the FDA may request or require post-market testing and surveillance to monitor the drug's safety or efficacy. The FDA also may impose requirements designed to ensure the safety of the drug up to and including distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims, are subject to further FDA review and approval before the changes can be implemented. The testing and approval process requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all.

Under the Biologics Price Competition and Innovation Act, enacted in the United States in 2010, the FDA now has the authority to approve biosimilar or interchangeable versions of biological products through an abbreviated pathway following periods of data and marketing exclusivity. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic, address the challenges of biologics manufacturing, and include a certain amount of safety and efficacy data which the FDA will evaluate on a case-by-case basis. A competitor seeking approval of an interchangeable biological product must demonstrate not only biosimilarity but also that the products can be expected to produce the same clinical effects in any given patient.

Under the data protection provisions of this law, the FDA cannot accept a biosimilar application until four years, or approve a biosimilar application until 12 years, after initial marketing approval of the innovator biologic. Regulators in the European Union and other countries also have been given the authority to approve biosimilars. The extent to which a biosimilar, once approved, will be approved as interchangeable with or substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

After the FDA approves a product, we, our suppliers, and our contract manufacturers must comply with a number of post-approval requirements. For example, holders of an approved NDA or BLA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, we and our contract manufacturers must continue to expend time, money, and effort to maintain compliance with cGMP and other aspects of regulatory compliance. In addition, discovery of problems such as safety problems may result in changes in labeling, imposition of a REMS, or other restrictions on a product manufacturer, or NDA or BLA holder, including removal of the product from the market.

We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Once an NDA is approved, the product covered thereby becomes a listed drug that can, in turn, be relied upon by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) application upon expiration of relevant patents and non-patent exclusivity periods, if any. The FDA may approve an ANDA if the product is the same in important respects as the listed drug or if the FDA has declared it suitable for an ANDA submission. In these situations, applicants must submit studies showing that the product is bioequivalent to the listed drug, meaning that the rate and extent of absorption of the drug does not show a significant difference from the rate and extent of absorption of the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical trials necessary to support an NDA or BLA. Drugs approved via ANDAs on the basis that they are the “same” as a listed drug are commonly referred to as "generic equivalents" to the

## Table of Contents

listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. A number of ANDAs have been filed with respect to Angiomax. The regulations governing marketing exclusivity and patent protection are complex, and until the outcomes of our effort to extend the patent term and our patent infringement litigation, we may not know the disposition of such ANDA submissions.

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 a method of using the 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. An ANDA applicant relying upon a listed drug is required to certify to the FDA concerning any patents listed for the listed drug product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

•the required patent information has not been filed;

•the listed patent has expired;

•the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

•the listed patent is invalid, unenforceable, or will not be infringed by the new product.

A certification that the proposed generic product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, 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 after the receipt of a Paragraph IV certification notice 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 also will not be approved until any applicable non-patent exclusivity period, such as exclusivity for obtaining approval of a new chemical entity, 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 during which the FDA cannot grant effective approval of an ANDA if a listed drug contains a previously approved active moiety but FDA requires as a condition of approval new clinical trials conducted by or for the sponsor. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination, or indication. Under the Best Pharmaceuticals for Children Act, federal law also provides that periods of patent and non-patent marketing exclusivity listed in the Orange Book for a drug may be extended by six months if the NDA sponsor conducts pediatric studies identified by the FDA in a written request. For written requests issued by the FDA after September 27, 2007, the date of enactment of the Food and Drug Administrative Amendment Act (FDAAA), the FDA must grant pediatric exclusivity no later than nine months prior to the date of expiration of patent or non-patent exclusivity in order for the six-month pediatric extension to apply to that exclusivity period.

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 previous approval of a similar product, or published literature, in support of its application. 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for

approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication(s) sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the

## Table of Contents

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA, which was amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, contains numerous provisions that impact the pharmaceutical and healthcare industries that are expected to be implemented over the next several years. We are continually evaluating the impact of the PPACA on our business. As of the date of this annual report, we have not identified any provisions that currently materially impact our business and results of operations. However, the potential impact of the PPACA on our business and results of operations is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined and the impact on our business and results of operations may change as and if our business evolves.

### Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to incurring the costs required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically reasonable or necessary or cost-effective. Even if a drug product is covered, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Third-party payors may provide coverage, but place stringent limitations on such coverage, such as requiring alternative treatments to be tried first. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug product candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for

which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement

## Table of Contents

limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA and a related reconciliation bill, which we collectively refer to as the Affordable Care Act, or ACA, contain provisions that may reduce the profitability of drug products, including, for example, increased rebates for covered outpatient drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### Foreign Regulations

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with Good Clinical Practices, or GCPs, and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA or BLA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Drugs can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

**Centralized EMA Procedure.** The EMA, formerly the EMEA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

For drugs that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the drug concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National EMA Procedures. There are also two other possible routes to authorize medicinal products outside the scope of the centralized procedure:

• Decentralised procedure. Using the decentralised procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European



## Table of Contents

Union country and that do not fall within the mandatory scope of the centralised procedure.

Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union member state, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization

### Research and Development

Our research and development expenses totaled \$110.2 million in 2011, \$85.2 million in 2010 and \$117.6 million in 2009.

### Employees

As of February 15, 2012, we employed 421 persons worldwide. We believe that our success depends greatly on our ability to identify, attract and retain capable employees. We have assembled a management team with significant experience in drug development and commercialization. In January 2010 and February 2010, we implemented workforce reductions in our office-based and field-based functions, eliminating a total of 72 positions with us. We implemented these reductions to improve efficiencies and better align our costs and structures for the future. In September 2011, we commenced the closure of our drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at our Leipzig facility. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

### Segments and Geographic Information

We have one reporting segment. For information regarding revenue and other information regarding our results of operations, including geographic segment information, for each of our last three fiscal years, please refer to our consolidated financial statements and note 19 to our consolidated financial statements, which are included in Item 8 of this annual report, and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of this annual report.

### Available Information

Our Internet address is <http://www.themedicinescompany.com>. The contents of our website are not part of this annual report on Form 10-K, and our Internet address is included in this document as an inactive textual reference only. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. We were incorporated in Delaware on July 31, 1996.

### Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this annual report. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall.

#### Risks Related to Our Financial Results

We have a history of net losses and may not achieve profitability in future periods or maintain profitability on an annual basis

Except for 2004, 2006, 2010 and 2011, we have incurred net losses on an annual basis since our inception. As of December 31, 2011, we had an accumulated deficit of approximately \$111.7 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with research and development, clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. We anticipate needing to generate greater revenue in future periods from our existing products and from our products in development in order to achieve and maintain profitability in light of our planned expenditures. If we are unable to generate greater revenue, we may not achieve profitability in future periods or at all, and may not be able to maintain any profitability we do achieve. Our ability to generate future revenue will be substantially

dependent on our ability to maintain market exclusivity for Angiomax. If we fail to achieve profitability or maintain profitability on a quarterly or annual basis within the time frame expected by investors or securities analysts, the market price of our common

Table of Contents

stock may decline.

Our business is very dependent on the commercial success of Angiomax. If Angiomax does not generate the revenues we anticipate, our business may be materially harmed

Angiomax has accounted for substantially all of our revenue since we began selling this product in 2001. Until the approval of Cleviprex by the FDA in August 2008 and the ready-to-use formulation of Argatroban in July 2011, Angiomax was our only commercial product. We expect revenue from Angiomax to account for substantially all of our revenue in 2012. The commercial success of Angiomax depends upon:

• our ability to maintain market exclusivity for Angiomax in the United States during the period following the expiration of the patent term of the '404 patent and the six month pediatric exclusivity to which we are entitled (which we believe will be June 15, 2015) through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering Angiomax;

• the continued acceptance by regulators, physicians, patients and other key decision-makers of Angiomax as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice or currently being developed;

• our ability to further develop Angiomax and obtain marketing approval of Angiomax for use in additional patient populations and the clinical data we generate to support expansion of the product label;

• the overall number of PCI procedures performed;

• the ability of our third-party supply and manufacturing partners to provide us with sufficient quantities of Angiomax;

• the impact of competition from existing competitive products and from competitive products that may be approved in the future;

• the continued safety and efficacy of Angiomax;

• to what extent and in what amount government and third-party payors cover or reimburse for the costs of Angiomax; and

• our success and the success of our international distributors in selling and marketing Angiomax in Europe and in other countries outside the United States.

We continue to develop Angiomax for use in additional patient populations, including in patients with structural heart disease, patients undergoing peripheral angioplasty, carotid angioplasty and cardiovascular surgery and patients with or at risk of HIT/HITS. Even if we are successful in obtaining approval of an expanded Angiomax label, the expanded label may not result in higher revenue or income on a continuing basis.

As of December 31, 2011, our inventory of Angiomax was \$44.3 million and we had inventory-related purchase commitments totaling \$52.9 million for 2012, \$29.7 million for 2013, \$7.5 million for 2014 and \$7.5 million for 2015 for Angiomax bulk drug substance. If sales of Angiomax were to decline, we could be required to make an allowance for excess or obsolete inventory or increase our accrual for product returns, which could negatively impact our results of operations and our financial condition.

If we are unable to meet our funding requirements, we may need to raise additional capital. If we are unable to obtain such capital on favorable terms or at all, we may not be able to execute on our business plans and our business,

financial condition and results of operations may be adversely affected

We expect to devote substantial financial resources to our research and development efforts, clinical trials, nonclinical and preclinical studies and regulatory approvals and to our commercialization and manufacturing programs associated with our approved products and our products in development. Our funding requirements to support these efforts and programs depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;

- our ability to maintain market exclusivity for Angiomax in the United States during the period following the expiration

Table of Contents

of the patent term of the '404 patent and the six month pediatric exclusivity to which we are entitled (which we believe will be June 15, 2015) through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering Angiomax;

the extent to which Cleviprex and the acute care generic products that we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

the extent to which we can successfully continue to implement our strategy of establishing a commercial infrastructure outside the United States;

the consideration paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex, as well as cangrelor, oritavancin and MDCO-157 and our other products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Cleviprex outside the United States, Australia, New Zealand and Switzerland and of our products in development globally;

the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;

the size, cost and effectiveness of our sales and marketing programs globally;

the amounts of our payment obligations to third parties as to our products and products in development; and

our ability to defend and enforce our intellectual property rights.

If our existing resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements, we may need to sell equity or debt securities or seek additional financing through other arrangements. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could adversely affect our business, financial condition and operating results.

If we seek to raise capital to fund acquisitions of development-stage compounds, clinical-stage product candidates, approved products, or businesses or for other reasons by selling equity or debt securities or through other arrangements, our stockholders could be subject to dilution and we may become subject to financial restrictions and covenants, which may limit our activities

If we seek to acquire any development-stage compounds, clinical-stage product candidates, approved products, or businesses or determine that raising additional capital would be in our interest and in the interest of our stockholders, we may seek to sell equity or debt securities or seek additional financings through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants

limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to comply with these financial restrictions and covenants could be dependent on our future performance, which is subject to prevailing economic conditions and other factors, including factors that are beyond our control such as foreign exchange rates, interest rates and changes in the level of competition. Failure to comply with the financial restrictions and covenants would adversely affect our business, financial condition and operating results.

Our revenue in the United States is completely dependent on our sole source distributor, ICS, and our revenue outside the United States is substantially dependent on a limited number of international distributors. If the buying patterns of ICS or these international distributors for our products are not consistent with underlying hospital demand, then our revenue will be subject to fluctuation from quarter to quarter based on these buying patterns and not underlying demand for the products. Any change in these buying patterns could adversely affect our financial results and our stock price.

We distribute Angiomax and Cleviprex, and prior to the December 2011 recall, distributed ready-to-use Argatroban, in the

## Table of Contents

United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax, and Cleviprex and, when and if available for sale, ready-to-use Argatroban, to our sole source distributor, ICS. ICS then sells Angiomax and Cleviprex, and, when and if available for sale, would sell ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products for which we acquired non-exclusive rights to sell and distribute from APP through the same sole source distribution model. Our revenue from sales of Angiomax in the United States is exclusively from sales to ICS pursuant to our agreement with them. We anticipate that our revenue from sales of Cleviprex and, if and when available, ready-to-use Argatroban and the acute care generic products for which we acquired non-exclusive rights to sell and distribute from APP in the United States will be exclusively from sales to ICS. In connection with a reduction in marketing, sales and distribution fees payable to ICS, we extended the ICS' payment terms under our distribution agreement with them from 30 days to 45 days, which can be further extended to 49 days if ICS pays by wire transfer. The amendment has caused, and we expect to continue to cause, an increase in accounts receivable. As a result of our relationship with ICS, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying patterns of ICS, which may be independent of underlying hospital demand.

In some countries outside the European Union and in a few countries in the European Union, we sell Angiomax to international distributors and these distributors then sell Angiomax to hospitals. Our reliance on a small number of distributors for international sales of Angiomax could cause our revenue to fluctuate from quarter to quarter based on the buying patterns of these distributors, independent of underlying hospital demand.

If inventory levels at ICS or at our international distributors become too high, these distributors may seek to reduce their inventory levels by reducing purchases from us, which could have a materially adverse effect on our revenue in periods in which such purchase reductions occur.

### Risks Related to Commercialization

Angiomax faces significant competition from all categories of anticoagulant drugs, which may limit the use of Angiomax and adversely affect our revenue

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant drugs currently on the market, awaiting regulatory approval or in development, including orally administered agents. Angiomax competes with, or may compete with in the future, these anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same or similar indications.

We have positioned Angiomax to compete primarily with heparin, platelet inhibitors such as GP IIb/IIIa inhibitors, and treatment regimens combining heparin and GP IIb/IIIa inhibitors. Because heparin is generic and inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax instead of heparin. GP IIb/IIIa inhibitors that Angiomax competes with include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin from Merck & Co., Inc., and Aggrastat from Iroko Pharmaceuticals, LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy to Angiomax in high risk patients. Physicians may choose to use heparin combined with GP IIb/IIIa inhibitors due to their years of experience with this combination therapy and reluctance to change existing hospital protocols and pathways. Physician resistance to the use of Angiomax due to either custom or efficacy could adversely affect our revenue.

In some circumstances, Angiomax competes with other anticoagulant drugs for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other

treatment therapies they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or other anticoagulant drugs or a GP IIb/IIIa inhibitor but not necessarily more than one of these drugs. If hospitals do not choose Angiomax in these instances, our revenue will be adversely affected.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than we anticipate. We have agreed that APP may sell a generic version of Angiomax beginning May 1, 2019 or earlier under certain conditions, and that Teva may sell a generic version of Angiomax beginning June 30, 2019, or earlier under certain conditions. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

Cleviprex faces significant competition from all categories of intravenous antihypertensive, or IV-AHT, drugs, which may limit the use of Cleviprex and adversely affect our revenue



## Table of Contents

Because different IV-AHT drugs act in different ways on the factors contributing to elevated blood pressure, physicians have several therapeutic options to reduce acutely elevated blood pressure.

We have positioned Cleviprex as an improved alternative drug for selected patient types with acute, severe hypertension. Because all other drug options for this use are available as generics, Cleviprex must demonstrate compelling advantages in delivering value to the hospital. In addition to advancements in efficacy, convenience, tolerability and/or safety, we may need to demonstrate that Cleviprex will save the hospital resources in other areas such as length of stay and other resource utilization in order to become commercially successful. Because generic therapies are inexpensive and have been widely used for many years, physicians and decision-makers for hospital resource allocation may be hesitant to adopt Cleviprex and fail to recognize the value delivered through a newer agent that offers precise blood pressure control. Physician resistance to the use of Cleviprex due to either custom or efficacy would adversely affect our revenue.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do

Our industry is highly competitive. Competitors in the United States and other countries include major pharmaceutical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do.

Our competitors may develop, market or license products or other novel technologies that are more effective, safer, more convenient or less costly than any that have been or are being developed or sold by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. There are well established products, including generic products, that are approved and marketed for the indications for which Angiomax, Cleviprex, ready-to-use Argatroban and the acute care generic products that we acquired the non-exclusive right to sell and distribute from APP are approved and the indications for which we are developing our products in development. In addition, competitors are developing products for such indications. In the case of the ready-to-use Argatroban, GlaxoSmithKline has marketed for a number of years and Sandoz recently commenced marketing formulations of Argatroban that compete with our ready-to-use formulation of Argatroban. In the case of the acute care generic products, such products will compete with their respective brand name reference products and other equivalent generic products that may be sold by APP and other third parties. We compete, in the case of Angiomax, Cleviprex and ready-to-use Argatroban, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration, price and economic value compared to drugs used in current practice or currently being developed. If we are not successful in demonstrating these attributes, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition and results of operations.

If we are unable to successfully identify and acquire or license development stage compounds, clinical stage product candidates or approved products and develop or commercialize those compounds and products, our business, financial condition and results of operations may be adversely affected

Our business strategy is based on us selectively licensing or acquiring and then successfully developing and commercializing development stage compounds, clinical stage product candidates and approved products. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. However, the acquisition and licensing of pharmaceutical products is a competitive area. A number of more established companies, which have acknowledged strategies to license and

acquire products, may have competitive advantages over us due to their size, cash flows and institutional experience. In addition, we may compete with emerging companies taking similar or different approaches to product acquisition.

Because of the intense competition for these types of product candidates and approved products, the cost of acquiring, in-licensing or otherwise obtaining rights to such candidates and products has grown dramatically in recent years and are often at levels that we cannot afford or that we believe are not justified by market potential. Any acquisition or license of product candidates or approved products that we pursue may not result in any short or long term benefit to us. We may incorrectly judge the value or worth of an acquired or licensed product candidate or approved product. Even if we succeed in acquiring product candidates, we may not be successful in developing them and obtaining marketing approval for them, manufacturing them economically or commercializing them successfully. We have previously acquired or licensed rights to clinical or development stage compounds and, after having conducted development activities, determined not to devote further resources to those compounds. In addition, our future success would depend in part on our ability to manage any required growth associated with some of these acquisitions and licenses. Any acquisition might distract resources from the development of our existing product candidates and could otherwise

## Table of Contents

negatively impact sales of our other marketed products. Furthermore, the development or expansion of any licensed or acquired product candidate or approved product may require a substantial capital investment by us, and we may not have these necessary funds to do so.

If we are unable to identify and acquire additional promising candidates or to develop and commercialize successfully those candidates we have, we will not be able to implement our business strategy and our business, operating results and financial condition may be materially and adversely affected.

If we are not able to convince hospitals to include our products on their approved formulary lists, our revenues may not meet expectations and our business, results of operations and financial condition may be adversely affected

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the formulary, the ability of our engagement partners and engagement managers to promote the drug may be limited or denied. In connection with the launch of Cleviprex, we experienced difficulties in getting Cleviprex included on hospitals' formulary lists, in part because hospital formularies may limit the number of IV-AHT drugs in each drug class, and revenues from Cleviprex were adversely affected. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our sales, results of operations and financial condition could be adversely affected

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

If physicians, patients and other key healthcare decision-makers do not accept clinical data from trials of Angiomax and Cleviprex, then sales of Angiomax and Cleviprex may be adversely affected

We believe that the near-term commercial success of Angiomax and Cleviprex will depend in part upon the extent to which physicians, patients and other key healthcare decision-makers accept the results of clinical trials of Angiomax and Cleviprex. For example, following the announcement of the original results of the REPLACE-2 clinical trial of Angiomax in 2002, additional hospitals granted Angiomax formulary approval and hospital demand for the product increased. However, some commentators have challenged various aspects of the trial design of the REPLACE-2 trial of Angiomax, the conduct of the clinical trial and the analysis and interpretation of the results from the clinical trial. Similarly, physicians, patients and other key decision-makers may not accept the results of the ACUITY and HORIZONS AMI clinical trials of Angiomax. The FDA, in denying our sNDA for an additional Angiomax dosing regimen in the treatment of ACS initiated in the emergency department, indicated that the basis of its decision involved the appropriate use and interpretation of non-inferiority trials such as our ACUITY trial. If physicians, patients and other key decision-makers do not accept clinical trial results, adoption and continued use of Angiomax

and Cleviprex may suffer, and our business will be materially adversely affected.

If the number of PCI procedures performed decreases, sales of Angiomax may be negatively impacted

The number of PCI procedures performed in the United States declined in 2007 due in part to the reaction to data from a clinical trial that was published in March 2007 in the New England Journal of Medicine entitled “Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation,” or “COURAGE”, and to the controversy regarding the use of drug-eluting stents. Since 2007, PCI procedure volume has remained similar to the 2007 levels and has not returned to the level of PCI procedures performed prior to the 2007 decline. With ongoing economic pressures on our hospital customers, PCI procedure volume might further decline and might not return to its previous levels. Because PCI procedures are the primary procedures during which Angiomax is used, a decline in the number of procedures may negatively impact sales of Angiomax, possibly materially.

Because we did not sell Cleviprex from the first quarter of 2010 through the first quarter of 2011, as a result of product

## Table of Contents

recalls and related supply issues, market acceptance of Cleviprex may be adversely affected

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex or sell Cleviprex from the first quarter of 2010 through the first quarter 2011. We began to resupply existing customers with Cleviprex in April 2011. In July 2011, the FDA approved our sNDA, for an improved formulation of Cleviprex. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care and cardiac surgery patients. However, physicians and decision makers who have used Cleviprex prior to the recalls may be reluctant to resume using Cleviprex and physicians and decision makers who had not used Cleviprex may be reluctant to begin using Cleviprex because of the recalls and the related supply issues. Physicians and healthcare decision makers who had adopted Cleviprex as their preferred antihypertensive therapy when it was available may also have adopted other antihypertensive therapies during the period when Cleviprex was not available and may be reluctant to change. In addition, in the re-launch of Cleviprex, we are focusing our marketing of Cleviprex on neurocritical care and cardiac surgery patients. We have not focused our marketing of Cleviprex in these areas previously and may not be successful in this change in marketing focus.

If we are unable to successfully expand our business infrastructure and develop our global operations, our ability to generate future product revenue will be adversely affected and our business, results of operations and financial condition may be adversely affected

To support the global sales and marketing of Angiomax, Cleviprex and our product candidates in development, if and when they are approved for sale and marketed outside the United States, we are developing our business infrastructure globally. Our ability to do this successfully will depend on our ability to expand our internal organization and infrastructure to accommodate additional anticipated growth. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we will need to continue building our organization and making significant additional investments in personnel, infrastructure, information management systems and other operational resources. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited. Such expansion may be more difficult, more expensive or take longer than we anticipate. If we are not able to successfully market and sell our products globally, our business, results of operations and financial condition may be adversely affected.

Future rapid expansion could strain our operational, human and financial resources. For instance, we may be required to allocate additional resources to the expanded business, which we would have otherwise allocated to another part of our business. In order to manage expansion, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

If we do not take these actions and are not able to manage our global business, then our global operations may be less successful than anticipated.

The success of our global operations may be adversely affected by international risks and uncertainties. If these operations are not successful, our business, results of operations and financial condition could be adversely affected

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. For the year ended December 31, 2011 we had \$31.6 million in sales outside of the United States and we have historically encountered difficulty in selling Angiomax outside of the United States. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States. These risks and uncertainties include:

- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance with complex and changing foreign legal, tax, accounting and regulatory requirements;

## Table of Contents

- language barriers and other difficulties in providing long-range customer support and service;
- longer accounts receivable collection times;
- significant foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;
- trade restrictions and restrictions on direct investment by foreign entities;
- reduced protection of intellectual property rights in some foreign countries; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our foreign operations could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations.

If reimbursement by government payors or other third-party payors is not available or limited for our products, drug pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payors, our ability to generate revenue would be adversely affected

Acceptable levels of coverage and reimbursement of drug treatments by government payors, such as Medicare and Medicaid programs, private health insurers and other organizations, have a significant effect on our ability to successfully commercialize our products. Reimbursement in the United States, Europe or elsewhere may not be available for any products we may develop or, if already available, may be decreased in the future. We may not get reimbursement or reimbursement may be limited if government payors, private health insurers and other organizations are influenced by the prices of existing drugs in determining whether our products will be reimbursed and at what levels. For example, the availability of numerous generic antibiotics at lower prices than branded antibiotics, such as oritavancin, if it were approved for commercial sale, could substantially affect the likelihood of reimbursement and the level of reimbursement for oritavancin. If reimbursement is not available or is available only at limited levels, we may not be able to commercialize our products, or may not be able to obtain a satisfactory financial return on our products.

In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. In some countries, pricing and reimbursement are set with limited, if any, participation in the process by the marketing authorization holder. In addition, it can take an extended period of time after the receipt of initial approval of a product to establish and obtain reimbursement or pricing approval. Reimbursement approval also may be required at the individual patient level, which can lead to further delays. In addition, in some countries, it may take an extended period of time to collect payment even after reimbursement has been established. If prices are set at unsatisfactory levels, such prices may negatively impact our revenues from sales in those countries. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Further, a number of European Union countries use drug prices from other countries of the European Union as “reference prices” to help determine pricing in their own countries. Consequently, a downward trend in drug prices for some countries could contribute to similar occurrences elsewhere. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Third-party payors, including Medicare and Medicaid increasingly are challenging prices charged for and the cost-effectiveness of medical products and services and they increasingly are limiting both coverage and the level of reimbursement for drugs. Also, the trend toward managed health care in the United States and the changes in health insurance programs may result in lower prices for pharmaceutical products and health care reform. The recently enacted Patient Protection and Affordable Care Act of 2010, or the PPACA, may also have a significant impact on pricing as the legislation contains a number of provisions that are intended to reduce or limit the growth of healthcare costs. The provisions of the PPACA could, among other things, increase pressure on drug pricing and, as a result, the number of procedures that are performed. In addition to federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures could adversely impact our business and future results. If governmental organizations and third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.



## Table of Contents

Use or misuse of our products may result in serious injuries or even death to patients and may subjects us to significant claims for product liability. If we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liability

Our business exposes us to potential significant product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. With respect to our commercial sales and our clinical trials, we are covered by product liability insurance in the amount of \$20.0 million per occurrence and \$20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover all or any product liability claims that we face

As we continue to commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

An adverse decision in the arbitration between us and Eagle could have a material adverse effect on our financial condition

We have received a Demand for Arbitration filed by Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claims that we failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount Eagle believes exceeds \$200 million. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously. Arbitration, like litigation, is inherently uncertain. An adverse decision in this arbitration could have a material adverse effect on our financial condition.

## Risks Related to our Dependence on Third Parties for Manufacturing, Research and Development, and Distribution Activities

We have no manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of our products. We depend on a limited number of suppliers for the production of bulk drug substance for our products and products in development and to carry out fill-finish activities. If any of these suppliers does not or cannot fulfill its manufacturing or supply obligations to us, our ability to meet commercial demands for our products and to conduct clinical trials of our products and products in development could be impaired and our business could be harmed.

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently rely on a limited number of manufacturers for bulk substance and to carry out fill-finish activities for our products and products in development. We expect to continue this manufacturing arrangement for the foreseeable future.

In the event that any of our third-party manufacturers is unable or unwilling to carry out its respective manufacturing or supply obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing or supply on commercially reasonable terms on a timely basis or at all. In addition, we purchase finished drug product from a number of our third-party manufacturers under purchase orders. In such cases, the third-party manufacturers have made no commitment to supply the drug product to us on a long-term basis and could reject our purchase orders. Only a limited number of manufacturers are capable of manufacturing our products and products in development. Consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or otherwise affect our existing contractual relationships.

If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for our products on a timely basis, which could reduce our revenue, and to supply product for clinical trials of Angiomax, Cleviprex and our products in development, which could affect our ability to complete clinical trials on a timely basis.

## Table of Contents

If third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations or we are unable to establish or maintain such arrangements, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct many of these activities on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of our products or establish and maintain arrangements to develop, manufacture and commercialize our products in development or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our products, our products in development or any additional products or product candidates we may acquire, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of our products, our products in development or any additional products or product candidates that we may acquire or develop;

- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or

- result in the termination of the development or commercialization of our products.

Our reliance on third-party manufacturers to supply our products and product candidates may increase the risk that we will not have appropriate supplies of our products or our product candidates, which could adversely affect our business, results of operations and financial condition

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products or products candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;

the possible breach of the manufacturing agreement by the third party; and

the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

For example, in December 2009 and March 2010 we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials that were manufactured for us by a third party. As a result, we were not able to supply the market with Cleviprex or sell Cleviprex from the first quarter of 2010 until April 2011. In addition, in December 2011 Eagle, the licensor and sole supplier of ready-to-use Argatroban, conducted a voluntary recall of the product due to the presence of particulate matter in some vials. As a result we have not been able to supply the market with or sell ready-to-use Argatroban since December 2011.

## Table of Contents

Our products and products in development may compete with products and product candidates of third parties for access to manufacturing facilities. If we are not able to obtain adequate supplies of our products and products in development, it will be more difficult for us to compete effectively, market and sell our approved products and develop our products in development.

Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to evaluate compliance with the FDA's cGMP, regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines and other monetary penalties, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, suspension of clinical trials, license revocation, seizures or recalls of product candidates or products, interruption of production, warning letters, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and products in development.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages

We conduct research and development activities that involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in the United States and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with applicable laws in the future. Also, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We have only limited insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may restrict our research, development and production efforts, which could harm our business, operating results and financial condition.

If we fail to acquire and develop additional development-stage compounds, clinical-stage product candidates or approved products, it will impair our ability to grow our business

We have sold and generated revenue from three products, Angiomax, Cleviprex and ready-to-use Argatroban. In order to generate additional revenue, our business plan is to acquire or license, and then develop and market, additional development-stage compounds, clinical-stage product candidates and approved products. From 2008 through February 2012, for instance, we acquired Curacyte Discovery and Targanta, licensed marketing rights to the ready-to-use formulation of Argatroban, licensed development and commercialization rights to MDCO-216 and MDCO-157 and licensed the non-exclusive rights to sell and distribute ten acute care generic products. The success of this growth strategy depends upon our ability to identify, select and acquire or license pharmaceutical products that meet the criteria we have established. Because we have only the limited internal scientific research capabilities that we acquired in our acquisitions of Curacyte Discovery and Targanta, and we do not anticipate establishing additional scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us. In addition, proposing, negotiating and implementing an economically viable acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of development-stage

compounds, clinical-stage product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our Chairman and Chief Executive Officer, Clive A. Meanwell, our President and Chief Financial Officer, Glenn P. Sblendorio, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

## Table of Contents

### Risks Related to Regulatory Matters

If we do not obtain regulatory approvals for our product candidates in any jurisdiction or for our products in any additional jurisdictions, we will not be able to market our products and product candidates in those jurisdictions and our ability to generate additional revenue could be materially impaired

We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. In addition, we must obtain approval from foreign regulatory authorities in order to sell our U.S.-approved products in other countries. Obtaining regulatory approval is uncertain, time-consuming and expensive. Any regulatory approval we ultimately obtain may limit the indicated uses for the product or subject the product to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not approve our applications, we will be unable to obtain regulatory approval. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of the products or product candidates in the jurisdiction for which approval is sought;

- diminish our competitive advantage; and

- defer or decrease our receipt of revenue.

The regulatory review and approval process to obtain marketing approval takes many years and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that data are insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product. For example, the FDA issued a complete response letter to Targanta in December 2008 before it was acquired by us with respect to the oritavancin NDA indicating that the FDA could not approve the NDA in its present form and that it would be necessary for Targanta to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with ABSSSI before the application could be approved. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress or foreign legislatures and increased caution by the FDA and comparable foreign regulatory authorities in reviewing applications for marketing approval.

In the fourth quarter of 2010, we initiated our SOLO I and SOLO II clinical trials of oritavancin pursuant to a Special Protocol Assessment, or SPA, with the FDA. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their drugs. Since we are developing oritavancin under an SPA, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoints in the SOLO trials are achieved, a SPA does not guarantee approval. An SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA was entered into become evident; the data, assumptions or information underlying the SPA request change or are called into question; other new scientific concerns regarding product safety or efficacy arise; or if we fail to comply with the agreed upon trial protocols. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may

also seek the guidance of an outside advisory committee prior to making its final decision.

The procedures to obtain marketing approvals vary among countries and can involve additional clinical trials or other pre-filing requirements. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval, or different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by the regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by the FDA or regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products and products in development in any market.

We cannot expand the indications for which we are marketing Angiomax unless we receive regulatory approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for Angiomax



## Table of Contents

In order to market Angiomax for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time-consuming and expensive. The regulatory review and approval process to obtain marketing approval for a new indication can take many years and require the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application. Alternatively, they may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication for a product.

For example, in 2006 we received a non-approvable letter from the FDA in connection with our application to market Angiomax for patients with or at risk of HIT/HITTS undergoing cardiac surgery. In addition, in May 2008, we received a non-approvable letter from the FDA with respect to an sNDA that we submitted to the FDA seeking approval of an additional indication for Angiomax for the treatment of patients with ACS in the emergency department. In its May 2008 letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. If we determine to pursue these indications, the FDA may require that we conduct additional studies of Angiomax, which studies could require the expenditure of substantial resources. Even if we undertook such studies, we might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. If we are unsuccessful in expanding the Angiomax product label, the size of the commercial market for Angiomax will be limited.

Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain. If we are unable to conduct clinical trials that demonstrate the safety and efficacy of our product candidates on a timely basis, then our costs of developing the product candidates may increase and we may not be able to obtain regulatory approval for our product candidates on a timely basis or at all.

Before we can obtain regulatory approvals to market any product for a particular indication, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product for such indication.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. For example, in May 2009 we discontinued enrollment in our Phase 3 CHAMPION clinical trial program of cangrelor in patients undergoing PCI after receiving a letter from the clinical program's independent Interim Analysis Review Committee that reported that the efficacy endpoints of the trial program would not be achieved.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our products, including:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials which even if undertaken cannot ensure we will gain approval;

- data obtained from pre-clinical testing and clinical trials may be subject to varying interpretations, which could result in the FDA or other regulatory authorities deciding not to approve a product in a timely fashion, or at all;

- the cost of clinical trials may be greater than we currently anticipate;

regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and

the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient

## Table of Contents

population targeted by some of our clinical trials may be small. Delays in patient enrollment in any of our current or future clinical trials may result in increased costs and program delays.

If we or our contract manufacturers fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products and product candidates are subject, our products could be subject to restrictions or withdrawal from the market, the development of our product candidates could be jeopardized, and we could be subject to penalties

The research, testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to current good manufacturing practice, or cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA, the EMA or other governmental authorities could result in, among other things, any of the following:

- delay in approving or refusal to approve a product;
- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- delays in, suspension of or prohibition of commencing, clinical trials of products in development;
- interruption of production;
- operating restrictions;
- untitled or warning letters;
- injunctions;
- fines and other monetary penalties;
- the imposition of civil or criminal penalties;
- disruption of importing and exporting activities; and
- unanticipated expenditures.

We may incur significant liability if it is determined that we are promoting the “off-label” use of any of our products

Physicians may prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has

not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or another regulatory or enforcement authority determines that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

If we do not comply with federal, state and foreign laws and regulations relating to the health care business, we could face substantial penalties

## Table of Contents

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;

- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;

- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and

- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

Failure to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, as well as the anti-bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences

We are subject to the FCPA, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries. In addition, we are subject to other anti-bribery laws of the nations in which we conduct business that apply similar prohibitions as the FCPA. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the Foreign Corrupt Practices Act and other anti-bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

## Risks Related to Our Intellectual Property

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other U.S. patents covering

Angiomax, Angiomax could be subject to generic competition earlier than we anticipate. Generic competition for Angiomax would have a material adverse effect on our business, financial condition and results of operations

The principal U.S. patent covering Angiomax, the '404 patent, was set to expire in March 2010, but was extended under the Hatch-Waxman Act following our litigation against the PTO, the FDA and HHS. We had applied, under the Hatch-Waxman Act, for an extension of the term of the '404 patent. However, the PTO rejected our application because in its view the application was not timely filed. As a result, we filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our application to extend the term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. The period for the government to appeal the federal district court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS.

## Table of Contents

On September 13, 2010, the federal district court denied APP's motion. APP appealed the denial of its motion and the federal district court's August 3, 2010 order (and all related and underlying orders). On January 22, 2012, as part of our settlement of our patent litigations with APP, APP agreed to dismiss its appeal. Upon dismissal of APP's appeal, all pending litigation regarding the '404 patent was resolved. Other third parties could challenge the '404 patent in separate proceedings, however.

On September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act, or the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications under the Hatch-Waxman Act. This clarification confirms the interpretation of the Hatch-Waxman Act adopted by the federal district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed. Prior to the dismissal of its appeal, APP had challenged the applicability of the America Invents Act to our matter and the constitutionality of the America Invents Act. If a third party were to make similar assertions in a new action and Section 37 of the America Invents Act was found to be unconstitutional or not to apply to the '404 patent, Angiomax could be subject to generic competition in the United States earlier than we anticipate. In addition, in October 2011, a legislative proposal was filed in the United States Senate to deny the PTO funding to implement Section 37 of the America Invents Act. This proposal was not brought up for a vote by the Senate, but could be brought up in the future. It is difficult to predict whether this proposal or other legislation amending or otherwise preventing the application of Section 37 of the America Invents Act might be proposed and enacted, or, if so enacted, the legal effect of such legislation. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva. In connection with the settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In addition, in certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers.

If we are unable to maintain our market exclusivity for Angiomax in the United States as a result of an adverse court decision or adverse legislation relating to the '404 patent or our inability to enforce our other U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than May 1, 2019.

Following our settlements with Teva and APP, we submitted the settlement documents for each settlement to the U.S. Federal Trade Commission, or FTC, and the U.S. Department of Justice, or the DOJ. The FTC and the DOJ could seek to challenge our settlements with Teva and APP, or a third-party could initiate a private action under antitrust or other laws challenging our settlements with Teva and APP. While we believe our settlements are lawful, we may not prevail in any such challenges or litigation, in which case the other party might obtain injunctive relief, remedial relief, or such other relief as a court may order. In any event, we may incur significant costs in the event of an investigation or in defending any such action and our business and results of operations could be materially impacted

if we fail to prevail against any such challenges.

Our litigation with the PTO, the FDA and HHS, APP's efforts to appeal the August 3, 2010 decision, the patent infringement suits and our settlements with Teva and APP are described in more detail in Part I, Item 3 of this annual report.

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications relating to each of our products and products in development other than MDCO-2010. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the



## Table of Contents

licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreements with respect to Angiomax, could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

We have entered into an agreement with Biogen Idec, one of our licensors of Angiomax, that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the PTO's initial denial of the application under the Hatch-Waxman Act for an extension of the term of the '404 patent on the grounds that it was filed late. We are also in discussions with Biogen Idec and HRI with respect to the possible resolution of any potential claims among the parties with respect to this matter. We may not reach any agreement with the parties on terms acceptable to us or at all.

If we are unable to obtain or maintain patent protection for the intellectual property relating to our products, the value of our products will be adversely affected

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. We cannot be certain that our patents and patent applications, including our own and those that we have rights through licenses from third parties will adequately protect our intellectual property. Our success in protection of our intellectual property depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license patents and patent applications for each of our products and products in development other than MDCO-2010, for which we own the patents and patent applications, and the acute care generic products that we licensed from APP on a non-exclusive basis which are not covered by any patents or patent applications. The patents covering our approved products and our product candidates are currently set to expire at various dates:

Angiomax. The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404

## Table of Contents

patent, was set to expire in March 2010, but was extended on an interim basis to August 13, 2012 under the Hatch-Waxman Act following our litigation against the PTO, the FDA and HHS. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. If the term of the '404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015.

Prior to the dismissal of its appeal, APP had challenged the applicability of the America Invents Act to our matter and the constitutionality of the America Invents Act. If a third party were to make similar assertions in a new action and Section 37 of the America Invents Act were found to be unconstitutional or not to apply to the '404 patent, Angiomax could be subject to generic competition in the United States earlier than we anticipate. In such event, a court or the FDA could determine that the '404 patent expired in March 2010. In such case, the pediatric exclusivity period for Angiomax would have expired in September 2010. It is also possible that a court or the FDA could determine that the '404 patent expired on a later date, in which case the pediatric exclusivity for Angiomax would run from that later date.

In the second half of 2009, the PTO issued to us the '727 patent and the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva. In connection with the settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In addition, in certain limited circumstances, the license to APP could include the right to sell a generic bivalirudin product under our NDA for Angiomax in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, Angiomax could be subject to generic competition earlier than May 1, 2019.

Our litigation with the PTO, the FDA and HHS, APP's efforts to appeal the August 3, 2010 decision, the patent infringement suits and our settlements with Teva and APP are described in more detail in Part 1, Item 3 of this annual report.

In Europe, the principal patent covering Angiomax expires in 2015.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which is set to expire in January 2016. Following receipt of marketing approval from the FDA, we submitted an application under the Hatch-Waxman Act to extend the term of the '346 patent. This application is currently pending. In addition, we have filed and are currently prosecuting a number of patent applications relating to Cleviprex covering compositions of matter and uses in the United States, Europe and other foreign countries. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we received regulatory approval and expect to file for supplementary protection certificates in other European countries as we receive approvals. In

Europe, the principal patent covering Cleviprex expires in November 2014 if no patent term extension is obtained.

Cangrelor. The principal U.S. and European patents for cangrelor are set to expire in February 2014 if no patent term extension is obtained. In addition, we have also filed and are currently prosecuting a number of patent applications related to cangrelor.

Oritavancin. The principal patent for oritavancin in both the United States and Europe is set to expire in November 2015 if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

MDCO-157. The principal patent application for MDCO-157 in both the United States and Europe, if issued, would expire in April 2028.

MDCO-2010. In connection with our acquisition of Curacyte Discovery, we acquired a portfolio of patents and patent applications covering MDCO-2010, its analogs or other similar protease inhibitors. We are currently prosecuting and maintaining

## Table of Contents

these patents and patent applications. In February 2012, the principal patent application for MDCO-2010 was allowed by the PTO, and, when issued, the resulting patent will be set to expire in September 2028 in the United States. The principal patent application in Europe is still pending and, if issued, would expire in October 2027.

MDCO-216. We are maintaining a number of U.S. patents with respect to MDCO-216, including patents that claim the use of MDCO-216 in certain disease indications. One of these U.S. patents is directed to the use of MDCO-216 for the treatment of ACS and is set to expire in October 2024. We have also filed and are prosecuting a number of patent applications related to the use and production of MDCO-216 in the United States, Europe and other foreign countries. In addition, as a biologic, we expect MDCO-216 to receive 12 years of regulatory exclusivity in the United States and 10 years of regulatory exclusivity in Europe from the date of the initial marketing approval of MDCO-216, if approved.

Ready-to-Use Argatroban. We exclusively licensed from Eagle rights to two U.S. patents covering certain formulations of Argatroban. Our exclusive license is limited to the United States and Canada. The patents are set to expire in September 2027. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. We are in the process of reviewing this correspondence and determining what further action we may take.

We plan to file applications for patent term extension for our products in development upon their approval. If we do not receive patent term extensions for the periods requested by us or at all, our patent protection for our products in development could be limited.

We are a party to a number of lawsuits that we brought against pharmaceutical companies that have notified us that they have filed ANDAs seeking approval to market generic versions of Angiomax. We cannot predict the outcome of these lawsuits. Involvement in litigation, regardless of its outcome, is time-consuming and expensive and may divert our management's time and attention. During the period in which these matters are pending, the uncertainty of their outcome may cause our stock price to decline. An adverse result in these matters whether appealable or not, will likely cause our stock price to decline. Any final, unappealable, adverse result in these matters will likely have a material adverse effect on our results of operations and financial conditions and cause our stock price to decline.

If upon expiration of our agreement with Lonza Braine, Lonza Braine breaches our agreement and fails to transfer the technology that was used to develop the Chemilog process, we would be unable to employ the Chemilog process to manufacture Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

Our agreement with Lonza Braine for the supply of Angiomax bulk drug substance requires that Lonza Braine transfer the technology that was used to develop the Chemilog process to a secondary supplier of Angiomax bulk drug substance or to us or an alternate supplier at the expiration of the agreement, which is currently scheduled to occur in September 2013, but is subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal at least one year prior to the expiration of the initial term or any renewal term. If Lonza Braine fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements and invention assignment agreements with our employees,

consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements or invention assignment agreements. In addition, our competitors may learn or independently develop our trade secrets. If our confidential information or trade secrets become publicly known, they may lose their value to us.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business may be adversely affected

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the

## Table of Contents

subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the PTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

## Risks Related to Our Common Stock

Fluctuations in our operating results could affect the price of our common stock

Our operating results may vary from period to period based on factors including the amount and timing of sales of and underlying hospital demand for our products, , our customers' buying patterns, the timing, expenses and results of clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement, including in Europe, sales and marketing expenses and the timing of regulatory approvals. If our operating results do not meet the expectations of securities analysts and investors as a result of these or other factors, the trading price of our common stock will likely decrease.

Our stock price has been and may in the future be volatile. This volatility may make it difficult for you to sell common stock when you want or at attractive prices

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2009 to February 24, 2012, the last reported sale price of our common stock ranged from a high of \$27.68 per share to a low of \$6.47 per share. The value of your investment could decline due to the effect upon the market price of our common stock of any of the following factors, many of which are beyond our control:

- achievement or rejection of regulatory approvals of our product candidates and our products;
- regulatory actions by the FDA or a foreign jurisdiction limiting or revoking the use of our products;
- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;

acquisitions and strategic partnerships;

announcements of technological innovations or new commercial products by us or our competitors or the filing of ANDAs or NDAs for products competitive with ours;

disclosure of results of clinical testing or regulatory proceedings by us or our competitors;

the timing, amount and receipt of revenue from sales of our products and margins on sales of our products;



## Table of Contents

• changes in governmental regulations;

• developments in patent rights or other proprietary rights, particularly with respect to our U.S. Angiomax patents;

• the extent to which Angiomax is commercially successful globally;

• our ability to maintain market exclusivity for Angiomax in the United States during the period following the expiration of the patent term of the '404 patent and the six month pediatric exclusivity to which we are entitled (which we believe will be June 15, 2015) through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering Angiomax;

• significant new litigation;

• developments or issues with our contract manufacturers;

• changes in our management; and

• general market conditions.

We believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

The stock markets in general, and The NASDAQ Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that security holders may consider desirable

The General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include

Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;

our board of directors has the authority to issue, without a vote or action of stockholders, up to 5,000,000 shares of a new series of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of our common stock;

our directors are elected to staggered terms, which prevents our entire board of directors from being replaced in any single year;

•

our directors may be removed only for cause and then only by the affirmative vote of the holders of at least 75% of the votes which all stockholders would be entitled to cast in any annual election of directors;

the size of our board of directors is determined by resolution of the board of directors;

any vacancy on our board of directors, however occurring, including a vacancy resulting from an enlargement of our board, may only be filled by vote of a majority of our directors then in office, even if less than a quorum;

only our board of directors, the chairman of the board or our president may call special meetings of stockholders;

our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the

## Table of Contents

stockholders would be entitled to cast in any annual election of directors;

• stockholders must provide us with advance notice, and certain information specified in our by-laws, in connection with nominations or proposals by such stockholder for consideration at an annual meeting;

• stockholders may not take any action by written consent in lieu of a meeting; and

our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors (and plus any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders).

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;

perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and

• if individuals are elected to our board of directors with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

### Item 1B. Unresolved Staff Comments

None.

### Item 2. Properties

We lease our principal offices in Parsippany, New Jersey. The lease covers 173,146 square feet and expires January 2024. We are still subject to a lease for our old office facility in Parsippany, New Jersey. The lease for our old office facility expires January 2013. We sublease the first floor of our previous office space under an agreement that expires in January 2013.

We also lease small offices and other facilities in Waltham, Massachusetts, U.S.; Montreal, Canada; Milton Park, Abingdon, United Kingdom; Basel, Switzerland; Zurich, Switzerland; Paris, France; Rome, Italy; Munich, and Leipzig, Germany; Vienna, Austria; Brussels, Belgium; Amsterdam, Netherlands; Madrid, Spain; Helsinki, Finland; Copenhagen, Denmark; Oslo, Norway; Stockholm, Sweden; Warsaw, Poland; Sydney, Australia; Auckland, New Zealand; Sao Paulo, Brazil and New Delhi, India.

We believe our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

Item 3. Legal Proceedings

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

'727 Patent and '343 Patent Litigations

Table of Contents

Teva Parenteral Medicines, Inc.

In September 2009, we were notified that Teva Parenteral Medicines, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent expires on July 27, 2028. On October 8, 2009, we filed suit against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Teva Pharmaceuticals, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva Pharmaceuticals filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania.

On October 6, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On December 28, 2009, we filed suit against Teva Pharmaceuticals in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the Teva Pharmaceuticals '727 patent case above.

The judge in the Eastern District of Pennsylvania has consolidated the Teva Pharmaceuticals '727 patent and '343 patent cases with the Pliva '727 patent and '343 patent cases (discussed below), the APP '727 patent and '343 patent cases (discussed below) and the Hospira '727 patent and '343 patent cases (discussed below).

On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, which included Pliva Hrvatska d.o.o., with respect to the patent infringement suits. Under the settlement agreement, Teva admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. Under the license agreement, we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On October 13, 2011, the district court entered a judgment and order of permanent injunction concluding our patent infringement suits against Teva. On October 13, 2011, we and Teva submitted the settlement agreement and license agreement to the FTC and the DOJ.

Pliva Hrvatska d.o.o.

In September 2009, we were notified that Pliva Hrvatska d.o.o. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against Pliva Hrvatska d.o.o., Pliva d.d., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., Barr Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Pliva, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 28, 2009, Pliva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania.

On October 6, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On December 28, 2009, we filed suit against Pliva in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the '727 patent case above.

On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, which included Pliva, with respect to the patent infringement suits, as described above.

#### APP Pharmaceuticals, LLC

In September 2009, we were notified that APP Pharmaceuticals, LLC had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc., which we refer to collectively as APP, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. An amended complaint was filed on February 5, 2010. APP's answer denied infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '727 patent from the Orange Book. On March 1, 2010, we filed a reply denying the counterclaims raised by APP.

On October 6, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product

## Table of Contents

made by processes described in the patent. In April 2010, we were notified by APP that it is seeking permission to market its generic version of Angiomax prior to the expiration of the '343 patent. On June 1, 2010, we filed suit against APP in the U.S. District Court for the District of Delaware for infringement of the '343 patent. On June 28, 2010, APP filed an answer denying infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '343 patent from the Orange Book. On July 16, 2010, we filed a reply denying the counterclaims raised by APP. The case has been assigned to a judge in the U.S. District Court for the District of Delaware. On October 14, 2010, the case was reassigned to the same judge in the Eastern District of Pennsylvania who was then presiding over the above APP '727 patent case and the Teva Pharmaceuticals '727 patent and '343 patent cases and the Pliva '727 patent and '343 patent cases. On the same day, the APP '343 patent case was consolidated with these other cases.

On February 25, 2011, APP filed a motion to amend its answers and add counterclaims of inequitable conduct and unclean hands. The motion was referred to a special master. Our opposition papers were filed on March 14, 2011 and APP filed a reply on March 24, 2011. The special master heard oral argument on April 13, 2011 and issued a report and recommendations on April 26, 2011. The parties briefed the issues raised to the judge. Following recent federal circuit decisions, the judge sent APP's motion back to the special master for further review. A second report and recommendation was issued on June 23, 2011. The issues were again briefed to the judge and the court issued an order adopting the special master's report and granting APP's motion. APP filed its amended answers and counterclaims on July 25, 2011.

On August 8, 2011, we filed a motion to dismiss, strike or alternatively bifurcate APP's allegations of inequitable conduct and unclean hands. The motion was referred to the special master. APP filed an answering brief on August 19, 2011. We filed a reply on August 24, 2011. On September 22, 2011 the special master issued a report and recommendation. The parties briefed the issues raised to the judge and the court issued an order adopting the special master's report and denying our motion. On October 21, 2011 we filed replies answering APP's counterclaims.

The special master also directed the parties to file supplemental briefing for a pretrial hearing known as a Markman hearing. Opening briefs were filed on October 7, 2011 and responding briefs on October 20, 2011.

On January 22, 2012, we entered into a settlement agreement and a license agreement with APP with respect to the patent infringement suits and APP's appeal of the August 2010 federal district court decision holding that our application for Hatch Waxman patent term extension of the '404 patent was timely filed (as described below). Under the settlement agreement, APP admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDAs. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product in the United States beginning on May 1, 2019. In certain limited circumstances, this license to APP could become effective prior to May 1, 2019 and could include an authorized generic bivalirudin product supplied by us. Contemporaneously with entering into the settlement agreement and license agreement, we entered into a contract manufacturing agreement, a license and supply agreement and an authorized generic supply agreement with APP, which we refer to collectively as the settlement documents (see note 21 to our consolidated financial statements, which are included in Item 8 of this annual report, for a description of the settlement documents). On January 24, 2012, the district court entered a consent judgment and order of permanent injunction concluding our patent infringement suits against APP. On February 1, 2012, we and APP submitted the settlement documents to the FTC and the DOJ.

Hospira, Inc.

In July 2010, we were notified that Hospira, Inc., or Hospira, had submitted two ANDAs seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On August 19, 2010,

we filed suit against Hospira in the U.S. District Court for the District of Delaware for infringement of the '727 patent and '343 patent. On August 25, 2010, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. Hospira's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On September 24, 2010, we filed a reply denying the counterclaims raised by Hospira.

On September 17, 2010, Hospira filed a motion to be consolidated with the Teva Pharmaceuticals, Pliva and APP cases. On October 13, 2010 the Court denied Hospira's motion to consolidate. As part of setting the schedule in this case, the Hospira '727 patent and '343 patent cases were consolidated on November 15, 2010 with the above Teva Pharmaceuticals, Pliva and APP cases. No trial date has been set.

Mylan Pharmaceuticals, Inc.

In January 2011, we were notified that Mylan Pharmaceuticals, Inc. had submitted an ANDA seeking permission to market



## Table of Contents

its generic version of Angiomax prior to the expiration of the '727 patent and '343 patent. On February 23, 2011, we filed suit against Mylan Inc., Mylan Pharmaceuticals Inc. and Bioniche Pharma USA, LLC, which we refer to collectively as Mylan, in the U.S. District Court for the Northern District of Illinois for infringement of the '727 patent and '343 patent. Mylan's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. On April 13, 2011, we filed a reply denying the counterclaims raised by Mylan. On May 4, 2011 the Court set a pretrial schedule. Following a joint request, the Court issued an amended scheduling order on September 22, 2011. On November 29, 2011, Mylan moved to amend its answer and add counterclaims of inequitable conduct and unclean hands. On January 13, 2012, we filed a motion to dismiss and strike Mylan's allegations of inequitable conduct and unclean hands. Mylan filed an answering brief on January 20, 2012. We filed a reply on January 27, 2012. On February 15, 2012 the judge denied the motion to dismiss the inequitable conduct claims and granted the motion to dismiss the unclean hands counterclaims. Our reply to the amended answer and counterclaims is due March 7, 2012. No trial date has been set.

### Dr. Reddy's Laboratories, Inc.

In March 2011, we were notified that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On April 28, 2011, we filed suit against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. and Gland Pharma, Inc., which we refer to collectively as Dr. Reddy's, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. Dr. Reddy's answer denied infringement of the '727 patent and '343 patent and raised counterclaims of non-infringement and invalidity of the '727 patent and '343 patent. An initial case scheduling conference was conducted before the Magistrate Judge on August 25, 2011. Following the conference, a pretrial scheduling order was issued setting dates following the New Jersey Local Patent Rules. The Court did not set a Markman hearing date or trial date.

### Sun Pharmaceutical Industries LTD

In October 2011, we were notified that Sun Pharmaceutical Industries LTD had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On November 21, 2011, we filed suit against Sun Pharma Global FZE, Sun Pharmaceutical Industries LTD., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, LTD., which we refer to collectively as Sun, in the U.S. District Court for the District of New Jersey for infringement of the '727 patent and '343 patent. The case has been assigned to the same judge and magistrate judge as the above referenced Dr. Reddy's action. Sun's answer denied infringement of the '727 patent and '343 patent. The Court has yet to set a schedule in the case.

### '404 Patent Litigation

#### PTO, FDA and HHS, et al.

On January 27, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, and HHS et al. seeking to set aside the denial of our application pursuant to the Hatch-Waxman Act to extend the term of the '404 patent. In our complaint, we primarily alleged that the PTO and the FDA each misinterpreted the filing deadlines in the Hatch-Waxman Act when they rendered their respective determinations that our application for extension of the term of the '404 patent was not timely filed. We asked the court to grant relief including to vacate and set aside the PTO's and the FDA's determinations regarding the timeliness of our application for patent term extension and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On March 10, 2010, the court conducted a hearing on the parties' cross motions for summary judgment. On March 16, 2010, the court set aside the PTO's denial of our patent term extension application and sent the matter back to the PTO for reconsideration. The court further ordered that the PTO take the actions necessary to

ensure that the '404 patent did not expire pending resolution of the court proceedings. On March 18, 2010, the PTO issued an interim extension of the '404 patent to May 23, 2010. On March 19, 2010, the PTO issued a decision again denying our application for patent term extension for the '404 patent.

On March 25, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, and HHS, et al. asking the court to set aside the PTO's March 19, 2010 decision, to instruct the PTO to accept our patent term extension application as timely filed and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On May 6, 2010, the court conducted a hearing on the parties' cross motions for summary judgment. On May 21, 2010, the court issued an order instructing the PTO to take the actions necessary to ensure that the '404 patent did not expire until at least 10 days after the court issued an order deciding the case. On August 3, 2010, the court granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired on October 4, 2010 without government appeal and the PTO sent our patent term extension application to the FDA for a determination on the length of the extension of the '404 patent. On

## Table of Contents

December 16, 2010, the FDA published its determination of the applicable regulatory review period for Angiomax. The PTO uses the regulatory review period determined by the FDA with several statutory limitations to calculate the length of a patent extension. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly.

On August 19, 2010, APP filed a motion to intervene in the U.S. District Court for the Eastern District of Virginia for purpose of appeal in our case against the PTO, FDA and HHS, et al. On September 13, 2010, the court issued an order denying APP's motion to intervene. On September 1, 2010, as amended on September 17, 2010, APP filed a notice of appeal to the United States Court of Appeals for the Federal Circuit of the district court's August 3, 2010 and September 13, 2010 orders (and all related and underlying orders). On October 5, 2010, we filed a motion to dismiss APP's appeal. On February 2, 2011, the federal circuit court issued an order denying our motion to dismiss and requesting additional briefings by both parties in connection with APP's appeal. The court expressed no opinion on the merits of APP's appeal. The parties fully briefed the issues in connection with APP's appeal.

On September 16, 2011, President Obama signed into law the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications under the Hatch-Waxman Act. This clarification confirms the interpretation of the Hatch-Waxman Act adopted in the district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed. We and APP then filed supplemental briefs concerning the America Invents Act. In its appeal, APP contended that Section 37 of the America Invents Act does not govern our matter and was challenging the constitutionality of the America Invents Act. In addition, on September 27, 2011, APP filed a Motion for Stay Pending Appeal in order to attempt to prevent the PTO from issuing a final certificate of extension for the '404 patent. The United States has intervened to defend the constitutionality of the America Invents Act. On October 25, 2011 the DOJ filed a brief with the Federal Circuit taking the position that Section 37 of the America Invents Act applies to our matter and is constitutional.

On January 22, 2012, we entered into a settlement agreement and a license agreement with APP with respect to APP's appeal and the patent infringement suits, as described in the APP '727 Patent and '343 Patent cases above. On January 24, 2012 the parties filed a joint dismissal of APP's appeal and on February 2, 2012 the Federal Circuit entered an order dismissing the appeal.

## Eagle Pharmaceuticals Arbitration

We have received a Demand for Arbitration filed by Eagle Pharmaceuticals, Inc., or Eagle, dated October 25, 2011. In the Demand for Arbitration, Eagle claims that we failed to meet our obligations under the license and development agreement between us, Eagle and certain other parties relating to the development of a new formulation of our product, Angiomax, and to our efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount it believes exceeds \$200 million. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously.

## Item 4. Mine Safety Disclosures

Not applicable.

## PART II

Item Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities  
5. Market Information and Holders

Our common stock trades on The NASDAQ Global Select Market under the symbol "MDCO". The following table reflects the range of the high and low sale price per share of our common stock, as reported on The NASDAQ Global Select Market for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Table of Contents

	Common Stock	
	Price High	Low
Year Ended December 31, 2010		
First Quarter	\$10.45	\$6.91
Second Quarter	8.99	6.82
Third Quarter	15.43	7.24
Fourth Quarter	15.33	11.65
Year Ended December 31, 2011		
First Quarter	\$17.73	\$13.97
Second Quarter	19.40	15.19
Third Quarter	17.12	12.33
Fourth Quarter	20.00	16.27

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on February 23, 2012, we had 179 holders of record of our common stock.

**Dividends**

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

**Performance Graph**

The graph below matches our cumulative five-year total return on common equity with the cumulative total returns of The NASDAQ Composite Index and The NASDAQ Biotechnology Index. The graph tracks the performance of a \$100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from December 31, 2006 to December 31, 2011. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*  
among The Medicines Company, NASDAQ Composite Index  
and The NASDAQ Biotechnology Index

Table of Contents


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* Fiscal year ended December 31.						
	12/06	12/07	12/08	12/09	12/10	12/11
The Medicines Company	100.00	60.4	46.44	26.29	44.55	58.76
NASDAQ Composite	100.00	110.26	65.65	95.19	112.1	110.81
NASDAQ Biotechnology	100.00	102.53	96.57	110.05	117.19	124.54

This performance graph shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

#### Item 6. Selected Financial Data

In the table below, we provide you with our selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2011, 2010, 2009, 2008, and 2007. In 2011 and 2010, we computed diluted earnings per share by giving effect to options and restricted stock awards outstanding at December 31, 2011 and December 31, 2010. We have not included options, restricted stock awards or warrants in the computation of diluted net loss per share for any other periods, as their effects in those periods would have been anti-dilutive. For further discussion of the computation of basic and diluted earnings (loss) per share, please see note 11 of the notes to our consolidated financial statements included in this report.

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and related notes included in this report and “Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report.

Table of Contents

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Statements of Operations Data					
Net revenue	\$484,732	\$437,645	\$404,241	\$348,157	\$257,534
Operating expenses:					
Cost of revenue	156,866	129,299	118,148	88,355	66,502
Research and development	110,180	85,241	117,610	105,720	77,255
Selling, general and administrative	159,617	158,690	193,832	164,903	141,807
Total operating expenses	426,663	373,230	429,590	358,978	285,564
Income (loss) from operations	58,069	64,415	(25,349	) (10,821	) (28,030
Legal settlement	17,984	—	—	—	—
Other (expense) income	1,790	(267	) (2,818	) 5,235	10,653
Income (loss) before income taxes	77,843	64,148	(28,167	) (5,586	) (17,377
(Provision for) benefit from income taxes	50,034	40,487	(48,062	) (2,918	) (895
Net income (loss)	\$127,877	\$104,635	\$(76,229	) \$(8,504	) \$(18,272
Basic earnings (loss) per common share	\$2.39	\$1.98	\$(1.46	) \$(0.16	) \$(0.35
Diluted earnings (loss) per common share	\$2.35	\$1.97	\$(1.46	) \$(0.16	) \$(0.35
Shares used in computing basic earnings (loss) per common share	53,496	52,842	52,269	51,904	51,624
Shares used in computing diluted earnings (loss) per common share	54,407	53,184	52,269	51,904	51,624
	As of December 31,				
	2011	2010	2009	2008	2007
	(In thousands)				
Balance Sheet Data					
Cash and cash equivalents, available for sale securities and accrued interest receivable	\$340,886	\$247,923	\$177,113	\$217,542	\$223,711
Working capital	327,088	239,251	156,103	212,222	208,568
Total assets	692,647	474,124	374,776	387,404	361,516
Long-term liabilities	26,370	31,156	47,768	5,771	—
Accumulated deficit	(111,665	) (239,542	) (344,177	) (267,948	) (259,444
Total stockholders' equity	511,642	357,598	240,389	298,025	277,896

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

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data" and our financial statements and accompanying notes included elsewhere in this annual report. In addition to the historical information, the discussion in this annual report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this annual report on Form 10-K, including under "Risk Factors" in Item 1A of this annual report.

**Overview****Our Business**

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have three marketed products, Angiomax®(bivalirudin), Cleviprex® (clevidipine butyrate) injectable emulsion and our ready-to-use formulation of Argatroban. We have not sold our ready-to-use formulation of Argatroban since its voluntary recall in

December 2011. We also have a pipeline of acute

59

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## Table of Contents

and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and two early stage development product candidates, MDCO-2010 and MDCO-216. In addition, in January 2012 we acquired from APP Pharmaceuticals, LLC, or APP, non-exclusive rights to market in the United States a portfolio of ten generic drugs, which we refer to as our acute care generic products.

Angiomax, Cleviprex, ready-to-use Argatroban and our products in development, their stage of development, their mechanism of action and the indications for which they have been approved for use or which they are intended to address are described in more detail in Part I, Item 1 of this annual report on Form 10-K. In addition, each of our acute care generic products and the therapeutic areas which they are intended to address are described in Part I, Item 1 of this annual report on Form 10-K. All of our marketed products and products in development are administered intravenously. All of our acute care generic products are injectable products.

Our revenues to date have been generated primarily from sales of Angiomax in the United States, but we continue to expand our sales and marketing efforts outside the United States. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to commercialize Cleviprex and our products in development, if and when they are approved outside the United States.

Research and development expenses represent costs incurred for licenses of rights to products, clinical trials, nonclinical and preclinical studies, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trials, nonclinical and preclinical studies and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, costs associated with general corporate activities and costs associated with marketing and promotional activities. Research and development expense, selling, general and administrative expense and cost of revenue also include stock-based compensation expense, which we allocate based on the responsibilities of the recipients of the stock-based compensation.

As of December 31, 2011, we had an accumulated deficit of approximately \$111.7 million. We expect to make substantial expenditures to further develop and commercialize our products and to develop our product candidates, including costs and expenses associated with clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization.

### Angiomax Patent Litigation

The principal U.S. patents covering Angiomax include the '404 patent, the '727 patent and the '343 patent. The '404 patent, was set to expire in March 2010, but was extended on an interim basis to August 13, 2012 under the Hatch-Waxman Act following our litigation against the U.S. Patent and Trademark Office, or PTO, the Food and Drug Administration, or FDA, and the U.S. Department of Health and Human Services, or HHS. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. If the term of the '404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015. On January 22, 2012, we entered into a legal settlement with APP in which APP agreed to dismiss its appeal of the federal district court's August 3, 2010 order that the PTO consider our patent term extension application timely filed. Upon dismissal of APP's appeal, all pending litigation regarding the '404 patent was resolved.

In the second half of 2009, the PTO issued to us U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made. The '727 patent and the '343 patent are set to expire in July 2028. In response to Paragraph IV Certification Notice letters we received with respect to abbreviated new drug applications, or ANDAs, filed with the

FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. On September 30, 2011, we settled our patent infringement litigation with Teva Pharmaceuticals USA, Inc. and its affiliates, which we refer collectively as Teva. In connection with the Teva settlement, we entered into a license agreement with Teva under which we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions. On January 22, 2012, we settled our patent infringement litigation with APP. In connection with the APP settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under an APP ANDA in the United States beginning on May 1, 2019. In certain limited circumstances, the license to APP could become effective prior to May 1, 2019. In addition, in certain limited circumstances, this license to APP could include the right to sell a generic bivalirudin product under our new drug application, or NDA, for Angiomax in the United

## Table of Contents

States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers as described in Part 1, Item 3, Legal Proceedings. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, then Angiomax could be subject to generic competition earlier than May 1, 2019.

In February 2011, we entered into a settlement agreement and release with the law firm Wilmer Cutler Pickering Hale and Dorr LLP, or WilmerHale, with respect to all potential claims and causes of action between the parties related to the '404 patent. Under the settlement agreement, WilmerHale agreed to make available to us up to approximately \$232 million, consisting of approximately \$117 million from the proceeds of professional liability insurance policies and \$115 million of payments from WilmerHale itself. WilmerHale agreed to pay approximately \$18 million from its professional liability insurance providers to us within 60 days after the date of the settlement agreement and delivered such amount in two equal payments in March 2011 and April 2011. The balance of the approximately \$232 million aggregate amount provided in the settlement agreement remains available to pay future expenses incurred by us in continuing to defend the extension of the '404 patent, and any damages that may be suffered by us in the event that a generic version of Angiomax is sold in the United States before June 15, 2015 because the extension of the '404 patent is held invalid on the basis that the application for the extension was not timely filed. Payments by WilmerHale itself would be made only after payments from its insurance policies are exhausted and cannot exceed \$2.875 million for any calendar quarter.

Our litigation with the PTO, the FDA and HHS, APP's past efforts to appeal the August 3, 2010 decision, the patent infringement suits and our settlements with Teva and APP are described in more detail in Item 3 of this annual report.

### Cleviprex Resupply, Re-launch and Formulation

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex and sell Cleviprex from the first quarter of 2010 through the first quarter of 2011. We cooperated with the FDA and our contract manufacturer to remedy the problem at the manufacturing site that resulted in the recalls.

We began to resupply existing customers with Cleviprex in April 2011. In June 2011, the FDA approved our supplemental New Drug Application, or sNDA, for an improved formulation of Cleviprex. The new formulation triples the maximum allowable infusion time per vial, commonly referred to in hospitals as "hang time", to 12 hours compared to the original 4-hour hang time vial approved by the FDA in 2008. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection.

### Distribution and Sales

We market and sell Angiomax and Cleviprex in the United States with a sales force that, as of February 15, 2012, consisted of 106 representatives, who we refer to as engagement partners and engagement managers, experienced in selling to hospital customers. Prior to the December 2011 recall of Argatroban, we used the same sales force to sell our ready-to-use Argatroban. We expect to use the same sales force to sell the acute care generic products for which we acquired the non-exclusive rights to sell and distribute from APP. In support of our sales efforts, we focus our Angiomax marketing in the United States on hospital systems, individual hospitals, and health care providers, including interventional cardiologists in cardiac catheterization laboratories and we focus the marketing of Cleviprex on neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection. We believe our ability to deliver relevant, advanced and reliable service and information to our concentrated customer base provides us with significant market advantage in the United States, and will provide us with such advantage outside the United States, even in highly competitive sub-segments of the hospital market such as cardiology and neurocritical care.

We distribute Angiomax, Cleviprex and, prior to the December 2011 recall, distributed ready-to-use Argatroban, in the United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax and Cleviprex and, when and if available for sale, ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax and Cleviprex, and, when and if available for sale, would sell ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products for which we acquired the non-exclusive rights to sell and distribute from APP through the same sole source distribution model.

Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate

Table of Contents

level of inventory based on our customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and other specified conditions.

In Europe, we market and sell Angiox with a sales force that, as of February 15, 2012, consisted of 41 engagement partners and engagement managers experienced in selling to hospital customers. Our European sales force targets hospitals with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. In October 2011, we entered into a local sales support agreement with Daiichi Sankyo, Inc., or Daiichi Sankyo, under which Daiichi Sankyo agreed to provide supplemental sales force coverage to approximately 480 hospitals in Germany treating acute coronary syndrome, or ACS, patients and call upon most interventional cardiologists in Germany. We also market and sell Angiomax outside the United States through distributors, including Sunovion Pharmaceuticals Inc., which distributes Angiomax in Canada, affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America, and through a joint venture with our partner, Windlas Healthcare Private Limited, in India. We also have agreements with other third parties for other countries outside of the United States, including Israel and Russia. In January 2012, we reacquired our rights to sell Angiomax from a distributor in Australia and New Zealand and have two engagement partners and one engagement manager selling the product in those countries. We are developing a global commercialization strategy for Cleviprex in anticipation of its further approval outside of the United States.

To support the commercialization and distribution efforts of Angiomax, we have developed, and continue to develop, our business infrastructure outside the United States, including forming subsidiaries, obtaining licenses and authorizations necessary to distribute Angiomax, hiring personnel and entering into arrangements for services from third parties, such as importation, packaging, quality control and distribution. We currently have operations in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, India, Italy, the Netherlands, New Zealand, Norway, Poland, Russia, Spain, Sweden, Switzerland and the United Kingdom and are developing our business infrastructure and capabilities in Brazil, China, Eastern Europe and Turkey. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to commercialize Cleviprex and our products in development, if and when they are approved outside the United States.

**Workforce Reductions**

**2010 Reductions.** On January 7, 2010 and February 9, 2010, we commenced two separate workforce reductions to improve efficiencies and better align our costs and structure for the future. As a result of the first workforce reduction, we reduced our office-based personnel by 30 employees. The second workforce reduction resulted in a reduction of 42 primarily field-based employees. In the year ended December 31, 2010, we recorded, in the aggregate, charges of \$6.8 million associated with these workforce reductions. During 2011, we recorded a \$0.1 million favorable adjustment to selling, general and administrative costs due to a reversal of costs associated with these workforce reductions, primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated.

**Leipzig Reduction.** On September 22, 2011, we commenced the closure of our drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at our Leipzig facility, which we refer to herein as the 2011 Leipzig closure. We transferred active pre-clinical projects to our research and development facility in Montreal, Canada and the MDCO-2010 back-up compound to the clinical team in Parsippany, New Jersey. Upon signing release agreements, the terminated employees received severance and other benefits. We recorded, in the aggregate, costs of \$2.2 million in 2011 associated with the 2011 Leipzig closure. These cost were recorded in research and development expenses in our financial statements. Of the \$2.2 million of charges related to the 2011 Leipzig closure, \$0.3 million related to asset write-offs were noncash charges. We paid out \$0.3 million during 2011 and expect to pay out \$1.6 million during 2012. We no longer have any research employees or research

capabilities in Leipzig.

#### Business Development Activity

**Curacyte Discovery Acquisition.** In August 2008, we acquired Curacyte Discovery GmbH, or Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, was primarily engaged in the discovery and development of small molecule serine protease inhibitors. In connection with the acquisition, we paid Curacyte AG an initial payment of €14.5 million in August 2008 (approximately \$22.9 million at the time of payment) and €3.5 million in December 2009 (approximately \$5.2 million at the time of payment) and €3.0 million in December 2010 (approximately \$4.3 million at the time of payment) upon achievement of clinical milestones. In addition, we achieved a €4.0 million clinical milestone in 2011 that we expensed in 2011 and for which we have agreed to pay Curacyte Discovery in the first quarter of 2012. We also agreed to pay

## Table of Contents

contingent milestone payments of up to an additional €25.0 million if we proceed with further clinical development of MDCO-2010 and achieve a commercial milestone and to pay royalties based on net sales.

The upfront cost of the Curacyte acquisition was approximately \$23.7 million, which consisted of a purchase price equal to the initial payment of approximately \$22.9 million and direct acquisition costs of \$0.8 million. Since the acquisition date, we have included results of Curacyte Discovery's operations in our consolidated financial statements. We allocated the purchase price to the estimated fair value of assets acquired and liabilities assumed based on a third-party valuation and management estimates. We allocated approximately \$21.4 million of the purchase price to in-process research and development, which we expensed upon completion of the acquisition.

Targanta Therapeutics Corporation. In February 2009, we acquired Targanta Therapeutics Corporation, or Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings.

Under the terms of our agreement with Targanta, we paid Targanta shareholders an aggregate of approximately \$42.0 million in cash at closing. In addition, we originally agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate. This amount has been reduced to \$85.1 million in the aggregate as certain milestones have not been achieved by specified dates. The current contingent cash payments milestones are:

Upon approval from the European Medicines Agency of a Marketing Authorization Application for oritavancin for the treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI (which were formerly referred to as complicated skin and skin structure infections) on or before December 31, 2013, approximately \$10.5 million.

Upon final approval from the FDA of a NDA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$10.5 million.

Upon final approval from the FDA of an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion on or before December 31, 2013, approximately \$14.7 million. This payment may become payable simultaneously with the payment described in the previous bullet above.

If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million.

We expensed transaction costs as incurred, capitalized as an indefinite lived intangible asset the value of acquired in-process research and development. We recorded contingent payments at their estimated fair value. We allocated the purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, to the net tangible and intangible assets of Targanta based on their estimated fair values. We have included the results of Targanta's operations in our consolidated financial statements since the acquisition date.

As a result of our acquisition of Targanta, we are a party to an asset purchase agreement that Targanta entered into with InterMune, Inc., or InterMune, in connection with Targanta's December 2005 acquisition of the worldwide rights to oritavancin from InterMune. Under the agreement, we are obligated to use commercially reasonable efforts to develop oritavancin and to make a \$5.0 million cash payment to InterMune if and when we receive from the FDA all approvals necessary for the commercial launch of oritavancin. We have no other milestone or royalty obligations to InterMune.

MDCO-157. In May 2011, we entered into a licensing agreement with Ligand, through its subsidiary CyDex Pharmaceuticals, Inc., under which we acquired an exclusive, worldwide license to patents claiming a Captisol®-enabled intravenous formulation of clopidogrel bisulfate, which we refer to as MDCO-157, and to related know-how. Under the license agreement, we paid Ligand an upfront payment of approximately \$1.8 million in June 2011 and agreed to make additional payments of up to \$22 million upon the achievement of certain clinical, regulatory and commercial milestones. We also agreed to pay to Ligand tiered royalties from high single digits up to low double digits on annual worldwide net sales. The license obligates us to use commercially reasonable efforts to develop a licensed product, and to make \$2.5 million per year in development expenditures until we submit a new drug application, or NDA.

GeNO, LLC. In December 2011, we made a \$7.5 million non-controlling equity investment in GeNO, LLC, or GeNO, an advanced, development-stage privately held technology company that has created unique nitric oxide generation

and delivery technology. In addition to acquiring the equity stake, we also acquired an exclusive option to license GeNO technologies in the acute and intensive care hospital setting in certain geographies. GeNO's product candidate is currently in clinical trials. Nitric oxide therapy is approved for the treatment of term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension and its use avoids more invasive and costly therapies for these infants.



Table of Contents

## U.S. Health Care Reform

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA, which was amended by the Health Care and Education Reconciliation Act of 2010. The PPACA, as amended, contains numerous provisions that impact the pharmaceutical and healthcare industries that are expected to be implemented over the next several years. We are continually evaluating the impact of the PPACA on our business. As of the date of this annual report, we have not identified any provisions that currently materially impact our business or results of operations. However, the potential impact of the PPACA on our business and results of operations is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined and the impact on our business and results of operations may change as and if our business evolves.

## Results of Operations

Years Ended December 31, 2011 and 2010

## Net Revenue:

Net revenue for the years ended December 31, 2011 and 2010 were as follows:

	Year Ended December 31,		Change	Change	
	2011	2010	\$	%	
	(In thousands)				
Angiomax	\$483,906	\$436,872	\$47,034	10.8	%
Cleviprex/Argatroban	826	773	53	6.9	%
Total net revenue	\$484,732	\$437,645	\$47,087	10.8	%

Net revenue increased by \$47.1 million, or 10.8%, to \$484.7 million in 2011 compared to \$437.6 million in 2010, reflecting increases of \$40.1 million or 9.7% in the United States, and \$7.0 million or 28.3% in international markets. The net revenue increase was comprised of net volume increases of \$32.2 million, price increases of \$13.6 million and the favorable impact from foreign exchange of \$1.3 million.

**Angiomax.** Angiomax net revenue increased by \$47.0 million or 10.8% to \$483.9 million in 2011 compared to \$436.9 million in 2010, primarily due to a price increase in the United States and increased unit sales globally. Net sales in the United States in both 2011 and 2010 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Under this program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. Chargebacks related to 340B Drug Pricing Program increased by \$5.5 million to \$42.2 million in 2011 compared to \$36.7 million in 2010, primarily due to increased usage by eligible hospital customers. Rebates related to the PPACA increased by \$0.1 million to \$0.7 million in 2011 compared to \$0.6 million in 2010 due to increased Medicaid rebates. Net sales for Angiomax outside the United States increased in 2011 compared to 2010 due to greater demand by existing hospital customers and the addition of new hospital customers in Canada, Italy, the United Kingdom, Sweden, Denmark, Belgium, the Netherlands and Australia.

**Cleviprex/Argatroban.** Cleviprex net sales increased by \$0.1 million in 2011 compared to 2010 as the 2010 period reflected an offset of \$0.7 million due to returns related to the Cleviprex recall. We began to resupply existing customers with Cleviprex in April 2011 and re-launched Cleviprex in October 2011 with a new formulation.

Ready-to-use Argatroban net sales in 2011 were completely offset by returns related to the Argatroban recall in December 2011. We did not recognize any revenue from sales of ready-to-use Argatroban in 2010 as it was not approved until July 2011.

## Cost of Revenue:

Cost of revenue in 2011 was \$156.9 million, or 32% of net revenue, compared to \$129.3 million, or 30% of net revenue, in 2010.

Cost of revenue during both periods consisted of expenses in connection with the manufacture of Angiomax, Cleviprex and ready-to-use Argatroban sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc., or HRI, related to Angiomax, our agreement with AstraZeneca AB, or AstraZeneca, related to Cleviprex, and our agreement with Eagle related

Table of Contents

to ready-to-use Argatroban and logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage and handling costs.

## Cost of Revenue

	Year Ended December 31,					
	2011	% of Total Cost		2010	% of Total Cost	
	(In thousands)			(In thousands)		
Manufacturing	\$32,595	21	%	\$29,868	23	%
Royalty	108,853	69	%	86,218	67	%
Logistics	15,418	10	%	13,213	10	%
Total cost of revenue	\$156,866	100	%	\$129,299	100	%

Cost of revenue increased by \$27.6 million in 2011 compared to 2010 primarily due to an increase in royalty expense to Biogen Idec due to a higher effective royalty rate under our agreement with Biogen Idec triggered by higher sales of Angiomax. The increase in cost of revenue was also related to an increase in manufacturing expense due to costs associated with obtaining an additional supplier for the manufacture of Angiomax. In addition, the increase in manufacturing expense reflects a \$0.9 million reduction in manufacturing costs in 2010 related to the reversal in 2010 of certain charges which were originally recorded in the fourth quarter of 2009 in connection with production failures at the third-party manufacturer for Angiomax.

## Research and Development Expenses:

Research and development expenses increased by 29% to \$110.2 million for 2011, from \$85.2 million in 2010. The increase primarily reflects additional costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin. The increase also reflects costs incurred in connection with the commencement of a Phase 1 clinical trial of MDCO-216, including the manufacturing of drug product for the Phase 1 trial, the licensing fee paid in connection with obtaining the rights to MDCO-157 and charges of approximately \$2.2 million associated with the 2011 Leipzig closure. These increases were offset by a decrease in manufacturing development expenses related to product lifecycle management activities of Angiomax and by certain expenses recorded in 2010 but not in 2011, related to the 2010 workforce reductions and a payment made to AstraZeneca in connection with a June 2010 amendment to our cangrelor license agreement with AstraZeneca.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-2010, MDCO-216 and MDCO-157 during 2012 and that our research and development expenses will increase in 2012. We expect research and development expenses in 2012 to include costs associated with our Phase 3 clinical trials of oritavancin and cangrelor, manufacturing development activities for Angiomax, Cleviprex, cangrelor and MDCO-216, our Phase 2 clinical trial program for MDCO-2010, our Phase 1 clinical trial of MDCO-216, product lifecycle management activities and the development of MDCO-157.

The following table identifies for each of our major research and development projects our spending for 2011 and 2010. Spending for past periods is not necessarily indicative of spending in future periods.

## Research and Development Spending

Table of Contents

	Year Ended December 31,				
	2011	% of		2010	% of
	(In thousands)	Total R&D		(In thousands)	Total R&D
Angiomax					
Clinical trials	\$6,606	6	%	\$6,439	7
Manufacturing development	288	—	%	4,466	5
Administrative and headcount costs	2,574	3	%	2,381	3
Total Angiomax	9,468	9	%	13,286	15
Cleviprex					
Clinical trials	1,492	1	%	1,545	2
Manufacturing development	295	—	%	1,777	2
Administrative and headcount costs	1,557	2	%	1,835	2
Total Cleviprex	3,344	3	%	5,157	6
Cangrelor					
Clinical trials	26,823	24	%	9,232	11
Manufacturing development	955	1	%	1,998	2
Administrative and headcount costs	6,671	6	%	7,328	9
Total Cangrelor	34,449	31	%	18,558	22
Oritavancin					
Clinical trials	21,944	20	%	6,196	7
Manufacturing development	3,454	3	%	8,199	10
Administrative and headcount costs	5,221	5	%	7,609	9
Total Oritavancin	30,619	28	%	22,004	26
MDCO-157					
Administrative and headcount costs	1,072	1	%	—	—
Acquisition license fee	1,750	2	%	—	—
Total MDCO-157	2,822	3	%	—	—
MDCO-2010					
Clinical trials	713	1	%	2,056	2
Manufacturing development	416	—	%	1,475	2
Administrative and headcount costs	4,637	4	%	4,288	5
Clinical milestone	5,275	5	%	4,329	5
Government subsidy	(222)	) —	%	(1,403)	) (1)
Total MDCO-2010	10,819	10	%	10,745	13
MDCO-216					
Clinical trials	692	1	%	689	1
Manufacturing development	2,364	2	%	2,716	3
Administrative and headcount costs	1,373	1	%	608	1
Total MDCO-216	4,429	4	%	4,013	5
Ready-to-Use Argatroban					
Manufacturing development	—	—	%	316	—
Administrative and headcount costs	491	—	%	629	1
Total Ready-to-Use Argatroban	491	—	%	945	1
Other	13,739	12	%	10,533	12
Total	\$110,180	100	%	\$85,241	100

Angiomax



Table of Contents

Research and development spending related to Angiomax during 2011 decreased by approximately \$3.8 million compared to 2010, primarily due to a decrease of \$4.2 million in manufacturing development expenses related to product lifecycle management activities. These decreases were partially offset by an increase of \$0.2 million in administrative and headcount expenses related to our efforts to further develop Angiomax for use in additional patient populations. Clinical trial costs were relatively unchanged, primarily due to increased expenditures in connection with our China Registration Study, which were offset by decreased expenditures in connection with our completed Phase 4 EUROVISION clinical trial. We are conducting a EUROMAX trial at sites in six European countries to assess whether the early administration of Angiox in ST-segment elevation myocardial infarction, or STEMI, patients intended for primary percutaneous coronary intervention, or PCI, presenting either via ambulance or to referral centers where PCI is not performed improves 30-day outcomes when compared to the current standard of care, heparin plus an optional GP IIb/IIIa inhibitor. We commenced enrollment in our EUROMAX clinical trial in March 2010. We expect to enroll approximately 3,680 patients in the EUROMAX trial and to complete enrollment in 2012.

We expect that our research and development expenses relating to Angiomax will increase in 2012 in connection with our efforts to further develop Angiomax for use in additional patient populations, as well as continued research and development expenses related to our product lifecycle management activities. We expect that this increase will be partially offset by decreased expenses due to the anticipated completion of enrollment of the EUROMAX trial in 2012 and decreased manufacturing and regulatory expenses.

**Cleviprex**

Research and development expenditures for Cleviprex decreased by approximately \$1.8 million during 2011 compared to 2010. The decrease was primarily due to the discontinuation in late 2009 through 2010 of clinical studies of Cleviprex due to the recalls and lack of supply of Cleviprex.

We expect total research and development expenses relating to Cleviprex will increase in 2012 as compared to 2011 levels. We expect we will incur increased research and development expenses in 2012 in connection with our efforts to obtain marketing approval of Cleviprex outside the United States and the re-commencement of clinical studies suspended due to recalls. We expect these increased costs to be partially offset by decreased manufacturing development expenses related to an improved formulation of Cleviprex which provides a longer infusion time that the FDA approved in June 2011.

**Cangrelor**

Research and development expenditures related to cangrelor increased by approximately \$15.9 million in 2011 compared to 2010. The increase primarily reflects increased clinical trial expenses related to our Phase 3 CHAMPION PHOENIX clinical trial, as well as an increase in the related administrative and headcount expenses. The 2010 period also included charges recorded associated with a \$3.0 million payment made to AstraZeneca in connection with the June 2010 amendment to our agreement with AstraZeneca.

We expect total research and development expenses relating to cangrelor in 2012 to remain similar to 2011 levels. We expect we will continue to incur research and development expenses in 2012 in connection with the CHAMPION PHOENIX clinical trial. We initially expect to enroll approximately 10,900 patients and we may enroll additional patients, in this double-blind parallel group randomized study which compares cangrelor to clopidogrel given according to institutional practice.

**Oritavancin**

Research and development expenditures related to oritavancin increased by approximately \$8.6 million in 2011 compared to 2010. The increase primarily reflects increased costs incurred in 2011 relating to our SOLO I and SOLO II Phase 3 clinical trials. This increase in expenditures in 2011 was partially offset by decreased headcount expenses and decreased manufacturing costs as we had manufactured product in 2010 for use in the SOLO I and SOLO II trials. Oritavancin research and development costs for 2010 also included approximately \$1.3 million of severance payments related to the workforce reductions initiated in the first quarter of 2010.

We expect to incur increased research and development expenses relating to oritavancin in 2012 as compared to 2011 due to the SOLO I and SOLO II clinical trials. We plan to enroll a total of approximately 2,000 patients in the SOLO I and SOLO II clinical trials and to test the use of a simplified dosing regimen involving a single dose of oritavancin as compared to multiple doses of vancomycin for the treatment of ABSSSI. We currently have enrolled approximately

700 patients in the SOLO I and SOLO II clinical trials. We have decided to focus on accelerating enrollment in the SOLO I trial and expect to complete enrollment in such trial in the third quarter of 2012. If the SOLO I trial results are positive, we plan to accelerate enrollment in the SOLO II trial. Under the accelerated timeline, if the results of the trials warrant it, we would expect to file an NDA in the first half of 2013.

MDCO-157

## Table of Contents

In May 2011, we entered into a licensing agreement with Ligand under which we acquired exclusive, worldwide license rights to MDCO-157, a novel intravenous formulation of clopidogrel bisulfate. Costs incurred during 2011 primarily related to the acquisition of the licensing agreement and administrative and headcount related expenses. Under the license agreement, we agreed to spend at least \$2.5 million annually on the development of MDCO-157 and therefore were obligated to spend the pro rata amount in 2011 on MDCO-157.

We expect total research and development expenses relating to MDCO-157 to increase in 2012 as compared to 2011, as clinical development progresses.

### **MDCO-2010**

Research and development expenditures related to MDCO-2010 increased by approximately \$0.1 million in 2011 compared to 2010. Costs incurred during 2011 primarily related to our ongoing Phase 2 clinical trial program, a clinical milestone payment of \$5.3 million to Curacyte Discovery, and the 2011 Leipzig closure. Costs incurred during 2010 primarily related to a clinical milestone payment of \$4.3 million to Curacyte Discovery, our Phase 1 clinical trial of MDCO-2010, which we commenced in July 2009 and which we completed in 2010 in healthy volunteers that demonstrated safety and tolerability at low doses. Costs related to our Phase 2 clinical trial program include headcount related costs and manufacturing expenses related to the production of drug product for the trial. Costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid in both 2011 and 2010.

We expect that our research and development expenses relating to MDCO-2010 will decrease in 2012 as compared to 2011, as 2011 expenses reflected the achievement of a €4.0 million clinical milestone in 2011 for which payment is owed Curacyte AG.

### **MDCO-216**

Research and development expenditures related to MDCO-216 increased by approximately \$0.4 million in 2011 compared to 2010. Costs incurred during 2011 primarily related to manufacturing development related to preclinical activities, clinical trial costs in connection with preparation for the commencement of a Phase 1 study of MDCO-216 and administrative and headcount expenses. Costs incurred during 2010 primarily related to manufacturing development, administrative and headcount expenses and clinical trial costs.

We expect that our research and development expenses relating to MDCO-216 will increase in 2012 as compared to 2011, as we commence a Phase 1 study of MDCO-216 in the first half of 2012.

### **Ready-to-Use Argatroban**

Research and development expenditures related to ready-to-use Argatroban decreased by approximately \$0.5 million in 2011 compared to 2010. Costs incurred during 2011 primarily related to administrative and headcount related expenses and costs incurred during 2010 primarily related to manufacturing development activities and administrative and headcount related expenses.

We expect total research and development expenses relating to ready-to-use Argatroban in 2012 to decrease from 2011 levels.

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

Research and development expenditures in this category includes infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic data, or PK/PD data, and product safety as well as expenses related to business development activities in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. Spending in this category increased by approximately \$3.2 million during 2011 compared to 2010, primarily due to an increase in administrative and headcount expenses.

Our success in further developing Angiomax and obtaining marketing approvals for Angiomax in additional countries and for additional patient populations, developing and obtaining marketing approvals for Cleviprex outside the United States, and developing and obtaining marketing approvals for our products in development, is highly uncertain. We cannot predict expenses associated with ongoing data analysis or regulatory submissions, if any. Nor can we reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to continue the



development of Angiomax, Cleviprex and our products in development, or the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, obtaining marketing approvals for Angiomax in additional countries and additional patient populations and for Cleviprex outside the United States or developing and obtaining marketing approvals for our products in development, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

Table of Contents

the scope, rate of progress and cost of our clinical trials and other research and development activities;  
 future clinical trial results;  
 the terms and timing of any collaborative, licensing and other arrangements that we may establish;  
 the cost and timing of regulatory approvals;  
 the cost and timing of establishing and maintaining sales, marketing and distribution capabilities;  
 the cost of establishing and maintaining clinical and commercial supplies of our products and product candidates;  
 the effect of competing technological and market developments; and  
 the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.  
 Selling, General and Administrative Expenses:

	Year Ended December 31,		Change	Change	
	2011	2010	\$	%	
	(In thousands)				
Selling, general and administrative expenses	\$159,617	\$158,690	\$927	(0.6	)%

The increase in selling, general and administrative expenses of \$0.9 million in 2011 as compared to 2010 reflects a \$0.9 million increase in selling, marketing, and promotional expenses primarily related to Angiomax, an \$8.1 million increase in general corporate and administrative spending largely in connection with our efforts with respect to the patent term extension of the '404 patent and settlement of our patent infringement litigation with Teva and APP, higher intangible amortization costs of \$0.6 million, increased site costs of \$0.7 million which includes lease termination costs as a result of vacating our previous office facility in New Jersey, and higher stock-based compensation costs of \$2.6 million. These increases were partially offset by a \$6.7 million gain from the reduction in the fair value of our contingent consideration obligation to the former Targanta shareholders and \$5.3 million of lower general and administrative spending resulting from a reduction in personnel costs due to the first quarter 2010 reduction in force and the closure of our Indianapolis site.

Legal settlement:

	Year Ended December 31,		Change	Change	
	2011	2010	\$	%	
	(In thousands)				
Legal settlement	\$17,984	\$—	\$17,984	100.0	%

We recorded approximately \$18.0 million in legal settlement income in connection with the settlement agreement we entered into with WilmerHale in February 2011. Pursuant to the settlement agreement, WilmerHale agreed to pay approximately \$18.0 million from its professional liability insurance providers to us within 60 days after the date of the settlement agreement and delivered such amount in two equal payments in March 2011 and April 2011. We did not record any legal settlement income in 2010.

Other income (expense):

	Year Ended December 31,		Change	Change	
	2011	2010	\$	%	
	(In thousands)				
Other income (expense)	\$1,790	\$(267)	\$2,057	770.4	%

Other income (expense), which is comprised of interest income, gains and losses on foreign currency transactions and impairment of investment, increased by \$2.1 million to \$1.8 million of income for 2011, from \$0.3 million of expense for 2010.



Table of Contents

This increase was primarily due to higher gains on foreign currency transactions in 2011 and increased interest due to higher levels of cash to invest.

Benefit from Income Tax:

	Year Ended December 31,		Change	Change
	2011	2010	\$	%
	(In thousands)			
Benefit from income tax	\$50,034	\$40,487	\$9,547	(23.6)%

On a periodic basis, we evaluate our ability to realize our deferred tax assets net of deferred tax liabilities and adjust such amounts in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, any regulatory or legislative actions by relevant authorities with respect to the Angiomax patents, and the status of litigation with respect to those patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods. During 2011, based on review of the following positive and negative evidence, we reduced our valuation allowance against our deferred tax assets by \$66.5 million and recorded a corresponding tax benefit.

Positive:

the principal U.S. patent covering Angiomax, the '404 patent, was set to expire in March 2010, but was extended under the Hatch-Waxman Act on an interim basis to August 13, 2012 following our litigation against the PTO, the FDA and the HHS. We had applied under the Hatch-Waxman Act, for an extension of the term of the '404 patent. However the PTO rejected our application because in its view the application was not timely filed. As a result we filed suit against the PTO, the FDA and HHS seeking to set aside the denial of our application to extend the term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia granted our motion for summary judgment and ordered the PTO to consider our patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in our case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP appealed the denial of its motion, as well as the federal district court's August 3, 2010 order. On January 22, 2012, we entered into a legal settlement with APP in which APP agreed to dismiss its appeal. Upon dismissal of APP's appeal, all pending litigation regarding the '404 patent was resolved. Following the expiration of the government's appeal period in the litigation, the FDA determined the applicable regulatory review period for Angiomax. On January 31, 2012, the PTO issued a notice of final determination finding the '404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the '404 patent. The PTO has not yet issued the certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the '404 patent. If the term of the '404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015;

on September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act, or the America Invents Act. Section 37 of the America Invents Act clarifies the filing timeline for patent term extension applications under the Hatch-Waxman Act. This clarification confirms the interpretation of the Hatch-Waxman Act adopted by the federal district court's August 3, 2010 decision in our suit against the PTO, the FDA and HHS, which ordered the PTO to consider our patent term extension application timely filed;

On September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, with respect to our patent infringement suits against Teva, which includes our suit against Pliva Hrvatska d.o.o., et al. As part of the

settlement agreement, Teva admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. Under the license agreement, we granted Teva a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions;

- on January 22, 2012, we entered into a settlement agreement and a license agreement with APP with respect to APP's appeal (as described in the first bullet above) and the patent infringement suits. Under the settlement agreement, APP

Table of Contents

admitted that the '727 patent and '343 patent are valid and enforceable and that they would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDAs. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the '727 patent and '343 patent to sell a generic bivalirudin for injection product in the United States beginning on May 1, 2019. In certain limited circumstances, this license to APP could become effective prior to May 1, 2019 and could include an authorized generic bivalirudin product supplied by us; and

• we have reported three years of cumulative U.S. income before income taxes.

## Negative:

we were, and currently are, involved in patent infringement litigation with four generic manufacturers with respect to our '343 and '727 patents, the negative outcomes of which may have a material impact on our future operations and profitability.

In 2011, we recorded a \$66.5 million income tax benefit by reducing our valuation allowance to \$4.2 million against \$112.5 million of deferred tax assets compared to a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets at December 31, 2010. Any changes to the valuation allowance or deferred tax assets in the future would impact our income taxes.

We recorded net benefits from income taxes of \$50.0 million and \$40.5 million, respectively, for 2011 and 2010, based on income before taxes for such periods of \$77.8 million and \$64.1 million.

In addition to the \$66.5 million tax benefit discussed above, our income tax benefit for 2011 also reflects a one-time \$2.5 million benefit resulting from a prospective change in the New Jersey income tax law enacted in the second quarter of 2011 and the tax treatment of a portion of the WilmerHale settlement. Both the 2011 and 2010 periods include a non-cash tax expense arising from purchase accounting for in-process research and development acquired in our acquisition of Targanta.

## Years Ended December 31, 2010 and 2009

## Net Revenue:

Net revenue increased 8% to \$437.6 million for 2010 as compared to \$404.2 million for 2009. The following table reflects the components of net revenue for the years ended December 31, 2010 and 2009:

## Net Revenue

	Year Ended December 31,		Change	Change	
	2010	2009	\$	%	
	(In thousands)				
U.S. sales	\$413,044	\$385,939	\$27,105	7.0	%
International net revenue	24,601	18,302	6,299	34.4	%
Total net revenue	\$437,645	\$404,241	\$33,404	8.3	%

Net revenue during 2010 increased by \$33.4 million compared to 2009 primarily due to an increase in sales of Angiox in Europe and an increase in sales of Angiomax in the United States. The net revenue increase was comprised of net volume increases of \$39.8 million, price decreases of \$5.5 million and the unfavorable impact from foreign exchange of \$0.9 million. Net sales in the United States in both 2011 and 2010 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Under this program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. These chargebacks were higher in 2010 than 2009, reflecting increased sales of Angiomax under the program. U.S. sales also include net revenue of \$0.8 million from sales of Cleviprex in 2010 compared to \$3.0 million in 2009,

as we did not sell any Cleviprex during 2010 after the first quarter as a result of the recalls and related supply issues. The \$0.8 million in sales of Cleviprex in 2010 reflects an offset of \$0.7 million due to returns related to the 2010 Cleviprex recall.

International net revenue increased by \$6.3 million during 2010 compared to 2009 primarily as a result of increased demand

Table of Contents

for Angiox in France, Italy, Sweden and the United Kingdom, which increased demand was partially offset by decreased sales of Angiomax in Canada.

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex and sell Cleviprex during 2010 after the first quarter.

**Cost of Revenue:**

Cost of revenue in 2010 was \$129.3 million, or 30% of net revenue, compared to \$118.1 million, or 29% of net revenue, in 2009. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec and HRI related to Angiomax and our agreement with AstraZeneca related to Cleviprex and the logistics costs related to Angiomax and Cleviprex, including distribution, storage and handling costs.

**Cost of Revenue**

	Year Ended December 31,				
	2010	% of Total Cost		2009	% of Total Cost
	(In thousands)			(In thousands)	
Manufacturing	\$29,868	23	%	\$28,520	24
Royalty	86,218	67	%	77,786	66
Logistics	13,213	10	%	11,842	10
Total cost of revenue	\$129,299	100	%	\$118,148	100

Cost of revenue increased by \$11.2 million during 2010 compared to 2009. The increase in cost of revenue was primarily related to the higher volume of goods sold, with a corresponding increase in royalty expense to Biogen Idec associated with the higher sales of Angiomax, and \$0.5 million related to inventory write offs associated with the 2010 Cleviprex recall. These increases were partially offset by \$0.9 million related to a reversal of certain charges originally recorded in the fourth quarter of 2009 in connection with production failures at the third-party manufacturer for Angiomax.

**Research and Development Expenses:**

Research and development expenses decreased by 28% to \$85.2 million for 2010, compared to \$117.6 million for 2009. The decrease primarily reflects reduced clinical activity for cangrelor as we discontinued enrollment in the CHAMPION clinical trial program for cangrelor in May 2009 and reduced regulatory and clinical activity for Cleviprex in 2010 as a result of the recalls and related supply issues. The decrease also reflects reduced research and development expenses related to Angiomax primarily as a result of a reduction in manufacturing development expense. These decreases were offset by an increase in costs incurred in preparation for Phase 3 trials of cangrelor and oritavancin, costs associated with the development of MDCO-2010 and MDCO-216 and charges of approximately \$1.7 million associated with our workforce reductions in the first quarter of 2010.

The following table identifies for each of our major research and development projects, our spending for 2010 and 2009. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**



Table of Contents

	Year Ended December 31,				
	2010	% of		2009	% of
	(In thousands)	Total R&D		(In thousands)	Total R&D
Angiomax					
Clinical trials	\$6,439	7	%	\$5,335	4
Manufacturing development	4,466	5	%	12,467	11
Administrative and headcount costs	2,381	3	%	4,437	4
Total Angiomax	13,286	15	%	22,239	19
Cleviprex					
Clinical trials	1,545	2	%	4,758	4
Manufacturing development	1,777	2	%	1,443	1
Administrative and headcount costs	1,835	2	%	5,025	4
Total Cleviprex	5,157	6	%	11,226	9
Cangrelor					
Clinical trials	9,232	11	%	21,680	19
Manufacturing development	1,998	2	%	2,665	2
Administrative and headcount costs	7,328	9	%	4,640	4
Total Cangrelor	18,558	22	%	28,985	25
Oritavancin					
Clinical trials	6,196	7	%	4,593	4
Manufacturing development	8,199	10	%	3,587	3
Administrative and headcount costs	7,609	9	%	3,086	3
Total Oritavancin	22,004	26	%	11,266	10
MDCO-2010					
Clinical trials	2,056	2	%	2,129	2
Manufacturing development	1,475	2	%	1,042	1
Administrative and headcount costs	4,288	5	%	2,717	2
Clinical milestone	4,329	5	%	5,182	4
Government subsidy	(1,403)	(1)	%)	(1,432)	(1)
Total MDCO-2010	10,745	13	%	9,638	8
MDCO-216					
Clinical trials	689	1	%	—	—
Manufacturing development	2,716	3	%	—	—
Administrative and headcount costs	608	1	%	—	—
Acquisition license fee	—	—	%	17,500	15
Total MDCO-216	4,013	5	%	17,500	15
Ready-to-Use Argatroban					
Manufacturing development	316	—	%	—	—
Administrative and headcount costs	629	1	%	—	—
Acquisition license fee	—	—	%	5,000	4
Total Ready-to-Use Argatroban	945	1	%	5,000	4
Other	10,533	12	%	11,756	10
Total	\$85,241	100	%	\$117,610	100

## Angiomax

Research and development spending related to Angiomax during 2010 decreased by approximately \$8.9 million compared to 2009, primarily due to a decrease of \$8.0 million in manufacturing development expenses related to product lifecycle management



## Table of Contents

activities. Administrative costs in 2010 decreased by \$2.0 million primarily reflecting the increased costs incurred in 2009 in connection with the regulatory filing filed with the FDA in the second quarter of 2009 related to the report of the clinical study conducted to obtain the pediatric extension. These decreases were partially offset by an increase of \$1.1 million in clinical trial costs, primarily due to increased expenditures in connection with our Phase 4 EUROMAX and EUROVISION clinical trials. We commenced enrollment in our Phase 4 EUROMAX clinical trial in March 2010. In October 2010 we completed enrollment in our EUROVISION trial with 2,022 patients at 70 sites in six European countries.

### **Cleviprex**

Research and development expenditures for Cleviprex decreased by approximately \$6.1 million during 2010 compared to 2009. The decrease is primarily due to the recalls of Cleviprex and the related supply issues and the resulting discontinuation in late 2009 of the clinical studies being conducted by hospitals and third-party researchers.

### **Cangrelor**

Research and development expenditures related to cangrelor decreased by approximately \$10.4 million in 2010 compared to 2009. The decrease primarily reflects lower clinical trial expenses related to our Phase 3 CHAMPION clinical trial program, in which we discontinued enrollment in May 2009. This decrease was partially offset by a payment made to AstraZeneca in the second quarter of 2010 in connection with the June 2010 amendment to our agreement with AstraZeneca. In October 2010, we commenced a Phase 3 clinical trial of cangrelor, which we refer to as the CHAMPION PHOENIX clinical trial.

### **Oritavancin**

Research and development expenditures related to oritavancin increased by approximately \$10.7 million in 2010 compared to 2009. The increase primarily reflects increased costs incurred in 2010 relating to preparation for our SOLO I and SOLO II Phase 3 clinical trials, including increased manufacturing costs as we manufactured product for use in the trials and increased headcount expenses. Oritavancin research and development costs for 2010 also include approximately \$1.3 million of severance payments related to the workforce reductions initiated in the first quarter of 2010. Following our acquisition of Targanta, we worked with the FDA to design a clinical trial responsive to the FDA's complete response letter. As a result, in the fourth quarter of 2010, we reached agreement with the FDA on a Special Protocol Assessment, or SPA, and commenced the SOLO I and SOLO II clinical trials.

### **MDCO-2010**

Research and development expenditures related to MDCO-2010 increased by approximately \$1.1 million in 2010 compared to 2009. The increase in research and development expenditures for MDCO-2010 primarily relates to costs incurred during 2010 with respect to our Phase 1 clinical trial of MDCO-2010, which we commenced in July 2009, and preparation for our Phase 2 trial of MDCO-2010, which we commenced in November 2010. Increased costs related to our Phase 2 trial include increased manufacturing expenses related to the production of drug product for the trial and headcount related costs. This increase was partially offset by a \$1.4 million German government research and development subsidy received in 2010.

### **MDCO-216**

Research and development expenditures related to MDCO-216 decreased by approximately \$13.5 million in 2010 compared to 2009. In December 2009, we paid \$17.5 million in connection with the acquisition of exclusive worldwide rights to MDCO-216 from Pfizer. Costs incurred during 2010 primarily related to administrative and headcount expenses, manufacturing development related to preclinical activities and our preparation for clinical trials. In 2010, we completed a technology transfer program with Pfizer related to improved manufacturing methodologies developed by Pfizer since the Phase 1/2 trial of MDCO-216. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in preclinical studies of MDCO-216 in 2010.

### **Ready-to-Use Argatroban**

Research and development expenditures related to ready-to-use Argatroban decreased by approximately \$4.1 million in 2010 compared to 2009. This decrease relates to the \$5.0 million technology license fee paid to Eagle in September 2009 in connection with the acquisition of marketing rights for a ready-to-use formulation of Argatroban in the United States and Canada. Costs incurred during 2010 primarily related to manufacturing development activities and administrative and headcount related expenses.

Other

Spending in this category includes infrastructure costs in support of our product development efforts, which includes expenses

74

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Table of Contents

for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic data, or PK/PD data and product safety as well as expenses related to business development activities in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. Spending in this category decreased by approximately \$1.2 million during 2010 compared to 2009, primarily due to a reduction of business development expenses.

## Selling, General and Administrative Expenses:

	Year Ended December 31, 2010                      2009 (In thousands)		Change \$	Change %	
Selling, general and administrative expenses	\$ 158,690	\$ 193,832	\$(35,142)	18.1	%

The decrease in selling, general and administrative expenses of \$35.1 million reflects the impact of the \$6.6 million in costs we incurred in 2009 in connection with the acquisition of Targanta and our U.S. headquarters relocation, a \$26.7 million decrease related to lower selling, marketing and promotional activity principally related to Angiomax and Cleviprex, approximately \$0.9 million of lower general corporate and administrative spending resulting primarily from a reduction in personnel costs due to the first quarter 2010 reduction in force, and a \$8.5 million decrease in stock-based compensation expense. The decrease in selling, marketing and promotional activity reflects in part a decrease in activity with respect to Cleviprex due to the recalls and the related supply issues. These decreases were partially offset by costs associated with our efforts to extend the patent term of the '404 patent and approximately \$5.1 million associated with our first quarter of 2010 reduction in force, including expenses related to employee severance arrangements and the closure of our Indianapolis site which we completed in February 2010.

## Other (Expense):

	Year Ended December 31, 2010                      2009 (In thousands)		Change \$	Change %	
Other (expense)	\$(267)	\$(2,818)	\$ 2,551	90.5	%

Other expense, which is comprised of interest income, gains and losses on foreign currency transactions and impairment of investment, decreased by \$2.5 million to \$0.3 million of expense for 2010, from \$2.8 million of expense for 2009. This decrease primarily reflects the impact of a \$5.0 million impairment charge taken in 2009 with respect to our equity investment in Eagle. This was partially offset by higher losses on foreign currency transactions and to lower rates of return on our available for sale securities in 2010.

## Benefit from (Provision for) Income Tax:

	Year Ended December 31, 2010                      2009 (In thousands)		Change \$	Change %	
Benefit from (provision for) income tax	\$40,487	\$(48,062)	\$ 88,549	184.2	%

We recorded a \$40.5 million net benefit from income taxes for 2010 based on income before taxes of \$64.1 million and a \$48.1 million provision for income taxes for 2009 based on losses before income taxes of \$28.2 million. Our effective income tax rates for 2010 and 2009 were approximately 63.1% and 170.6%, respectively. The net benefit from income taxes in 2010 was driven mainly by our decision to reduce the valuation allowance against our deferred tax assets by \$45.2 million as it is more likely than not that we will realize the future benefit of these assets. The 2009

provision for income taxes was driven mainly by our decision to increase the valuation allowance against our deferred tax assets by \$47.7 million to \$171.4 million (100%) as we determined at that time that it was more likely than not that we would not realize the future benefit of any of these assets.

## Table of Contents

During the fourth quarter of 2010, based on review of the following positive and negative evidence, we adjusted our valuation allowance to the amount that we determined to be more likely than not to be realized.

### Positive:

- our deferred tax assets primarily relate to U.S. net operating losses and tax credits, the oldest of which will not expire until 2028;

- for the most recent three fiscal years, our reported cumulative U.S. income before income taxes totaled approximately \$95 million and we utilized approximately \$137 million of net operating loss carryforwards in our U.S. income tax returns;

- in 2010, our operating income exceeded \$64 million and we expect to be profitable in 2011;

- in August 2010, the U.S. District Court for the Eastern District of Virginia ordered the PTO to consider our patent extension application for the '404 patent that covers Angiomax timely filed;

- in August 2010, the PTO granted a one-year interim extension of the term of the '404 patent that covers Angiomax;

- the PTO and FDA thereafter initiated the regulatory process to reach a final determination of the extension of the term of the '404 patent, which is proceeding as set forth in the regulations;

- in October 2010, the period for the U.S. government to appeal the federal district court's August 2010 decision expired and the U.S. government did not appeal;

- additional U.S. patents that cover Angiomax exist through July 2028;

- in February 2011, we entered into a settlement agreement with one of our law firms resolving our potential claims related to the '404 patent. Terms of the settlement include \$18 million in expense reimbursement paid upfront and up to an additional \$214 million available for damages in the event of launch of a generic version of Angiomax in the United States before June 15, 2015 as a result of the extension of the '404 patent being held invalid on the basis that the application for the extension was not timely filed; and

- our second product, Cleviprex, was approved for sale in the United States; we expect it to generate revenue well past the term of the '404 patent.

### Negative:

- since inception, except for 2004, 2006 and 2010, we have incurred net losses on an annual basis, as of December 31, 2010, we had an accumulated deficit of approximately \$239.5 million;

- our primary revenue generating product, Angiomax, could face generic competition before June 15, 2015 if the extension of the '404 patent is held invalid and we are not successful in defending the additional Angiomax patents that expire in July 2028; and

- we are currently involved in patent infringement litigation relating to the additional U.S. Angiomax patents with a number of companies that, if unfavorably resolved, would adversely affect future operations and profit levels.

At the end of 2010, we maintained a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets.

#### Liquidity and Capital Resources

##### Sources of Liquidity

Since our inception, we have financed our operations principally through revenues from sales of Angiomax, the sale of common stock, sales of convertible promissory notes and warrants and interest income. We had \$340.5 million in cash, cash equivalents and available for sale securities as of December 31, 2011.

##### Cash Flows

As of December 31, 2011, we had \$315.4 million in cash and cash equivalents, as compared to \$126.4 million as of



## Table of Contents

December 31, 2010. Our primary sources of cash during 2011 included \$96.4 million of net cash provided by operating activities, which includes the impact of the approximately \$18.0 million received from the legal settlement with WilmerHale, \$78.4 million in net cash provided by investing activities and \$16.1 million in net cash provided by financing activities.

Net cash provided by operating activities was \$96.4 million in 2011, compared to net cash provided by operating activities of \$67.5 million in 2010. The cash provided by operating activities in 2011 included net income of \$127.9 million offset by non-cash items of \$47.5 million consisting primarily of deferred tax benefit, stock-based compensation expense and depreciation and amortization. Cash provided by operating activities in 2011 also included an increase of \$16.0 million due to changes in working capital items. These changes in working capital items reflect an increase in inventory of \$19.8 million due to purchases under our supply agreement with Teva API, Inc., or Teva API, which was formerly known as Plantex USA Inc., of certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply, an increase in accrued expenses of \$71.6 million primarily due to our efforts with respect to the patent term extension of the '404 patent and settlement of our patent litigation with Teva, and an increase in accounts receivable of \$28.1 million. This increase in accounts receivable is due in part to increased volume of our sales of Angiomax and to an extension of ICS' payment terms under our distribution agreement with them from 30 days to 45 days, which can be further extended to 49 days if ICS pays by wire transfer. We agreed to this extension in connection with a reduction in marketing, sales and distribution fees payable to ICS. The adjusted payment terms began to be implemented midway through the first quarter of 2011.

The cash provided by operating activities in 2010 reflected a net income of \$104.6 million, offset by non-cash items of \$24.8 million consisting primarily of a deferred tax benefit of \$43.6 million, stock-based compensation expense of \$8.3 million and depreciation and amortization of \$6.1 million. Cash provided by operating activities in 2010 also included a decrease of \$12.4 million due to changes in working capital items. These changes in working capital items reflect an increase in accounts receivable of \$16.6 million due to increased volume of our sales of Angiomax. During 2011, \$78.4 million in net cash was provided by investing activities, which reflected \$126.7 million in proceeds from the maturity and sale of available for sale securities and a \$1.0 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices, offset by \$33.6 million used to purchase available for sale securities, \$7.0 million used to acquire intangible assets, \$7.5 million used for a non-controlling equity investment in GeNO, LLC and \$1.3 million used to purchase fixed assets.

During 2010, \$18.4 million in net cash was used in investing activities, which reflected \$128.2 million used to purchase available for sale securities, offset by \$108.6 million in proceeds from the maturity and sale of available for sale securities and a \$1.3 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices.

We received \$16.1 million in 2011 and \$3.4 million in 2010, respectively, in net cash provided by financing activities, which consisted of proceeds to us from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan.

### **Funding Requirements**

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with our products and products in development. Our funding requirements to support these efforts and programs depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;
- our ability to maintain market exclusivity for Angiomax in the United States during the period following the expiration of the patent term of the '404 patent and the six month pediatric exclusivity to which we are entitled (which we believe will be June 15, 2015) through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax, through the enforcement of our other U.S. patents covering Angiomax;
- the extent to which Cleviprex and the acute care generic products for which we acquired the non-exclusive right to sell and distribute from APP are commercially successful in the United States;

the extent to which we can successfully continue to implement our strategy of establishing a commercial infrastructure outside the United States;

the consideration paid by us in connection with acquisitions and licenses of development-stage compounds, clinical-stage product candidates, approved products, or businesses, and in connection with other strategic arrangements;

## Table of Contents

the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex, as well as cangrelor, oritavancin and MDCO-157 and our other products in development;

the cost and outcomes of regulatory submissions and reviews for approval of Angiomax in additional countries and for additional indications, of Cleviprex outside the United States, Australia, New Zealand and Switzerland and of our products in development globally;

the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;

the size, cost and effectiveness of our sales and marketing programs globally;

the amounts of our payment obligations to third parties as to our products and products in development; and

our ability to defend and enforce our intellectual property rights.

If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to slower than anticipated sales of Angiomax and Cleviprex or higher than anticipated costs globally, we may need to sell equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all.

If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

### Certain Contingencies

We may be, from time to time, a party to various disputes and claims arising from normal business activities. We accrue for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. We believe that the ultimate resolution of these matters will not have a material adverse effect on our financial condition or liquidity. However, adjustments, if any, to our estimates could be material to operating results for the periods in which adjustments to the liability are recorded. Currently, we are party to the legal proceedings described in Part I, Item 3 of this annual report. We have assessed such legal proceedings and do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings.

### Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of our products, research and development service agreements, income tax contingencies, operating leases, selling, general and administrative obligations, increases to our restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey and royalties, milestone payments and other contingent payments due under our license and acquisition agreements.

Future estimated contractual obligations as of December 31, 2011 are:



Table of Contents

Contractual Obligations (in thousands) <sup>(1)</sup>	Total	Less Than			More Than
		1 Year	1 - 3 Years	3 - 5 Years	5 Years
Inventory related commitments	\$104,185	\$59,499	\$37,186	\$7,500	—
Research and development	4,294	2,953	1,341	—	—
Operating leases	56,932	7,939	10,746	8,930	29,317
Selling, general and administrative	2,682	1,962	720	—	—
Unrecognized tax benefits	1,891	1,891	—	—	—
Total contractual obligations	\$169,984	\$74,244	\$49,993	\$16,430	\$29,317

This table does not include (a) any milestone and royalty payments which may become payable to third parties for which the timing and likelihood of such payments are not known, as discussed below, and (b) commitments to (1) purchase from APP a specified minimum percentage of our requirements for Angiomax finished product for the sale of the Angiomax product in the United States under a contract manufacturing agreement as this agreement was entered into in January 2012.

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments to Lonza Braine totaling \$26.4 million for 2012 and \$14.7 million for 2013 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$6.4 million is non-cancellable.

We lease our principal offices in Parsippany, New Jersey. The lease covers 173,146 square feet and expires January 2024. We remain subject to a lease for our former office facility in Parsippany, New Jersey. The lease for our old office facility expires in January 2013. In the second half of 2009, we subleased the first floor of our old office facility. The sublease, covering the first floor of our previous office space, expires in January 2013. Additionally, certain other costs such as leasing commissions and legal fees are being expensed as incurred in conjunction with the sublease of the vacated office space.

Approximately 89% of the total operating lease commitments above relate to our principal office building in Parsippany, New Jersey. Also included in total property lease commitments are automobile leases, computer leases, the operating lease from our previous office space and other property leases that we entered into while expanding our global infrastructure.

Aggregate rent expense under our property leases was approximately \$7.3 million in 2011, \$5.8 million in 2010 and \$7.5 million in 2009.

In addition to the amounts shown in the above table, we are contractually obligated to make potential future success-based development, regulatory and commercial milestone payments and royalty payments in conjunction with collaborative agreements or acquisitions we have entered into with third-parties. The amount of these contingent payments could be significant. These contingent payments include royalty payments with respect to Angiomax under our license agreements with Biogen Idec and HRI, royalty and milestone payments with respect to Cleviprex, contingent cash payments of up to approximately \$85.1 million that would be owed to former Targanta shareholders under our merger agreement with Targanta and contingent payments with respect to cangrelor, MDCO-157, MDCO-2010, MDCO-216 and ready-to-use Argatroban. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. For these reason, these contingent payments have not been included in the table above. Further, the timing of any future payment is not reasonably estimable. In 2011 and 2010, the Company paid aggregate royalties to Biogen Idec and HRI of \$85.5 million and \$77.4 million and royalties to AstraZeneca with respect to Cleviprex of \$0.7 million and \$0.4 million.

#### Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS", or ASU 2011-04, that clarifies the application of existing guidance and disclosure requirements, changes certain fair value measurement principles and requires additional disclosures about fair value measurements. ASU

2011-04 will be effective for interim and annual periods beginning on or after December 15, 2011 and therefore is effective for us in our first quarter of fiscal 2012 and will be applied prospectively. We do not expect our adoption of ASU 2011-04 to have a material impact on our financial statements.

In June 2011, the FASB issued ASU 2011-05, "Presentation of Comprehensive Income", or ASU 2011-05, that requires the presentation of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 also requires presentation of adjustments for items that are reclassified from other comprehensive income to net income in the statement where the components of net income and the components of other comprehensive income are presented. ASU 2011-05 requires

## Table of Contents

retrospective application, and it is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and therefore will be effective for us in our first quarter of fiscal 2012. Early adoption of ASU 2011-05 is permitted; however, we do not expect that we will do so. We believe the adoption of ASU 2011-05 will change the order in which certain financial statements are presented and provide additional detail on those financial statements when applicable, but will not have any other impact on our financial statements.

In September 2011, the FASB issued ASU 2011-08, "Testing Goodwill for Impairment", or ASU 2011-08, that allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of an asset in a reporting period is less than its carrying amount, the quantitative two-step goodwill impairment test is required. An entity has the unconditional option to bypass the qualitative assessment and proceed directly to performing the first step of the goodwill impairment test. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 and therefore will be effective for us in our first quarter of 2012. We anticipate that the adoption of this standard will not have a material impact on our consolidated financial statements and footnote disclosures.

### Application of Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in note 2 to our consolidated financial statements included in this annual report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, stock-based compensation and income taxes described below are "critical accounting estimates."

### Revenue Recognition

**Product Sales.** We distribute Angiomax, Cleviprex and, prior to the December 2011 recall of ready-to-use Argatroban, distributed ready-to-use Argatroban, in the United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax and Cleviprex and, when and if available for sale, expect to sell ready-to-use Argatroban to our sole source distributor, ICS and record revenue upon shipment of Angiomax to ICS. ICS then sells Angiomax and Cleviprex, and, when and if available for sale, would sell, ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products that we acquired the non-exclusive rights to sell and distribute from APP through the same sole source distribution model. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on our customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either

party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and other specified conditions.

Outside of the United States, we sell Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals. We had deferred revenue of \$0.4 million as of December 31, 2011 and \$0.5 million as of December 31, 2010 associated with sales of Angiomax to wholesalers outside of the United States. We recognize revenue from such sales when hospitals purchase the product.



## Table of Contents

We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

We recognize sales from Cleviprex and ready-to-use Argatroban under a deferred revenue model. Under our deferred revenue model, we do not recognize revenue upon product shipment to ICS. Instead, upon product shipment, we invoice ICS, record deferred revenue at gross invoice sales price, classify the cost basis of the product held by ICS as finished goods inventory held by others and include such cost basis amount within prepaid expenses and other current assets on our consolidated balance sheets. We currently recognize the deferred revenue when hospitals purchase product and will do so until such time that we have sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. When such estimates are developed, we expect to recognize Cleviprex revenue upon shipment to ICS in the same manner as we recognize Angiomax revenue. During the third quarter of 2009, we reduced our contract price for Cleviprex, which had the effect of reducing deferred revenue by approximately \$4.0 million. In the fourth quarter of 2009, we announced a voluntary recall of 11 lots of Cleviprex, including any remaining unsold inventory associated with its initial wholesaler orders which resulted in a reduction of deferred revenue of approximately \$2.0 million. We recognized \$0.9 million, \$0.8 million and \$3.0 million of revenue associated with Cleviprex during 2011, 2010 and 2009, respectively, related to purchases by hospitals.

We record allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and report revenue net of such amounts. In determining the amounts of certain allowances and accruals, we must make significant judgments and estimates. For example, in determining these amounts, we estimate hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by ICS. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. We receive data periodically from ICS and wholesalers on inventory levels and levels of hospital purchases and we consider this data in determining the amounts of these allowances and accruals.

The nature of our allowances and accruals requiring critical estimates, and the specific considerations we use in estimating our amounts are as follows.

**Product returns.** Our customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the accrual for product returns, we must estimate the likelihood that product sold might not be used within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration. We consider all of these factors and adjust the accrual periodically throughout each quarter to reflect actual experience. When customers return product, they are generally given credit against amounts owed. The amount credited is charged to our product returns accrual.

In estimating the likelihood of product being returned, we rely on information from ICS and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. We also consider the past buying patterns of ICS and wholesalers, the estimated remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

In the fourth quarter of 2011, Eagle, the licensor of ready-to use Argatroban, announced a voluntary recall of 4 lots of ready-to use Argatroban, which caused us to increase our product returns reserve to \$3.4 million.

At December 31, 2011 and December 31, 2010, our accrual for product returns was \$3.9 million and \$0.6 million, respectively. A 10% change in our accrual for product returns would have had an approximately \$0.4 million effect on our reported net revenue for the year ended December 31, 2011.

**Chargebacks and rebates.** Although we primarily sell products to ICS in the United States, we typically enter into agreements with hospitals, either directly or through group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products.

Based on these agreements, most of our hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, we typically provide a credit to

ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, we typically pay the rebate directly to the hospitals.

As a result of these agreements, at the time of product shipment, we estimate the likelihood that product sold to ICS might be ultimately sold to a contracting hospital or group purchasing organization. We also estimate the contracting hospital's or group purchasing organization's volume of purchases.

Table of Contents

We base our estimates on industry data, hospital purchases and the historic chargeback data we receive from ICS, most of which ICS receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds. Our allowance for chargebacks was \$15.6 million and \$13.9 million at December 31, 2011 and December 31, 2010, respectively. A 10% change in our allowance for chargebacks would have had an approximate \$1.6 million effect on our reported net revenue for the year ended December 31, 2011. Our accrual for rebates was \$1.2 million at December 31, 2011. We did not have any significant allowance for rebates at December 31, 2010 or 2009.

**Fees-for-service.** We offer discounts to certain wholesalers and ICS based on contractually determined rates for certain services. We estimate our fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. Our discounts are accrued at the time of the sale and are typically settled with the wholesalers or ICS within 60 days after the end of each respective quarter. Our fee-for-service accruals and allowances were \$3.3 million and \$2.6 million at December 31, 2011 and December 31, 2010, respectively. A 10% change in our fee-for-service accruals and allowances would have had an approximately \$0.3 million effect on our net revenue for the year ended December 31, 2011.

We have adjusted our allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past based on actual sales experience, and we will likely be required to make adjustments to these allowances and accruals in the future. We continually monitor our allowances and accruals and make adjustments when we believe actual experience may differ from our estimates.

The following table provides a summary of activity with respect to our sales allowances and accruals during 2011, 2010 and 2009 (amounts in thousands):

	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for- Service
Balance at January 1, 2009	\$682	\$975	\$1,186	\$431	\$1,956
Allowances for sales during 2009	8,291	3,764	13,439	212	9,582
Allowances for prior year sales	—	274	—	—	—
Actual credits issued for prior year's sales	(648)	) (1,249	) (1,174	) (275	) (1,670)
Actual credits issued for sales during 2009	(7,661)	) —	(8,787	) (357	) (6,743)
Balance at December 31, 2009	664	3,764	4,664	11	3,125
Allowances for sales during 2010	9,817	3,420	53,756	—	10,976
Allowances for prior year sales	—	1,163	—	—	—
Actual credits issued for prior year's sales	(688)	) (3,811	) (4,041	) —	(3,051)
Actual credits issued for sales during 2010	(8,674)	) (3,909	) (40,516	) —	(8,416)
Balance at December 31, 2010	1,119	627	13,863	11	2,634
Allowances for sales during 2011	10,911	3,807	60,318	1,159	9,136
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,119)	) (556	) (8,481	) —	(2,294)
Actual credits issued for sales during 2011	(9,062)	) (7	) (50,060	) —	(6,207)
Balance at December 31, 2011	\$1,849	\$3,871	\$15,640	\$1,170	\$3,269

**International Distributors.** Under our agreements with our primary international distributors, we sell Angiomax to these distributors at a fixed price. The established price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the price is 50% of the average net unit selling price.

Revenue associated with sales to our international distributors during 2011, 2010 and 2009 was \$6.0 million, \$4.5 million and \$4.4 million, respectively.

**Inventory**

We record inventory upon the transfer of title from our vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw

materials and its costs are determined using acquisition costs from our contract manufacturers. We record work-in-progress costs of filling, finishing and

## Table of Contents

packaging against specific product batches. We obtain all of our Angiomax bulk drug substance from Lonza Braine, S.A. and Teva API. Under the terms of our agreement with Lonza Braine, we provide forecasts of our annual needs for Angiomax bulk substance 18 months in advance. We also have a separate agreements with Ben Venue Laboratories, Inc., Patheon Italia S.p.A and APP for the fill-finish of Angiomax drug product.

We review inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected revenues. If annual and expected volumes are less than expected, we may be required to make additional allowances for excess or obsolete inventory in the future.

### Stock-Based Compensation

We have established equity compensation plans for our employees, directors and certain other individuals. All grants and terms are authorized by our Board of Directors or the Compensation Committee of our Board of Directors, as appropriate. We may grant non-qualified stock options, restricted stock awards, stock appreciation rights and other stock-based awards under our Amended and Restated 2004 Stock Incentive Plan. From April 2009 to May 2010, we granted non-qualified stock options under our 2009 Equity Inducement Plan to new employees as an inducement to their entering into employment with us.

We account for stock-based compensation in accordance with FASB Accounting Standards Codification, or ASC, 718-10, and recognize expense using the accelerated expense attribution method. ASC 718-10 requires companies to recognize compensation expense in an amount equal to the fair value of all stock-based awards granted to employees. We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, and prevailing interest rates. ASC 718-10 also requires us to estimate forfeitures in calculating the expense relating to stock-based compensation as opposed to only recognizing forfeitures and the corresponding reduction in expense as they occur.

We have based our assumptions on the following:

#### Assumption

- Estimated expected term of options
- Expected volatility
- Risk-free interest rate
- Forfeiture rates

#### Method of Estimating

- Employees' historical exercise experience and, at times, estimates of future exercises of unexercised options based on the midpoint between the vesting date and end of the contractual term
- Historical price of our common stock and the implied volatility of the stock of our peer group
- Yields of U.S. Treasury securities corresponding with the expected life of option grants
- Historical forfeiture data

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

### Income Taxes

Our annual effective tax rate is based on pre-tax earnings adjusted for differences between GAAP and income tax accounting, existing statutory tax rates, limitations on the use of net operating loss and tax credit carryforwards and tax planning opportunities available in the jurisdictions in which we operate.

In accordance with ASC 740, we use a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. The first step is recognition: we determine whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, we presume that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. The second step is measurement: we measure a tax position that meets the more-likely-than-not recognition threshold to determine

the amount of benefit to recognize in our financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. Significant judgment is required in evaluating our tax position. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution. Our liability for uncertain tax positions is reflected as a reduction to our deferred tax assets in our consolidated balance sheet.

On a periodic basis, we evaluate the realizability of our deferred tax assets net of deferred tax liabilities and adjust such amounts

## Table of Contents

in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, any regulatory or legislative actions by relevant authorities with respect to the Angiomax patents, and the status of litigation with respect to those patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods.

In 2011, we recorded a \$66.5 million income tax benefit by reducing our valuation allowance to \$4.2 million against \$112.5 million of deferred tax assets at December 31, 2011 compared to a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets at December 31, 2010. Any changes to the valuation allowance or deferred tax assets in the future would impact our income taxes.

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

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At December 31, 2011, we held \$340.5 million in cash, cash equivalents and available for sale securities, which had an average interest rate of approximately 0.38%. A 10 basis point change in such average interest rate would have had an approximate \$0.1 million impact on our interest income. At December 31, 2011, all cash, cash equivalents and available for sale securities were due on demand or within one year and 95% is held in the United States.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of December 31, 2011, we had receivables denominated in currencies other than the U.S. dollar. A 10.0% change would have had an approximate \$0.9 million impact on our other income and cash.

### Item 8. Financial Statements and Supplementary Data

All financial statements and schedules required to be filed hereunder are filed as Appendix A to this annual report on Form 10-K and incorporated herein by this reference.

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

None.

### Item 9A. Controls and Procedures

#### Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2011. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed

and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

The report required to be filed hereunder is included in Appendix A to this annual report on Form 10-K and incorporated herein by this reference.



## Table of Contents

### Attestation Report of Independent Registered Public Accounting Firm

The report required to be filed hereunder is included in Appendix A to this annual report on Form 10-K and incorporated herein by this reference.

### Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### Item 9B. Other Information

None.

## PART III

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our proxy statement to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2011 in connection with our 2011 annual meeting of stockholders. We refer to such proxy statement herein as our 2012 Proxy Statement.

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

The information required by this item will be contained in our 2012 Proxy Statement under the captions “Discussion of Proposals,” “Information About Corporate Governance,” “Information About Our Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” and is incorporated herein by this reference.

We have adopted a code of business conduct and ethics applicable to all of our directors and employees, including our principal executive officer, principal financial officer and our controller. The global code of conduct and ethics is available on the corporate governance section of “Investor Relations” of our website, [www.themedicinescompany.com](http://www.themedicinescompany.com). Any waiver of the code of business conduct and ethics for directors or executive officers, or any amendment to the code that applies to directors or executive officers, may only be made by the board of directors. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by filing a Form 8-K disclosing such waiver, or, to the extent permitted by applicable NASDAQ regulations, by posting such information on our website, at the address and location specified above. To date, no such waivers have been requested or granted.

### Item 11. Executive Compensation

The information required by this item will be contained in our 2012 Proxy Statement under the captions “Information About Corporate Governance” and “Information About Our Executive Officers” and is incorporated herein by this reference.

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

The information required by this item will be contained in our 2012 Proxy Statement under the captions “Principal Stockholders,” “Information About Our Executive Officers” and “Equity Compensation Plan Information” and is incorporated herein by this reference.

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

The information required by this item will be contained in our 2012 Proxy Statement under the caption “Information About Corporate Governance” and “Information About Our Executive Officers” and is incorporated herein by this reference.

### Item 14. Principal Accountant Fees and Services

The information required by this item will be contained in our 2012 Proxy Statement under the caption “Independent Registered Public Accounting Firm Fees and Other Matters” and “Discussion of Proposals” and is incorporated herein by this reference.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this annual report:

(1) Financial Statements. The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this annual report. The Consolidated Financial Statements include:

<u>Management's Report on Consolidated Financial Statements and Internal Control over Financial Reporting</u>	Page <u>F - 2</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F - 3</u>
<u>Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting</u>	<u>F - 4</u>
<u>Consolidated Balance Sheets</u>	<u>F - 5</u>
<u>Consolidated Statements of Operations</u>	<u>F - 6</u>
<u>Consolidated Statements of Stockholders' Equity</u>	<u>F - 7</u>
<u>Consolidated Statements of Cash Flows</u>	<u>F - 8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F - 9</u>

(2) Exhibits. The exhibits set forth on the Exhibit Index following the signature page to this annual report are filed as part of this annual report. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report.

Table of Contents

## 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, on February 29, 2012.

THE MEDICINES COMPANY

By: /s/ Clive A. Meanwell  
Clive A. Meanwell  
Chairman and Chief Executive Officer

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

Signature	Title(s)	
/s/ Clive A. Meanwell Clive A. Meanwell	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 29, 2012
/s/ Glenn P. Sblendorio Glenn P. Sblendorio	President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer); Director	February 29, 2012
/s/ William W. Crouse William W. Crouse	Director	February 29, 2012
/s/ Robert J. Hugin Robert J. Hugin	Director	February 29, 2012
/s/ John C. Kelly John C. Kelly	Director	February 29, 2012
/s/ Armin M. Kessler Armin M. Kessler	Director	February 29, 2012
/s/ Robert G. Savage Robert G. Savage	Director	February 29, 2012
/s/ Hiroaki Shigeta Hiroaki Shigeta	Director	February 29, 2012
/s/ Melvin K. Spigelman Melvin K. Spigelman	Director	February 29, 2012
/s/ Elizabeth H.S. Wyatt Elizabeth H.S. Wyatt	Director	February 29, 2012

Table of Contents

APPENDIX A

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS OF  
THE MEDICINES COMPANY

	Page
<u>Management's Report on Consolidated Financial Statements and Internal Control over Financial Reporting</u>	<u>F - 2</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F - 3</u>
<u>Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting</u>	<u>F - 4</u>
<u>Consolidated Balance Sheets</u>	<u>F - 5</u>
<u>Consolidated Statements of Operations</u>	<u>F - 6</u>
<u>Consolidated Statements of Stockholders' Equity</u>	<u>F - 7</u>
<u>Consolidated Statements of Cash Flows</u>	<u>F - 8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F - 9</u>

Table of Contents

Management's Report on Consolidated Financial Statements and  
Internal Control over Financial Reporting

The management of The Medicines Company has prepared, and is responsible for, The Medicines Company's consolidated financial statements and related footnotes. These consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles.

The Medicines Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of the Company's principal executive and principal financial officers and effected by the Company's board of directors, management, and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of The Medicines Company;

- 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 Medicines Company are being made only in accordance with authorizations of management and directors of The Medicines Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of The Medicines 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.

The Medicines Company's management assessed the Company's internal control over financial reporting as of December 31, 2011. Management's assessment was based upon the criteria established in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that, as of December 31, 2011, The Medicines Company's internal control over financial reporting is effective based on those criteria.

/s/ Clive A. Meanwell  
Chairman and  
Chief Executive Officer

/s/ Glenn P. Sblendorio  
President and  
Chief Financial Officer

Dated February 29, 2012

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of The Medicines Company

We have audited the accompanying consolidated balance sheets of The Medicines Company as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of The Medicines Company at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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 Medicines Company's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, NJ

February 29, 2012

Table of Contents

Report of Independent Registered Public Accounting Firm  
on Internal Control over Financial Reporting

The Board of Directors and Stockholders of The Medicines Company

We have audited The Medicines Company's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Medicines 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 Report on Consolidated Financial Statements and Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, The Medicines Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2011 consolidated financial statements of The Medicines Company and our report dated February 29, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, NJ

February 29, 2012



Table of ContentsTHE MEDICINES COMPANY  
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2011	2010
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$315,382	\$126,364
Available for sale securities	25,130	120,280
Accrued interest receivable	374	1,279
Accounts receivable, net of allowances of approximately \$18.1 million and \$15.5 million at December 31, 2011 and 2010	74,559	46,551
Inventory	45,145	25,343
Deferred tax assets	9,395	—
Prepaid expenses and other current assets	11,738	4,804
Total current assets	481,723	324,621
Fixed assets, net	17,979	20,662
Intangible assets, net	87,329	82,925
Goodwill	14,671	14,671
Restricted cash	4,714	5,778
Deferred tax assets	78,441	25,197
Other assets	7,790	270
Total assets	\$692,647	\$474,124
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$6,587	\$8,594
Accrued expenses	147,382	76,242
Deferred revenue	666	534
Total current liabilities	154,635	85,370
Contingent purchase price	20,431	25,387
Other liabilities	5,939	5,769
Total liabilities	181,005	116,526
Stockholders' equity:		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$.001 par value per share, 125,000,000 shares authorized; 54,313,107 and 53,464,145 issued and outstanding at December 31, 2011 and 2010, respectively	54	53
Additional paid-in capital	623,801	596,667
Accumulated deficit	(111,665)	(239,542)
Accumulated other comprehensive income (loss)	(548)	420
Total stockholders' equity	511,642	357,598
Total liabilities and stockholders' equity	\$692,647	\$474,124

See accompanying notes to consolidated financial statements.



Table of ContentsTHE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
Net revenue	\$484,732	\$437,645	\$404,241
Operating expenses:			
Cost of revenue	156,866	129,299	118,148
Research and development	110,180	85,241	117,610
Selling, general and administrative	159,617	158,690	193,832
Total operating expenses	426,663	373,230	429,590
Income (loss) from operations	58,069	64,415	(25,349 )
Legal settlement	17,984	—	—
Other income (loss)	1,790	(267 )	(2,818 )
Income (loss) before income taxes	77,843	64,148	(28,167 )
Benefit (provision) for income taxes	50,034	40,487	(48,062 )
Net income (loss)	\$127,877	\$104,635	\$(76,229 )
Basic earnings (loss) per common share	\$2.39	\$1.98	\$(1.46 )
Diluted earnings (loss) per common share	\$2.35	\$1.97	\$(1.46 )
Weighted average number of common shares outstanding:			
Basic	53,496	52,842	52,269
Diluted	54,407	53,184	52,269

See accompanying notes to consolidated financial statements.

Table of Contents

THE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
For The Years Ended December 31, 2009, 2010 and 2011

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	(Loss) Income	Stockholders' Equity
	(In thousands)		Capital			
Balance at January 1, 2009	52,280	52	565,083	(267,948 )	838	298,025
Employee stock purchases	231	—	1,803			1,803
Issuance of restricted stock awards	319	1				1
Non-cash stock compensation			19,437			19,437
Tax effect of option exercises			(1,645 )			(1,645 )
Net loss				(76,229 )		(76,229 )
Currency translation adjustment					(297 )	(297 )
Unrealized gain on available for sale securities (net of tax)					(706 )	(706 )
Comprehensive loss						(77,232 )
Balance at December 31, 2009	52,830	\$53	\$584,678	\$(344,177 )	\$ (165 )	\$240,389
Employee stock purchases	558	—	3,361			3,361
Issuance of restricted stock awards	76	—				—
Non-cash stock compensation			8,336			8,336
Tax effect of option exercises			292			292
Net income				104,635		104,635
Currency translation adjustment					611	611
Unrealized loss on available for sale securities (net of tax)					(26 )	(26 )
Comprehensive income						105,220
Balance at December 31, 2010	53,464	\$53	\$596,667	\$(239,542 )	\$ 420	\$357,598
Employee stock purchases	609	1	6,724			6,725
Issuance of restricted stock awards	239	—				—
Non-cash stock compensation			11,017			11,017
Tax effect of option exercises			9,393			9,393
Net income				127,877		127,877
Currency translation adjustment					(968 )	(968 )
Comprehensive income						126,909
Balance at December 31, 2011	54,312	\$54	\$623,801	\$(111,665 )	\$ (548 )	\$511,642

See accompanying notes to consolidated financial statements.

Table of ContentsTHE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Cash flows from operating activities:			
Net income (loss)	\$ 127,877	\$ 104,635	\$ (76,229 )
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	6,231	6,124	5,767
Impairment of investment	—	—	5,000
Amortization of net premiums and discounts on available for sale securities	2,021	3,260	2,118
Unrealized foreign currency transaction (gains) losses, net	562	(1,217 )	—
Non-cash stock compensation expense	11,017	8,336	19,437
Loss on disposal of fixed assets	299	293	—
Loss on available for sale securities	—	—	33
Deferred tax (benefit) provision	(53,246 )	(43,592 )	47,737
Excess tax benefit from share-based compensation arrangements	(9,393 )	292	—
Change in contingent consideration obligation	(4,956 )	1,720	486
Changes in operating assets and liabilities:			
Accrued interest receivable	905	(364 )	414
Accounts receivable	(28,086 )	(16,627 )	3,182
Inventory	(19,794 )	701	2,774
Prepaid expenses and other current assets	(6,763 )	5,031	(1,713 )
Accounts payable	(2,203 )	165	(7,851 )
Accrued expenses	71,608	(736 )	8,343
Deferred revenue	125	(616 )	(8,519 )
Other liabilities	171	62	(28 )
Net cash provided by operating activities	96,375	67,467	951
Cash flows from investing activities:			
Purchases of available for sale securities	(33,583 )	(128,240 )	(133,700 )
Proceeds from maturities and sales of available for sale securities	126,713	108,640	161,646
Purchases of fixed assets	(1,269 )	(340 )	(342 )
Acquisition of intangible assets	(7,000 )	—	—
Investment in GeNO	(7,500 )	—	—
Adjustment to goodwill	—	263	—
Acquisition of business, net of cash acquired	—	—	(37,168 )
Decrease (increase) in restricted cash	1,049	1,278	(1,652 )
Net cash provided by (used in) investing activities	78,410	(18,399 )	(11,216 )
Cash flows from financing activities:			
Proceeds from issuances of common stock, net	6,725	3,361	1,804
Excess tax benefit from share-based compensation arrangements	9,393	—	—
Net cash provided by financing activities	16,118	3,361	1,804
Effect of exchange rate changes on cash	(1,885 )	1,710	(332 )
Increase (decrease) in cash and cash equivalents	189,018	54,139	(8,793 )
Cash and cash equivalents at beginning of period	126,364	72,225	81,018
Cash and cash equivalents at end of period	\$ 315,382	\$ 126,364	\$ 72,225
Supplemental disclosure of cash flow information:			

Taxes paid	\$6,850	\$1,699	\$358
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See accompanying notes to consolidated financial statements.

F - 8

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## Table of Contents

### THE MEDICINES COMPANY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business

The Medicines Company (the Company) is a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. The Company has three marketed products, Angiomax<sup>®</sup> (bivalirudin), Cleviprex<sup>®</sup> (clevidipine butyrate) injectable emulsion and a ready-to-use formulation of Argatroban. The Company also has a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and two early stage development product candidates, MDCO-2010 and MDCO-216. The Company believes that its marketed products and products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the acute and intensive care hospital product market and offer, or, in the case of its products in development, have the potential to offer, improved performance to hospital businesses. In addition, in January 2012, the Company acquired from APP Pharmaceuticals, LLC (APP Pharmaceuticals) non-exclusive rights to market in the United States a portfolio of ten generic drugs, which the Company refers to as its acute care generic products.

#### 2. Significant Accounting Policies

##### Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

##### Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive income/(loss) that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different.

##### Risks and Uncertainties

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of intellectual property rights.

##### Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents, available for sale securities and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments in high-quality financial instruments with high quality institutions. At December 31, 2011 and 2010, approximately \$25.2 million and \$12.2 million, respectively, of the Company's cash and cash equivalents was invested in a single fund, the Dreyfus Cash Management Money Market Fund, a no-load money market fund with Capital Advisors Group.

In March 2007, the Company began selling Angiomax in the United States to a sole source distributor, Integrated Commercialization Solutions, Inc. (ICS). The Company began selling Cleviprex to ICS in September 2008. ICS accounted for 96%, 94% and 96% of the Company's net revenue for 2011, 2010 and 2009, respectively. At December 31, 2011 and 2010, amounts due from ICS represented approximately \$85.1 million and \$55.2 million, or 92% and 90%, of gross accounts receivable, respectively. At December 31, 2011 and 2010, the Company maintained an allowance for doubtful accounts for its ICS accounts receivable of \$0.0 million and \$0.1 million, respectively.

##### Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of \$290.2 million and \$114.1

million at December 31, 2011 and December 31, 2010, respectively. Cash and cash equivalents at December 31, 2011 and December 31, 2010 included investments of \$25.2 million and \$12.2 million, respectively, in money market funds and commercial paper with original maturities of less than three months. These investments are carried at cost, which approximates fair value. The Company measures all original

F - 9

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

maturities from the date the investment was originally purchased by the Company.

The Company considers securities with original maturities of greater than three months to be available for sale securities. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary.

The Company held available for sale securities with a fair value totaling \$25.1 million at December 31, 2011 and \$120.3 million at December 31, 2010. These available for sale securities included various United States government agency notes, United States treasury notes and corporate debt securities. At December 31, 2011, all of the \$25.1 million of available for sale securities were due within one year. At December 31, 2010, approximately \$115.2 million of available for sale securities were due within one year. The remaining \$5.1 million were due within two years. Available for sale securities, including carrying value and estimated fair values, are summarized as follows:

	As of December 31, 2011				As of December 31, 2010			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(In thousands)							
U.S. government agency notes	\$901	\$901	\$901	\$—	\$55,222	\$55,222	\$55,222	\$—
U.S. treasury notes	3,021	3,022	3,022	1	—	—	—	—
Corporate debt securities	21,204	21,207	21,207	3	65,055	65,058	65,058	3
Total	\$25,126	\$25,130	\$25,130	\$4	\$120,277	\$120,280	\$120,280	\$3

**Investments**

The Company accounts for its investment in a minority interest of a company over which it does not exercise significant influence on the cost method in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 325-20, "Cost Method Investments" (ASC 325-20). Under the cost method, an investment is carried at cost until it is sold or there is evidence that changes in the business environment or other facts and circumstances suggest it may be other than temporarily impaired based on criteria outlined in ASC 325-20. These non-marketable securities have been classified as investments and included in other assets on the consolidated balance sheets.

**Restricted Cash**

The Company had restricted cash of \$4.7 million at December 31, 2011 and \$5.8 million at December 31, 2010, which is included in restricted cash on the consolidated balance sheets. Restricted cash of \$4.1 million and \$5.5 million at December 31, 2011 and December 31, 2010, respectively, collateralizes outstanding letters of credit associated with the lease of its corporate office space in Parsippany, New Jersey. The funds are invested in certificates of deposit. The letter of credit permits draws by the landlord to cure defaults by the Company. The amount of the letter of credit is subject to reduction upon the achievement of certain regulatory and operational milestones relating to the Company's products. However, in no event will the amount of the letter of credit be reduced below approximately \$1.0 million. In addition, as a result of the acquisition of Targanta Therapeutics Corporation (Targanta) in 2009, the Company had at December 31, 2011 and December 31, 2010 restricted cash of \$0.3 million and \$0.3 million, respectively, in the form of a guaranteed investment certificate collateralizing an available credit facility. The Company also had at December 31, 2011 restricted cash of \$0.3 million related to certain foreign tender requirements.

**Revenue Recognition**

Product Sales. The Company distributes its products in the United States through a sole source distribution model. Under this model, the Company sells to its sole source distributor, ICS, which then sells its products to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. The Company's agreement with ICS, provides that ICS will be the Company's exclusive distributor of its products in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of its products to maintain an appropriate level of inventory based on our customers' historical purchase volumes. In addition, ICS assumes all credit and inventory risks and is subject to our standard return policy. ICS has sole responsibility for determining the

Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

prices at which it sells the Company's products, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and in other specified conditions. Outside the United States, the Company sells its products either directly to hospitals or to wholesalers or international distributors, which then sell to hospitals.

The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

When the Company lacks sufficient information to develop reasonable estimates of returns and other adjustments to gross revenues, the Company records deferred revenue upon product shipment at gross invoice sales price, classifies the cost basis of the product held by the distributor as finished goods inventory held by others and includes such cost basis amount within prepaid expenses and other current assets on its consolidated balance sheets. The Company recognizes the deferred revenue when hospitals purchase product and will do so until such time that it has sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. The Company had deferred revenue of \$0.4 million as of December 31, 2011 and \$0.5 million as December 31, 2010 associated with sales of Angiomax to wholesalers outside of the United States. The Company recognizes revenue from such sales when hospitals purchase the product from the wholesaler. The Company had deferred revenue of \$0.2 million as of December 31, 2011 and \$0.0 million as of December 31, 2010 associated with sales of Cleviprex and Argatroban in the United States. When the Company has sufficient information to develop estimates of expected returns and other adjustments to gross revenue, the Company expects to recognize Cleviprex and Argatroban revenue upon shipment to ICS in the same manner as it recognizes Angiomax revenue.

In the fourth quarter of 2009, the Company announced a voluntary recall of 11 lots of Cleviprex, including any remaining unsold inventory associated with its initial wholesaler orders, which resulted in a reduction of deferred revenue of approximately \$2.0 million. The Company recognized \$0.9 million, \$0.8 million and \$3.0 million of revenue associated with Cleviprex during 2011, 2010 and 2009, respectively, related to purchases by hospitals. The Company records allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by ICS. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. The Company receives data periodically from ICS and wholesalers on inventory levels and levels of hospital purchases and the Company considers this data in determining the amounts of these allowances and accruals. The nature of the Company's allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows.

- **Product returns.** The Company's customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the accrual for product returns, the Company must estimate the likelihood that product sold might not be used within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration. The Company considers all of these factors and adjusts the accrual periodically throughout each quarter to reflect actual experience. When customers return product, they are generally given credit against amounts owed. The amount credited is charged to the

Company's product returns accrual.

In estimating the likelihood of product being returned, the Company relies on information from ICS and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. The Company also considers the past buying patterns of ICS and wholesalers, the estimated remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

In the fourth quarter of 2011, Eagle Pharmaceuticals, Inc. (Eagle), the licensor of ready-to use Argatroban, announced a voluntary recall of 4 lots of ready-to use Argatroban, which caused the Company to increase its product returns reserve to \$3.4 million. At December 31, 2011 and December 31, 2010, the Company's accrual for product returns was \$3.9

F - 11

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

million and \$0.6 million, respectively.

Chargebacks and rebates. Although the Company primarily sells products to ICS in the United States, the Company typically enters into agreements with hospitals, either directly or through group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products.

Based on these agreements, most of the Company's hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, the Company typically provides a credit to ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, the Company typically pays the rebate directly to the hospitals.

As a result of these agreements, at the time of product shipment, the Company estimates the likelihood that product sold to ICS might be ultimately sold to a contracting hospital or group purchasing organization. The Company also estimates the contracting hospital's or group purchasing organization's volume of purchases.

The Company bases its estimates on industry data, hospital purchases and the historic chargeback data it receives from ICS, most of which ICS receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds. The Company's allowance for chargebacks was \$15.6 million and \$13.9 million at December 31, 2011 and December 31, 2010, respectively. The Company's accrual for rebates was \$1.2 million at December 31, 2011. The Company did not have any significant allowance for rebates at December 31, 2010.

Fees-for-service. The Company offers discounts to certain wholesalers and ICS based on contractually determined rates for certain services. The Company estimates its fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. The Company's discounts are accrued at the time of the sale and are typically settled with the wholesalers or ICS within 60 days after the end of each respective quarter. The Company's fee-for-service accruals and allowances were \$3.3 million and \$2.6 million at December 31, 2011 and December 31, 2010, respectively.

The Company adjusts its allowances for chargebacks and accruals for product returns, rebates and fees-for-service based on actual sales experience, and the Company will likely be required to make adjustments to these allowances and accruals in the future. The Company continually monitors its allowances and accruals and makes adjustments when the Company believes actual experience may differ from its estimates.

The following table provides a summary of activity with respect to the Company's sales allowances and accruals during 2011, 2010 and 2009 (amounts in thousands):

	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for- Service
Balance at January 1, 2009	\$682	\$975	\$1,186	\$431	\$1,956
Allowances for sales during 2009	8,291	3,764	13,439	212	9,582
Allowances for prior year sales	—	274	—	—	—
Actual credits issued for prior year's sales	(648)	(1,249)	(1,174)	(275)	(1,670)
Actual credits issued for sales during 2009	(7,661)	—	(8,787)	(357)	(6,743)
Balance at December 31, 2009	664	3,764	4,664	11	3,125
Allowances for sales during 2010	9,817	3,420	53,756	—	10,976
Allowances for prior year sales	—	1,163	—	—	—
Actual credits issued for prior year's sales	(688)	(3,811)	(4,041)	—	(3,051)
Actual credits issued for sales during 2010	(8,674)	(3,909)	(40,516)	—	(8,416)
Balance at December 31, 2010	1,119	627	13,863	11	2,634
Allowances for sales during 2011	10,911	3,807	60,318	1,159	9,136
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,119)	(556)	(8,481)	—	(2,294)

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Actual credits issued for sales during 2011	(9,062	) (7	) (50,060	) —	(6,207	)
Balance at December 31, 2011	\$1,849	\$3,871	\$15,640	\$1,170	\$3,269	

F - 12

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

International Distributors. Under the Company's agreements with its primary international distributors, the Company sells Angiomax to these distributors at a fixed price. The established price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the price is 50% of the average net unit selling price.

Revenue associated with sales to the Company's international distributors during 2011, 2010 and 2009 was \$6.0 million, \$4.5 million and \$4.4 million, respectively.

Cost of Revenue

Cost of revenue consists of expenses in connection with the manufacture of Angiomax, Cleviprex and ready-to-use Argatroban sold, royalty expenses under the Company's agreements with Biogen Idec (Biogen) and Health Research Inc. (HRI) related to Angiomax, with AstraZeneca AB (AstraZeneca) related to Cleviprex and with Eagle related to ready-to-use Argatroban and the logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage and handling costs.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs were approximately \$0.6 million, \$1.5 million and \$2.1 million for the years ended December 31, 2011, 2010, and 2009, respectively.

Inventory

The Company records inventory upon the transfer of title from the Company's vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw materials and its costs are determined using acquisition costs from the Company's contract manufacturers. The Company records work-in-progress costs of filling, finishing and packaging against specific product batches. The Company obtains all of its Angiomax bulk drug substance from Lonza Braine, S.A. and from Teva API, Inc. (Teva API), which was formerly known as Plantex USA Inc. The Company also has separate agreements with Ben Venue Laboratories, Inc., Patheon Italia S.p.A and APP Pharmaceuticals for the fill-finish of Angiomax drug product.

Fixed Assets

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

Recoverability of Long-Lived Assets

The Company reviews the carrying value of goodwill and indefinite lived intangible assets annually and whenever indicators of impairment are present. The Company determines whether goodwill may be impaired by comparing the carrying value of its reporting unit to the fair value of its reporting unit. A reporting unit is defined as an operating segment or one level below an operating segment. Long-lived assets used in operations and amortizing intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that carrying amounts may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and the fair value. Based on the Company's analysis, there was no impairment of goodwill and indefinite lived intangible assets in connection with the annual impairment tests that were performed during 2011.

Research and Development

Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company accounts for share-based compensation in accordance with ASC 718-10 (ASC 718-10), and recognizes expense using the accelerated expense attribution method. ASC 718-10 requires companies to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees. The Company estimates the fair value of its options on the date of grant using the Black-Scholes closed-form option-pricing model.

Expected volatilities are based on historic volatility of the Company's common stock as well as implied volatilities of peer

F - 13

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

companies in the life science industry over a range of periods from 12 to 60 months and other factors. The Company uses historical data to estimate forfeiture rate. The expected term of options represents the period of time that options granted are expected to be outstanding. The Company has made a determination of expected term by analyzing employees' historical exercise experience and has made estimates of future exercises of unexercised options based on the midpoint between the vesting date and end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant corresponding with the expected life of the options.

Foreign Currencies

The functional currencies of the Company's foreign subsidiaries are the local currencies: Euro, Swiss franc, and British pound sterling. The Company's assets and liabilities are translated using the current exchange rate as of the balance sheet date. Stockholders' equity is translated using historical rates at the balance sheet date. Expenses and items of income are translated using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net earnings (loss) and are accumulated in a separate component of stockholders' equity. Foreign exchange transaction gains and losses are included in other income (loss) in the Company's results of operations.

Income Taxes

The Company provides for income taxes in accordance with ASC topic 740 (ASC 740).

In accordance with ASC 740, the Company uses a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. The first step is recognition: the Company determines whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the Company presumed that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The recognition of this tax benefit may impact the effective income tax rate if such tax benefit is more likely than not to be realized when such benefit is recognized. The Company does not anticipate a significant change in its unrecognized tax benefits in the next twelve months. The Company is no longer subject to federal, state or foreign income tax audits for tax years prior to 2008. However, such taxing authorities can review any net operating losses or tax credit carryforwards utilized by the Company in years subsequent to 2007.

In accordance with ASC 740, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

The Company recognizes potential interest and penalties relating to income tax positions as a component of the benefit (provision) for income taxes.

Comprehensive Income (Loss)

The Company reports comprehensive income (loss) and its components in accordance with the provisions of ASC topic 220-10 (ASC 220-10). Comprehensive income (loss) includes net income (loss), all changes in equity for cumulative translations adjustments resulting from the consolidation of foreign subsidiaries' financial statements and unrealized gain (loss) on available for sale securities net of tax.

Recent Accounting Pronouncements

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS (ASU 2011-04) that clarifies the application of existing guidance and disclosure requirements, changes certain fair value measurement principles and requires additional disclosures about fair value measurements. ASU 2011-04 will be effective for interim and annual periods beginning on or after December 15, 2011 and therefore is effective for the Company in its first quarter of fiscal 2012 and will be applied prospectively. The Company does not expect its adoption of ASU 2011-04 to have a material impact on its financial statements.

Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In June 2011, the FASB issued ASU 2011-05, "Presentation of Comprehensive Income" (ASU 2011-05) that requires the presentation of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 also requires presentation of adjustments for items that are reclassified from other comprehensive income to net income in the statement where the components of net income and the components of other comprehensive income are presented. ASU 2011-05 requires retrospective application, and it is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and therefore will be effective for the Company in its first quarter of fiscal 2012. Early adoption of ASU 2011-05 is permitted; however, the Company does not expect that it will do so. The Company believes the adoption of ASU 2011-05 will change the order in which certain financial statements are presented and provide additional detail on those financial statements when applicable, but will not have any other impact on its financial statements.

In September 2011, the FASB issued ASU 2011-08, "Testing Goodwill for Impairment" (ASU 2011-08) that allows entities to first assess qualitatively whether it is necessary to perform the two-step goodwill impairment test. If an entity believes, as a result of its qualitative assessment, that it is more likely than not that the fair value of an asset in a reporting period is less than its carrying amount, the quantitative two-step goodwill impairment test is required. An entity has the unconditional option to bypass the qualitative assessment and proceed directly to performing the first step of the goodwill impairment test. ASU 2011-08 will be effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 and therefore will be effective for the Company in its first quarter of 2012. The Company anticipates that the adoption of this standard will not have a material impact on its consolidated financial statements and footnote disclosures.

## 3. Inventory

The major classes of inventory were as follows:

Inventory	2011	2010
	(In thousands)	
Raw materials	\$23,234	\$9,801
Work-in-progress	19,203	7,183
Finished goods	2,708	8,359
Total	\$45,145	\$25,343

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected volume. If annual volume is less than expected, the Company may be required to make additional allowances for excess or obsolete inventory in the future.

## 4. Fixed Assets

Fixed assets consist of the following:

	Estimated Life (Years)	December 31, 2011	2010
		(In thousands)	
Furniture, fixtures and equipment	3-7	\$11,647	\$12,376
Computer software	3	2,333	1,924
Computer hardware	3	2,282	2,204
Leasehold improvements	5-15	19,157	19,170
		35,419	35,674

Less: Accumulated depreciation	(17,440	) (15,012	)
	\$17,979	\$20,662	

Depreciation expense was approximately \$3.6 million, \$4.4 million and \$4.6 million for the years ended December 31, 2011, 2010 and 2009, respectively.

F - 15

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## Table of Contents

### 5. Investment

In December 2011, the Company made a non-controlling equity investment of \$7.5 million in GeNO, LLC (GeNO), an advanced, development-stage privately held technology company that has created unique nitric oxide generation and delivery technology. In addition to the equity stake, this investment provides the Company with an exclusive option to license GeNO technologies in the acute and intensive care hospital setting in certain geographies. The Company classified the \$7.5 million as investments and included it in other assets on the Company's consolidated balance sheets. The Company holds less than 10% of the issued and outstanding shares of GeNO and does not have significant influence over the company. Accordingly, the Company has accounted for the investment under the cost method.

### 6. Acquisitions

#### Targanta Therapeutics Corporation

In February 2009, the Company acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings. The Company accounted for the acquisition under the revised authoritative guidance in ASC 805.

Under the terms of the Company's agreement with Targanta, it paid Targanta shareholders an aggregate of approximately \$42.0 million in cash at closing. In addition, the Company originally agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate. This amount has been reduced to \$85.1 million in the aggregate as certain milestones have not been achieved by specified dates. The current contingent cash payments milestones are:

Upon approval from the European Medicines Agency (EMA) of a Marketing Authorization Application (MAA) for oritavancin for the treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections (ABSSSI) (which were formerly referred to as complicated skin and skin structure infections (cSSSI)) on or before December 31, 2013, approximately \$10.5 million.

Upon final approval from the FDA of a new drug application (NDA) for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$10.5 million.

Upon final approval from the FDA of an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion on or before December 31, 2013, approximately \$14.7 million. This payment may become payable simultaneously with the payment described in the previous bullet above.

If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million.

The Company expensed transaction costs as incurred, capitalized as an indefinite lived intangible asset the value of acquired in-process research and development and recorded contingent payments at their estimated fair value. In 2009, the Company incurred a total of \$4.3 million of cost related to its acquisition of Targanta, which was included in selling, general and administrative expenses. The results of Targanta's operations since the acquisition date have been included in the Company's consolidated financial statements. The Company allocated the purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, to the net tangible and intangible assets of Targanta based on their estimated fair values. Below is a summary which details the assets and liabilities acquired as a result of the acquisition:

Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	(In thousands)
Acquired assets:	
Cash and cash equivalents	\$4,815
Available for sale securities	397
Prepaid expenses & other current assets	2,440
Fixed assets, net	1,960
In-process research and development	69,500
Goodwill	14,671
Other assets	70
Total assets	93,853
Liabilities assumed:	
Accounts payable	3,280
Accrued expenses	6,976
Contingent purchase price	23,181
Deferred tax liability	17,877
Other liabilities	556
Total liabilities	51,870
Total cash purchase price paid upon acquisition	\$41,983

The Company allocated the purchase price to the estimated fair value of assets acquired and liabilities assumed based on a valuation and management estimates. The Company recorded a deferred tax liability for the difference in basis of the identifiable intangible assets.

In determining the fair value of all of the Company's in-process research and development projects related to oritavancin, the Company used the income approach, specifically a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. This method requires a forecast of cash inflows, cash outflows, and pro forma charges for economic returns of and on tangible assets employed, including working capital, fixed assets and assembled workforce. Cash outflows include direct and indirect expenses for clinical trials, manufacturing, sales, marketing, general and administrative expenses and taxes. For purposes of these forecasts, the Company assumed that cash outflows for research and development, general administrative and marketing expenses from February 2009 and continuing through 2013 would not exceed \$165 million. All internal and external research and development expenses are expensed as incurred.

The Company expects its oritavancin development efforts to have a material impact on its research and development expenses.

The Company defines an in-process research and development project by specific therapeutic treatment indication. At this time, the Company is pursuing four therapeutic treatment indications for oritavancin. After applying a risk adjusted discount rate of 12% to each project's expected cash flow stream, the Company determined a value for each project as set forth below. In determining these values, the Company assumed that it would generate cash inflows from oritavancin for ABSSSI in 2014 and from the other projects thereafter.

Project	(In thousands)
ABSSSI	\$54,000
Bacteremia	5,900
Anthrax	6,400

Clostridium difficile infections	3,200
Total	\$69,500

The Company's success in developing and obtaining marketing approval for oritavancin for ABSSSI and for any of the other

F - 17

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

indications is highly uncertain. The Company cannot know or predict the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, oritavancin due to the numerous risks and uncertainties associated with developing and commercializing drugs. These risks and uncertainties, including their impact on the timing of completing clinical trial and development work and obtaining regulatory approval, would have a material impact on each project's value.

## 7. Intangible Assets and Goodwill

The following information details the carrying amounts and accumulated amortization of the Company's intangible assets subject to amortization:

		As of December 31, 2011			As of December 31, 2010		
	Weighted Average Useful Life (In thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Identifiable intangible assets							
Customer relationships <sup>(1)</sup>	8 years	\$7,457	\$ (2,863 )	\$4,594	\$7,457	\$ (1,715 )	\$5,742
Distribution agreement <sup>(1)</sup>	8 years	4,448	(1,708 )	2,740	4,448	(1,023 )	3,425
Trademarks <sup>(1)</sup>	8 years	3,024	(1,161 )	1,863	3,024	(695 )	2,329
Product license <sup>(2)</sup>	7.75 years	7,000	(226 )	6,774	—	—	—
Cleviprex milestones <sup>(3)</sup>	13 years	2,000	(142 )	1,858	2,000	(71 )	1,929
Total	9 years	\$23,929	\$ (6,100 )	\$17,829	\$16,929	\$ (3,504 )	\$13,425

(1) The Company amortizes intangible assets related to Angiox based on the ratio of annual forecasted revenue compared to total forecasted revenue from the sale of Angiox through the end of its patent life.

(2) The Company amortizes intangible assets related to the product license over its expected useful life.

(3) The Company amortizes intangible assets related to the Cleviprex approval over the remaining life of the patent.

Amortization expense was approximately \$2.6 million, \$1.8 million and \$1.2 million for the years ended December 31, 2011, 2010 and 2009, respectively. The Company expects annual amortization expense related to these intangible assets to be \$3.3 million, \$3.9 million, \$4.5 million, \$1.7 million and \$1.1 million for the years ending December 31, 2012, 2013, 2014, 2015 and 2016, respectively, with the balance of \$3.3 million being amortized thereafter. Amortization of customer relationships, distribution agreements and trademarks will be recorded in selling, general and administrative expense on the consolidated statements of operations. Amortization of product license and Cleviprex milestones will be recorded in cost of revenue on the consolidated statements of operations.

The following information details the carrying amounts of the Company's intangible assets not subject to amortization:

	As of December 31, 2011			As of December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
(In thousands)						
Intangible assets not subject to amortization:						
In-process research and development	\$69,500	\$ —	\$69,500	\$69,500	\$ —	\$69,500
Total	\$69,500	\$ —	\$69,500	\$69,500	\$ —	\$69,500



The changes in goodwill for the years ended December 31, 2011 and December 31, 2010 are as follows:

F - 18

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	December 31, 2011 (In thousands)	December 31, 2010
Balance at beginning of period	\$ 14,671	\$ 14,934
Adjustment to goodwill	—	(263 )
Balance at end of period	\$ 14,671	\$ 14,671

The goodwill acquired during 2009 is solely attributable to the Targanta acquisition (Note 6).

## 8. Accrued Expenses

Accrued expenses consisted of the following at December 31:

	2011 (In thousands)	2010
Royalties	\$ 32,183	\$ 24,739
Research and development services	25,133	16,873
Compensation related	23,424	18,780
Product returns, rebates and other fees	13,351	3,300
Legal, accounting and other	13,819	7,450
Manufacturing, logistics and related fees	38,336	2,534
Sales and marketing	1,136	2,566
	\$ 147,382	\$ 76,242

## 9. Stockholders' Equity

## Preferred Stock

The Company has 5,000,000 shares of preferred stock (Preferred Stock) authorized, none of which are issued.

## Common Stock

Common stockholders are entitled to one vote per share and dividends when declared by the Company's Board of Directors, subject to the preferential rights of any outstanding shares of Preferred Stock.

Employees and directors of the Company purchased 609,386 shares, 557,725 shares, and 231,022 shares of common stock during the years ended December 31, 2011, 2010 and 2009, respectively, pursuant to option exercises and the Company's employee stock purchase plan. The aggregate net proceeds to the Company resulting from these purchases were approximately \$6.7 million, \$3.4 million, and \$1.8 million during the years ended December 31, 2011, 2010 and 2009, respectively, and are included within the financing activities section of the consolidated statements of cash flows. The Company issued 239,576 shares, 76,044 shares and 319,348 shares under restricted stock awards during the years ended December 31, 2011, 2010 and 2009, respectively.

## 10. Stock-Based Compensation

## Stock Plans

The Company has adopted the following stock incentive plans:

- the 2009 Equity Inducement Plan (the 2009 Plan),
- the 2007 Equity Inducement Plan (the 2007 Plan),
- the 2004 Stock Incentive Plan (the 2004 Plan),
- the 2001 Non-Officer, Non-Director Stock Incentive Plan (the 2001 Plan),
- the 2000 Outside Director Stock Option Plan (the 2000 Director Plan), and
- the 1998 Stock Incentive Plan (the 1998 Plan).

F - 19

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Each of these plans provides for the grant of stock options and other stock-based awards to employees, officers, directors, consultants and advisors of the Company and its subsidiaries. Stock option grants have an exercise price equal to the fair market value of the Company's common stock on the date of grant and generally have a 10-year term. The fair value of stock option grants is recognized, net of an estimated forfeiture rate, using an accelerated method over the vesting period of the options, which is generally four years.

2009 Plan

In February 2009, the Board of Directors adopted the 2009 Plan, which provided for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to any person who (a) was not previously an employee or director of the Company or (b) was commencing employment with the Company following a bona fide period of non-employment by the Company, as an inducement material to the individual entering into employment with the Company. The purpose of the 2009 Plan was to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who were expected to make important contributions to the Company and providing such persons with equity ownership opportunities that were intended to better align their interests with those of the Company's stockholders. The 2009 Plan was administered by the Compensation Committee of the Board of Directors, which had the authority to grant awards under the 2009 Plan. Under the 2009 Plan, the Company was authorized to issue up to 1,500,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2009 Plan. Options granted under the 2009 Plan generally have a 10-year term and vest 25% one year after grant and thereafter in equal monthly installments over a three-year period. The 2009 Plan terminated on May 31, 2010. As of December 31, 2011, an aggregate of 204,939 options had been issued and remained outstanding under the 2009 Plan.

2007 Plan

In December 2007, the Board of Directors adopted the 2007 Plan, which provided for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to any person who (a) was not previously an employee or director of the Company or (b) was commencing employment with the Company following a bona fide period of non-employment by the Company, as an inducement material to the individual entering into employment with the Company. The purpose of the 2007 Plan was to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who were expected to make important contributions to the Company and providing such persons with equity ownership opportunities that were intended to better align their interests with those of the Company's stockholders. The 2007 Plan was administered by the Compensation Committee of the Board of Directors, which had the authority to grant awards under the 2007 Plan. Under the 2007 Plan, the Company was authorized to issue up to 1,700,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2007 Plan. Options granted under the 2007 Plan generally have a 10-year term and vest 25% one year after grant and thereafter in equal monthly installments over a three-year period. The 2007 Plan terminated on May 29, 2008. As of December 31, 2011, an aggregate of 181,500 options had been issued and remained outstanding under the 2007 Plan.

2004 Plan

In April 2004, the Board of Directors adopted, subject to stockholder approval, the 2004 Plan, which provides for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants and advisors, including any individuals who have accepted an offer of employment. The Company's stockholders approved the 2004 Plan in May 2004. The 2004 Plan has been amended three times to increase the number of shares issuable under the 2004 Plan and to replace the existing sublimit on certain types of awards that may be granted under the 2004 Plan with a fungible share pool.

The Company may issue up to 13,900,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2004 Plan. Shares awarded under the 2004 Plan that are subsequently cancelled are available to be granted again under the 2004 Plan. The Board of Directors has delegated its authority under the 2004 Plan to the Compensation Committee, consisting of independent directors, which administers

the 2004 Plan, including granting options and other awards under the 2004 Plan. In addition, pursuant to the terms of the 2004 Plan, the Board of Directors has delegated to the Company's executive officers limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. Options granted under the 2004 Plan generally have a 10-year term and vest 25% one year after grant and thereafter in equal monthly installments over a three-year period.

The Board of Directors has adopted a program under the 2004 Plan providing for automatic grants of options to the Company's non-employee directors. Each non-employee director is granted non-statutory stock options under the 2004 Plan to purchase:

F - 20

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

20,000 shares of common stock on the date of his or her initial election to the Board of Directors (the Initial Options); and

7,500 shares of the common stock on the date of each annual meeting of the Company's stockholders (the Annual Options), except if such non-employee director was initially elected to the Board of Directors at such annual meeting. The lead director will be granted an additional option to purchase 5,000 shares of the common stock on the date of each annual meeting of the Company's stockholders.

Each non-employee director also receives an award of 3,750 shares of restricted stock on the date of each annual meeting of the Company's stockholders.

These options have an exercise price equal to the closing price of the common stock on the NASDAQ Global Select Market on the date of grant and have a 10-year term. The Initial Options vest in 36 equal monthly installments beginning on the date one month after the grant date. The Annual Options vest in 12 equal monthly installments beginning on the date one month after the date of grant. All vested options are exercisable at any time prior to the first anniversary of the date the director ceases to be a director. The restricted stock awards vest on the first anniversary date after the grant date.

As of December 31, 2011, the Company had granted an aggregate of 9,674,531 shares as restricted stock or subject to issuance upon exercise of stock options under the 2004 Plan, of which 7,800,312 shares remained subject to outstanding options.

2001 Plan

In May 2001, the Board of Directors approved the 2001 Plan, which provides for the grant of non-statutory stock options to employees, consultants and advisors of the Company and its subsidiaries, including individuals who have accepted an offer of employment, other than those employees who are officers or directors of the Company. The 2001 Plan provided for the issuance of up to 1,250,000 shares of common stock. Shares awarded under the 2001 Plan that were subsequently cancelled were available to be granted again under the 2001 Plan. The Board of Directors delegated its authority under the 2001 Plan to the Compensation Committee, which administers the 2001 Plan, including granting options under the 2001 Plan. In addition, pursuant to the terms of the 2001 Plan, the Board of Directors delegated to the Company's chief executive officer limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. The Company ceased making grants under the 2001 Plan following adoption of an amendment to the 2004 Plan at the Company's annual stockholders' meeting on May 25, 2006.

As of December 31, 2011, an aggregate of 1,111,241 shares had been issued under the 2001 Plan and options to purchase an aggregate of 121,270 shares remained outstanding.

2000 Director Plan

Prior to the adoption of the 2004 Plan, the Company granted non-statutory stock options to the Company's non-employee directors pursuant to the 2000 Director Plan. The Company ceased making grants under the 2000 Director Plan following adoption of the 2004 Plan.

As of December 31, 2011, an aggregate of 177,086 shares had been issued under the 2000 Directors Plan and options to purchase an aggregate of 99,167 shares remained outstanding.

1998 Plan

In April 1998, the Company adopted the 1998 Plan, which provided for the grant of stock options, restricted stock and other stock-based awards to employees, officers, directors, consultants, and advisors of the Company and its subsidiaries, including any individuals who have accepted an offer of employment. The 1998 Plan terminated in April 2008. Under the 1998 Plan, the Board of Directors had authority to determine the term of each option, the option price, the number of shares for which each option is granted and the rate at which each option becomes exercisable. The 1998 Plan provided that 6,118,259 shares of common stock could be issued pursuant to awards under the 1998 Plan. Shares awarded under the 1998 Plan that were subsequently cancelled were available to be granted again under the 1998 Plan. During 1999, the Board of Directors amended all then-outstanding options to allow holders to exercise

the options prior to vesting, provided that the shares of common stock issued upon exercise of the option would be subject to transfer restrictions and vesting provisions that allowed the Company to repurchase unvested shares at the exercise price. The Board of Directors delegated its authority under the 1998 Plan to the Compensation Committee, which administered the 1998 Plan, including granting options and other awards under the 1998 Plan. In addition, pursuant to the terms of the 1998 Plan, the Board of Directors delegated to the Company's chief executive officer limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. Options granted under the 1998 Plan generally vest in increments over four years and have a ten-year term. The Company ceased making grants under the 1998

F - 21

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Plan following adoption of an amendment to the 2004 Plan at its annual stockholders' meeting on May 25, 2006. As of December 31, 2011, an aggregate of 5,086,910 shares had been issued under the 1998 Plan and options to purchase an aggregate of 729,489 shares remained outstanding.

**Stock Option Activity**

The following table presents a summary of option activity and data under the Company's stock incentive plans as of December 31, 2011:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2009	10,765,521	20.92		
Granted	1,533,850	10.92		
Exercised	(18,505)	) 5.85		
Forfeited and expired	(1,286,459)	) 20.23		
Outstanding, December 31, 2009	10,994,407	19.63		
Granted	1,079,700	9.01		
Exercised	(357,225)	) 5.77		
Forfeited and expired	(3,691,471)	) 20.31		
Outstanding, December 31, 2010	8,025,411	\$ 18.51		
Granted	2,108,510	17.04		
Exercised	(451,600)	) 11.04		
Forfeited and expired	(545,644)	) 17.30		
Outstanding, December 31, 2011	9,136,677	\$ 18.61	6.16	\$19,286,018
Vested and expected to vest, December 31, 2011	8,928,570	\$ 18.69	6.09	\$18,581,532
Exercisable, December 31, 2011	6,419,100	\$ 20.15	5.07	\$9,132,587
Available for future grant at December 31, 2011	3,861,360			

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the options at December 31, 2011, for those options for which the quoted market price was in excess of the exercise price. The weighted-average grant date fair value of options granted during the years ended December 31, 2011, 2010 and 2009 was \$7.38, \$4.27, and \$4.69, respectively. The total intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was \$3.0 million, \$1.0 million, and \$0.1 million, respectively.

In accordance with ASC 718-10, the Company recorded approximately \$11.0 million, \$8.3 million and \$19.4 million of stock-based compensation expense related to the options, restricted stock and ESPP for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, there was approximately \$11.3 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. This cost is expected to be recognized over a weighted average period of 1.32 years.

The Company recorded approximately \$8.0 million, \$5.9 million, and \$15.4 million in compensation expense related to options in the years ended December 31, 2011, 2010 and 2009.

For purposes of performing the valuation, employees were separated into two groups according to patterns of historical exercise behavior; the weighted average assumptions below include assumptions from the two groups of employees exhibiting different behavior.



The Company estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table.

F - 22

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Years Ended December 31,			
	2011	2010	2009	
Expected dividend yield	—	% —	% —	%
Expected stock price volatility	49	% 52	% 47	%
Risk-free interest rate	1.73	% 2.13	% 2.05	%
Expected option term (years)	4.75	5.17	5.12	

The fair value of each option element of the Company's 2000 Employee Stock Purchase Plan and 2010 Employee Stock Purchase Plan (the 2000 ESPP and the 2010 ESPP) is estimated on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table. Expected volatilities are based on historical volatility of the Company's common stock. Expected term represents the six-month offering period for the 2000 ESPP. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant.

	Years Ended December 31,			
	2011	2010	2009	
Expected dividend yield	—	% —	% —	%
Expected stock price volatility	38	% 65	% 79	%
Risk-free interest rate	0.1	% 0.19	% 0.32	%
Expected option term (years)	0.5	0.5	0.5	

The following table summarizes information regarding options outstanding as of December 31, 2011:

	Options Outstanding			Options Vested	
	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
Range of Exercise	Outstanding	(Years)	Per Share	Exercisable	Per Share
Prices Per Share	at 12/31/11			at 12/31/11	
\$6.47 — \$8.07	736,579	7.97	\$7.48	318,447	\$7.48
\$8.14 — \$12.95	669,703	7.26	10.62	400,338	10.38
\$13.04 — \$17.58	2,580,077	7.99	16.6	945,060	16.54
\$17.62 — \$18.60	1,115,390	5.98	18.26	832,266	18.29
\$18.65 — \$19.06	208,562	5.16	18.91	198,041	18.92
\$19.09 — \$19.36	948,704	5.97	19.34	910,310	19.34
\$19.42 — \$21.54	847,514	4.72	20.35	806,369	20.36
\$21.55 — \$27.53	865,670	3.74	24.41	843,791	24.43
\$27.56 — \$34.95	1,164,478	3.67	28.83	1,164,478	28.83
	9,136,677	6.16	\$18.61	6,419,100	\$20.15

The following table presents a summary of the Company's outstanding shares of restricted stock awards granted as of December 31, 2011:



Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Number of Shares	Weighted Average Grant-Date Fair Value
Outstanding, January 1, 2009	188,870	22.35
Awarded	408,184	12.42
Vested	(77,938)	) 21.56
Forfeited	(88,836)	) 15.67
Outstanding, December 31, 2009	430,280	14.45
Awarded	172,874	8.82
Vested	(128,196)	) 14.76
Forfeited	(96,830)	) 12.85
Outstanding, December 31, 2010	378,128	12.18
Awarded	250,224	17.59
Vested	(168,443)	) 13.43
Forfeited	(10,648)	) 13.42
Outstanding, December 31, 2011	449,261	\$14.7

The Company grants restricted stock awards under the 2004 Plan. The restricted stock granted to employees generally vests in equal increments of 25% per year on an annual basis commencing twelve months after grant date. The restricted stock granted to non-employee directors generally vests on the first anniversary date after the grant date. Expense of approximately \$2.9 million, \$1.8 million and \$3.2 million was recognized related to restricted stock awards in the years ended December 31, 2011, 2010 and 2009, respectively. The remaining expense of approximately \$2.5 million will be recognized over a period of 1.14 years. The total fair value of the restricted stock that vested during the years ended December 31, 2011, 2010 and 2009 was \$3.0 million, \$1.9 million and \$1.7 million, respectively.

**2000 ESPP**

In May 2000, the Board of Directors and the Company's stockholders approved the 2000 ESPP. The 2000 ESPP provided for the issuance of up to 805,500 shares of common stock. The 2000 ESPP permitted eligible employees to purchase shares of common stock at the lower of 85% of the fair market value of the common stock at the beginning or at the end of each offering period. Employees who owned 5% or more of the common stock were not eligible to participate in the 2000 ESPP. Participation was voluntary.

As of December 31, 2011, the Company had issued 805,437 shares over the life of the 2000 ESPP. The Company issued 169,241 shares, and 212,517 shares under the 2000 ESPP during the years ended December 31, 2010 and 2009, respectively. The Company canceled the 2000 ESPP upon approval of the 2010 ESPP. The Company recorded approximately \$0.3 million, and \$0.8 million in compensation expense related to the 2000 ESPP in the years ended December 31, 2010 and 2009, respectively.

**2010 ESPP**

In June 2010, the Board of Directors and the Company's stockholders approved the 2010 ESPP, which provides for the issuance of up to 1,000,000 shares of common stock. The 2010 ESPP permits eligible employees to purchase shares of common stock at the lower of 85% of the fair market value of the common stock at the beginning or at the end of each offering period. Employees who own 5% or more of the common stock are not eligible to participate in the 2010 ESPP. Participation in the 2010 ESPP is voluntary.

The Company issued 157,786 shares, and 31,259 shares under the 2010 ESPP during the year ended December 31, 2011 and 2010, and currently has 810,955 shares in reserve for future issuance under the 2010 ESPP. The Company recorded approximately \$0.6 million, and \$0.3 million in compensation expense related to the 2010 ESPP in the year

ended December 31, 2011 and 2010.

Common Stock Reserved for Future Issuance

At December 31, 2011, there were 810,955 shares of common stock available for grant under the 2010 ESPP and 3,861,360 shares of common stock available for grant under the 2004 Plan.

F - 24

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 11. Earnings (Loss) per Share

The following table sets forth the computation of basic and diluted earnings (loss) per share for the years ended December 31, 2011, 2010 and 2009.

	Years Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
Basic and diluted			
Net income (loss)	\$ 127,877	\$ 104,635	\$ (76,229 )
Net weighted average common shares outstanding, basic	53,496	52,842	52,269
Plus: net effect of dilutive stock options and restricted common shares	911	342	—
Weighted average common shares outstanding, diluted	54,407	53,184	52,269
Income (loss) per common share, basic	\$ 2.39	\$ 1.98	\$ (1.46 )
Income (loss) per common share, diluted	\$ 2.35	\$ 1.97	\$ (1.46 )

Basic earnings (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. For the years ended December 31, 2011, 2010 and 2009, options to purchase 6,970,991 shares, 8,079,671 shares, and 10,962,627 shares, respectively, of common stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. For the years ended December 31, 2011, 2010 and 2009, 62,473 shares, 6,375 shares, and 87,068 shares, respectively, of unvested restricted stock that could potentially dilute basic earnings per share in the future were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive.

## 12. Income Taxes

The benefit from (provision for) income taxes in 2011, 2010 and 2009 consists of current and deferred federal, state and foreign taxes based on income and state taxes based on net worth as follows:

	2011	2010	2009
	(In thousands)		
Current:			
Federal	\$ (1,299 )	\$ (1,380 )	\$ (237 )
State	(1,677 )	(1,433 )	(238 )
Foreign	(226 )	—	150
	(3,202 )	(2,813 )	(325 )
Deferred:			
Federal	48,384	43,582	(43,740 )
State	5,077	(282 )	(3,997 )
Foreign	(225 )	—	—
	53,236	43,300	(47,737 )
Total benefit from (provision for) income taxes	\$ 50,034	\$ 40,487	\$ (48,062 )

The components of income (loss) before income taxes consisted of:

F - 25

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	2011	2010	2009
	(In thousands)		
Domestic	\$84,390	\$80,765	\$(15,744 )
International	(6,547 )	(16,617 )	(12,423 )
Total	\$77,843	\$64,148	\$(28,167 )

The difference between tax expense and the amount computed by applying the statutory federal income tax rate of 35% in 2011, 2010, and 2009 to income (loss) before income taxes is as follows:

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Statutory rate applied to pre-tax income (loss)	\$27,245	\$22,452	\$(9,858 )
Add (deduct):			
State income taxes, net of federal benefit	(2,210 )	1,115	2,753
Foreign	(1,263 )	1,551	168
Tax exempt portion of WilmerHale settlement	(4,344 )	—	—
Revaluation of Targanta contingent purchase price	(1,735 )	602	—
Tax credits	(1,000 )	—	(1,408 )
Lobbying costs	—	1,324	1,701
Acquisition costs	—	—	1,398
Meals and entertainment	349	390	272
Uncertain tax positions	—	510	—
Other	(567 )	181	326
Net operating loss utilization	—	(23,438 )	(5,783 )
(Decrease) increase to valuation allowances	(66,509 )	(45,174 )	58,493
Income tax (benefit) provision	\$(50,034 )	\$(40,487 )	\$48,062

The significant components of the Company's deferred tax assets are as follows:



Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	December 31, 2011	2010
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$32,437	\$74,314
Tax credits	24,072	24,931
Intangible assets	23,352	22,922
Stock based compensation	15,692	14,894
Other	14,841	13,002
Total deferred tax assets	110,394	150,063
Valuation allowance	(4,190)	(104,334)
Total deferred tax assets net of valuation allowance	106,204	45,729
Deferred tax liabilities:		
Fixed assets	\$(979)	\$(1,065)
Indefinite lived intangible assets	(17,389)	(19,467)
Total deferred tax liabilities	(18,368)	(20,532)
Net deferred tax assets	\$87,836	\$25,197

At December 31, 2010, \$9.4 million of the deferred tax asset valuation allowance related to net operating loss carryforwards was associated with anticipated tax benefits from exercises of non-qualified stock options. In the third quarter of 2011, such benefits were credited to additional paid-in capital when the related valuation allowance was eliminated.

During the third quarter of 2011 and the fourth quarter of 2010, the Company reduced its valuation allowance and recognized deferred tax assets of approximately \$66.5 million and \$45.2 million, respectively, because management believes these assets are more likely than not to be realized in future periods. The Company recorded corresponding deferred income tax benefits in the related quarter and full-year income tax provisions. The Company considered positive and negative evidence including its level of past and future operating income, the utilization of carryforwards, the status of litigation with respect to the Angiomax patents and other factors in arriving at its decision to recognize the deferred tax assets.

In the third quarter of 2011, the Company eliminated \$22.1 million of deferred tax assets (principally state and foreign net operating losses) and their related full valuation allowances with no impact on income. Management concluded that realization of these assets was remote. Following these adjustments, the Company's valuation allowance at the end of 2011 is \$4.2 million, which relates to net operating losses in foreign jurisdictions.

During 2009, the Company increased the valuation allowance associated with its net deferred tax assets to \$171.4 million (100% ) because it considered at that time that future realization of these assets would not be more likely than not.

The Company continues to evaluate the realizability of its deferred tax assets and liabilities on a periodic basis and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development and the extension of the patent rights relating to Angiomax. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's income taxes. In 1998 and 2002, the Company experienced a change in ownership as defined in Section 382 of the Internal Revenue Code. Section 382 can potentially limit a company's ability to use net operating losses, tax credits and other tax attributes in periods subsequent to a change in ownership. However, based on the market value of the Company at such dates, the Company believes that these ownership changes will not significantly impact its ability to use net operating losses or tax credits in the future to offset taxable income. On February 26, 2009 the Company acquired

100% of the stock of Targanta and became a successor to certain of its net operating loss and tax credit carryforwards. These tax attributes are also subject to a limitation under Internal Revenue Code Section 382 and the amounts combined with those of the Company in the table below have been reduced for such limitation.

At December 31, 2011, the Company has federal net operating loss carryforwards available to reduce taxable income and federal research and development tax credit carryforwards available to reduce future tax liabilities. They expire approximately as follows:

F - 27

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Year of Expiration	Federal Net Operating Loss  Carryforwards (In thousands)	Federal Research and Development Tax Credit Carryforwards
2018	\$—	\$95
2019	—	923
2020	—	1,083
2021	—	477
2022	—	1,856
2023	—	2,031
2024	—	1,795
2025	—	3,436
2026	6,052	1,971
2027	30,804	1,028
2028	43,710	1,186
2029	—	899
	\$80,566	\$16,780

At December 31, 2011 the Company has the following additional carryforwards: Alternative Minimum Tax Credits of \$5.0 million with no expiration date and foreign net operating losses of approximately \$15.0 million expiring between 2013 and 2029.

ASC 740 clarifies the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements and provides guidance on de-recognition, measurement, classification and disclosure of tax positions. The Company reduced its deferred tax asset attributable to certain tax credits by approximately \$0.5 million in 2010 to appropriately measure the amount of such deferred tax asset to be realized. No adjustment was made in 2011. The recognition of these tax benefits will impact the Company's effective income tax rate when recognized. The Company does not anticipate a significant change in its unrecognized tax benefits in the next twelve months. The Company is no longer subject to federal, state or foreign income tax audits for tax years prior to 2008. However such taxing authorities can review and adjust any net operating losses and tax credit carryforwards utilized by the Company in years subsequent to 2007. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	Gross Unrecognized Tax Benefits (In thousands)
Balance at January 1, 2010	\$1,381
Additions related to current year tax positions	—
Additions for prior year tax positions	510
Reductions for prior year tax positions	—
Settlements	—
Balance at December 31, 2010	1,891
Additions related to current year tax positions	—
Additions for prior year tax positions	—

Reductions for prior year tax positions	—
Settlements	—
Balance at December 31, 2011	\$1,891

The Company classifies interest and penalties related to unrecognized tax benefits in income tax expense. The Company has not accrued any interest or penalties as of December 31, 2011.

F - 28

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 13. Fair Value Measurements

On January 1, 2008, the Company adopted the provisions of ASC 820-10, “Fair Value Measurements and Disclosures” (ASC 820-10) for financial assets and liabilities. As permitted by ASC 820-10, the Company elected to defer until January 1, 2009 the adoption of ASC 820-10 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. ASC 820-10 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1 Quoted prices in active markets for identical assets or liabilities. The Company’s Level 1 assets and liabilities consist of money market investments.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company’s Level 2 assets and liabilities consist of U.S. government agency and corporate debt securities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company’s Level 3 assets and liabilities consist of the contingent purchase price associated with the Targanta acquisition (note 6). The fair value of the contingent purchase price was determined utilizing a probability weighted discounted financial model.

The following table sets forth the Company’s assets and liabilities that were measured at fair value on a recurring basis at December 31, 2011 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

	Quoted Prices in Active Markets for Identical Assets (Level 1) (In thousands)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2010
Assets and Liabilities				
Assets:				
Money market	\$25,240	\$—	\$—	\$25,240
U.S. treasury notes	3,022	—	—	3,022
U.S. government agency	—	901	—	901
Corporate debt securities	—	21,207	—	21,207
Total assets at fair value	\$28,262	\$22,108	\$—	\$50,370
Liabilities:				
Contingent purchase price	\$—	\$—	\$20,431	\$20,431
Total liabilities at fair value	\$—	\$—	\$20,431	\$20,431

The changes in fair value of the Company's Level 3 contingent purchase price during the year ended December 31, 2011 were as follows:

F - 29

---

Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Level 3
	(In thousands)
Balance at December 31, 2010	\$25,387
Fair value adjustment to contingent purchase price included in net income	(4,956 )
Balance at December 31, 2011	\$20,431

Under the terms of the Company's agreement with Targanta, the first contingent payment relates to approval from the EMA of an MAA for oritavancin for the treatment of serious gram-positive bacterial infections, including ABSSSI (which were formerly referred to as cSSSI) on or before December 31, 2013, approximately \$10.5 million, which the Company believes is now unlikely to be achieved. The value of the contingent consideration obligation, which represents the fair value of the Company's liability for all potential payments under the Targanta agreement, decreased from \$25.4 million at December 31, 2010 to \$20.4 million at December 31, 2011. The reduction in the fair value of the Company's liability was recognized as a gain of \$6.7 million in selling general and administrative expenses on the Consolidated Statements of Operations for the year ended December 31, 2011.

No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the year ended December 31, 2011.

## 14. Restructuring Costs and Other, Net

On September 22, 2011, the Company commenced the closure of its drug discovery research and development facility and operations in Leipzig, Germany and terminated ten employees at its Leipzig facility. The Company transferred active pre-clinical projects from Leipzig to its research and development facility in Montreal, Canada and the MDCO-2010 back-up compound to the clinical team in Parsippany, New Jersey. Upon signing release agreements, the terminated employees received severance and other benefits. The Company recorded, in the aggregate, charges of \$2.2 million in 2011 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in the Company's consolidated financial statements. Of the \$2.2 million of charges related to the 2011 Leipzig closure, \$0.3 million related to asset write-offs were noncash charges. The Company paid out \$0.3 million during 2011 and expects to pay out \$1.6 million during 2012. The Company no longer has any research employees or research capabilities in Leipzig.

During 2011, the Company recorded a \$0.1 million favorable adjustment to selling, general and administrative costs due to a reversal of costs associated with the 2010 workforce reductions, primarily due to the charges for employee severance and other employee-related termination costs being slightly lower than originally estimated. The 2010 workforce reductions were effected in two separate actions, which were designed to improve efficiencies and better align the Company's costs and structure for the future. The 2010 workforce reductions reduced office based personnel by 30 and field based personnel by 42.

The Company recorded, in the aggregate, charges of \$6.8 million in 2010 associated with the 2010 workforce reductions. These charges were recorded in research and development and selling, general and administrative costs in the Company's financial statements.

The following table sets forth details regarding the activities described above during the year ended December 31, 2011 are as follows:

Balance as of January 1,	Expenses, Net	Cash	Noncash	Balance as of December 31,
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	2011				2011	
	(In thousands)					
Employee severance and other personnel benefits:						
2011 Leipzig closure	\$—	\$950	\$(253	)	\$—	\$ 697
2010 workforce reductions	134	(119	)	(15	)	—
Leases and equipment write-offs	10	304	(10	)	(304	) —
Other associated costs	—	918	—	—	—	918
Total	\$144	\$2,053	\$(278	)	\$(304	) \$ 1,615

F - 30

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

15. License Agreements

Angiomax

In March 1997, the Company entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, for the license of the anticoagulant pharmaceutical bivalirudin, which the Company has developed as Angiomax. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, the Company paid \$2.0 million on the closing date and is obligated to pay up to an additional \$8.0 million upon the first commercial sale of Angiomax for the treatment of AMI in the United States and Europe. In addition, the Company is obligated to pay royalties on sales of Angiomax and on any sublicense royalties on a country-by-country basis earned until the later of (1) 12 years after the date of the first commercial sales of the product in a country or (2) the date on which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. Under the terms of the agreement, the royalty rate due to Biogen Idec on sales increases with growth in annual sales of Angiomax. The agreement also stipulates that the Company use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least \$20.0 million for certain development and commercialization activities, which the Company met in 1998. The license and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 90 days after written notice. In addition, the Company may terminate the agreement for any reason upon 90 days prior written notice. The Company recognized royalty expense under the agreement of \$107.9 million in 2011, \$85.5 million in 2010 and \$77.4 million in 2009 for Angiomax sales.

Cleviprex

The Company exclusively licensed Cleviprex in March 2003 from AstraZeneca for all countries other than Japan. In May 2006, the Company amended its license agreement with AstraZeneca to provide exclusive license rights in Japan in exchange for an upfront payment. The Company acquired this license after having studied Cleviprex under a study and exclusive option agreement with AstraZeneca that the Company entered into in March 2002. Under the terms of the agreement, the Company has the rights to the patents, trademarks, inventories and know-how related to Cleviprex. In exchange for the license, the Company paid \$1.0 million in 2003 upon entering into the license and agreed to pay up to an additional \$5.0 million upon reaching certain regulatory milestones, including a payment of \$1.5 million that was remitted in September 2007 after the FDA accepted the NDA for Cleviprex for the treatment of acute hypertension and a payment of \$1.5 million paid in the third quarter of 2008 upon the FDA's approval of Cleviprex. In addition, the Company is obligated to pay royalties on a country-by-country basis on annual sales of Cleviprex, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell Cleviprex in a country or (2) ten years from the Company's first commercial sale of Cleviprex in such country. Under the agreement, the Company is obligated to use commercially reasonable efforts to develop, market and sell Cleviprex. The licenses and rights under the agreement remain in force on a country-by-country basis until the Company ceases selling Cleviprex in such country or the agreement is otherwise terminated. The Company may terminate the agreement upon 30 days written notice, unless AstraZeneca, within 20 days of having received the Company's notice, requests that the Company enter into good faith discussions to redress its concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days. The Company recognized royalty expense under the agreement of \$0.8 million in 2011, \$0.7 million in 2010 and \$0.4 million in 2009 for Cleviprex sales.

Cangrelor

In December 2003, the Company acquired from AstraZeneca exclusive license rights to cangrelor for all countries other than Japan, China, Korea, Taiwan and Thailand. Under the terms of the agreement, the Company has the rights to the patents, trademarks, inventories and know-how related to cangrelor. In June 2010, the Company entered into an amendment to its license agreement with AstraZeneca. The amendment requires the Company to commence certain clinical studies of cangrelor, eliminates the specific development time lines set forth in the license agreement and terminates certain regulatory assistance obligations of AstraZeneca. In exchange for the license, the Company paid an upfront payment of \$1.5 million in January 2004 upon entering into the license and \$3.0 million in June 2010 upon entering the amendment to the license. The Company also agreed to make additional milestone payments of up to \$54.5 million in the aggregate upon reaching agreed upon regulatory and commercial milestones. To date, the Company has paid AstraZeneca approximately \$4.7 million pursuant to the license agreement, which includes the \$1.5 million upfront payment, \$3.0 million in connection with the amendment of the agreement and \$0.2 million for the transfer of technology in 2004. The Company is obligated to pay royalties on a country-by-country basis on annual sales of cangrelor, and on any sublicense income earned, until the later of the duration of the licensed patent rights which are necessary

F - 31

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

to manufacture, use or sell cangrelor in a country or ten years from the Company's first commercial sale of cangrelor in such country. Under the agreement the Company is obligated to use commercially reasonable efforts to diligently and expeditiously file NDAs in the United States and in other agreed upon major markets. The licenses and rights under the agreement remain in force on a country-by-country basis until the Company ceases selling cangrelor in such country or the agreement is otherwise terminated. The Company may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received the Company's notice, requests that the Company enter into good faith discussions to redress the Company's concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days' written notice. In the event that a change of control of the Company occurs in which the Company is acquired by a specified company at a time when that company is developing or commercializing a specified competitor product AstraZeneca may terminate the agreement upon 120 days written notice. Either party may terminate the agreement for material breach upon 60 days' prior written notice if the breach is not cured within such 60 days.

**Oritavancin**

As a result of the Company's acquisition of Targanta, it is a party to a license agreement with Eli Lilly through its Targanta subsidiary. Under the terms of the agreement, the Company has exclusive worldwide rights to patents and other intellectual property related to oritavancin and other compounds claimed in the licensed patent rights. The Company is required to make payments to Eli Lilly upon reaching specified regulatory and sales milestones. In addition, the Company is obligated to pay royalties based on net sales of products containing oritavancin or the other compounds in any jurisdiction in which it holds license rights to a valid patent. The royalty rate due to Eli Lilly on sales increases as annual sales of these products increase. The Company is obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for oritavancin in the United States and to commercialize oritavancin in the United States. If the Company breaches that obligation, Eli Lilly may terminate the Company's license in the United States, license rights to oritavancin could revert to Eli Lilly and the Company would lose its rights to develop and commercialize oritavancin. The license rights under the agreement remain in force, on a country-by-country basis, until there is no valid patent in such country and the Company's obligation to pay royalties ceases in that country. Either party may terminate the agreement upon an uncured material breach by the other party. In addition, either party may terminate the agreement upon the other party's insolvency or bankruptcy.

**MDCO-157**

In May 2011, the Company entered into a licensing agreement with Ligand Pharmaceuticals Incorporated (Ligand) through its subsidiary CyDex Pharmaceuticals, Inc., under which the Company acquired an exclusive, worldwide license to patents claiming a Captisol®-enabled intravenous formulation of clopidogrel bisulfate, which the Company refers to as MDCO-157, and to related know-how. Under the license agreement, the Company paid Ligand an upfront payment of approximately \$1.8 million in June 2011 and agreed to make additional payments of up to \$22 million upon the achievement of certain clinical, regulatory and commercial milestones. The Company also agreed to pay to Ligand tiered royalties from high single digits up to low double digits on annual worldwide net sales. The license obligates the Company to use commercially reasonable efforts to develop a licensed product, and to make \$2.5 million per year in development expenditures until the Company submits a new drug application (NDA). Either party may terminate the agreement for material breach upon 30 days' prior written notice for breaches involving non-payment of amounts due under the license agreement or 120 days for all other material breaches (which can be extended for up to 90 days if the breaching party submits a reasonable plan to cure the breach), if the breach is not cured within the applicable period. The Company may terminate the agreement for any reason upon specified written notice. Ligand may terminate the agreement if the Company does not meet certain timelines or fulfill certain obligations under the license agreement. Finally, the license agreement will terminate if the Company terminates the supply agreement without cause or Ligand terminates it due to the Company's material breach.

Under a separate supply agreement entered in May 2011, Ligand has agreed to supply the Company with clinical materials of Captisol, an excipient in MDCO-157, for the MDCO-157 development program. If the intravenous formulation is approved for commercialization, the Company has agreed that Ligand will be the exclusive supplier of Captisol for the product. This agreement will expire or automatically terminate simultaneously with the expiration or termination, respectively, of the licensing agreement, and either party may terminate it for the other's material breach on the same terms as those of the licensing agreement.

#### MDCO-216

In December 2009, the Company entered into an agreement with Pfizer Inc. (Pfizer) with respect to the compound designated by Pfizer as ETC-216 (ETC-216), a variant of ApoA-I Milano, a naturally occurring variant of a protein found in human high-density lipoprotein. Pursuant to the agreement, Pfizer granted the Company an exclusive, worldwide, royalty-bearing license under specified Pfizer patents, patent applications and know-how to develop, manufacture and commercialize products containing ETC-216 and improvements to ETC-216 (collectively, the Products). The Company may sublicense the intellectual property to third parties, provided that it has complied with Pfizer's right of first negotiation and, in the case of sublicenses, to unaffiliated

Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

third parties in certain countries, provided that it has first obtained Pfizer's consent. The Company, itself or through its affiliates or sublicensees, has agreed to use commercially reasonable efforts to develop at least one Product and to commercialize any approved Products.

Under the agreement, the Company paid Pfizer an upfront payment of \$10.0 million and upon the achievement of clinical, regulatory and sales milestones will pay up to an aggregate of \$410.0 million. The Company has also agreed to make royalty payments to Pfizer on the sale of the Products by the Company, its affiliates or sublicensees. The royalties are payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the last patent or patent application covering the Product, the expiration of any market exclusivity, and a specified period of time after first commercial sale of the Product. The Company has also agreed to pay Pfizer a portion of the consideration received by the Company or its affiliates in connection with sublicenses. The Company also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments on sales of MDCO-216.

The Company has agreed to indemnify Pfizer against third party claims arising from (a) the development and commercialization of the Products by the Company, its affiliates, subcontractors or sublicensees, (b) the negligence or wrongful intentional acts or omissions of the Company, its affiliates, subcontractors or sublicensees, (c) a breach of the agreement by the Company, or (d) claims by a Brewer/Matin Party (as defined in the agreement with Pfizer) resulting from the agreement or any agreement or arrangement between the Company and a Brewer/Matin Party.

The agreement will expire upon expiration of the Company's obligation to make royalty payments. Each party may terminate the agreement if (a) the other party breaches its material obligations under the agreement and fails to cure such breach during a specified period of time, (b) the other party become insolvent or bankrupt, or (c) the other party is subject to a force majeure event for a specified period of time. Pfizer may also terminate the agreement if the Company provides written notice to Pfizer that the Company intends to permanently abandon the development, manufacture and commercialization of the Products or if the Company otherwise ceases, for a specified period of time, to use commercially reasonable efforts to develop, manufacture and commercialize, as applicable, at least one Product. The Company may terminate the agreement in its entirety, or on a Product-by-Product basis, at any time and for any reason upon prior written notice.

Upon termination of the agreement, the licenses to the Company terminate. If Pfizer terminates the agreement due to the Company's uncured breach, bankruptcy, force majeure event, abandonment of the Products or ceasing to use commercially reasonable efforts to develop and commercialize at least one Product, or if the Company terminates the agreement for convenience, the Company will grant Pfizer a sublicenseable, royalty-free, perpetual license under any intellectual property licenseable by the Company that arose from the Company's development or commercialization of the terminated Products, to develop, manufacture and commercialize the terminated Products. This license will be non-exclusive with respect to trademarks and exclusive with respect to other intellectual property.

Ready-to-Use Argatroban.

In September 2009, the Company licensed marketing rights in the United States and Canada to an intravenous, ready-to-use formulation of Argatroban from Eagle. Under the license agreement, the Company paid Eagle a \$5.0 million technology license fee. The Company also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties on net sales of the ready-to-use formulation. The license agreement expires at the later of the termination of the development plan under the agreement or upon the Company ceasing to exploit the products under the agreement. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured after receipt of written notice within 30 days or up to 60 days if the breaching party gives notice that it is in good faith attempting to cure the breach. In addition, the Company has the right to terminate the agreement at any time upon 60 days' notice.

16. Commitments and Contingencies

The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of the Company's products, research and development service agreements, operating leases and selling, general and administrative obligations, increases to the Company's restricted cash in connection with its new principal office space in Parsippany, New Jersey, and royalty and milestone payments due.

Future estimated contractual obligations as of December 31, 2011 are:

F - 33

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Contractual Obligations <sup>(1)</sup>	2012	2013	2014	2015	2016	Later Years	Total
	(In thousands)						
Inventory related commitments	\$59,499	\$29,686	\$7,500	\$7,500	\$—	\$—	\$104,185
Research and development	2,953	1,341	—	—	—	—	4,294
Operating leases	7,939	5,886	4,860	4,539	4,391	29,317	56,932
Selling, general and administrative	1,962	720	—	—	—	—	2,682
Unrecognized tax benefits	1,891	—	—	—	—	—	1,891
Total contractual obligations	\$74,244	\$37,633	\$12,360	\$12,039	\$4,391	\$29,317	\$169,984

<sup>(1)</sup> This table does not include any milestone and royalty payments which may become payable to third parties for which the timing and likelihood of such payments are not known, as discussed below.

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments to Lonza Braine totaling \$26.4 million for 2012 and \$14.7 million for 2013 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$6.4 million is non-cancellable.

The Company leases its principal offices in Parsippany, New Jersey. The lease covers 173,146 square feet and expires January 2024. The lease for the Company's old office facility in Parsippany expires January 2013. In the second half of 2009, the Company subleased the first floor of this previous old office space the sublease, covering the first floor of the Company's previous office space, expires in January 2013. Additionally, certain other costs such as leasing commissions and legal fees will be expensed as incurred in conjunction with the sublease of the vacated office space. Approximately 89% of the total operating lease commitments above relate to the Company's principal office building in Parsippany, New Jersey. Also included in total property lease commitments are automobile leases, computer leases, the operating lease from the Company's previous office space and other property leases that the Company entered into while expanding the its global infrastructure.

Aggregate rent expense under the Company's property leases was approximately \$7.3 million in 2011, \$5.8 million in 2010 and \$7.5 million in 2009.

In addition to the amounts shown in the above table, the Company is contractually obligated to make potential future success-based development, regulatory and commercial milestone payments and royalty payments in conjunction with collaborative agreements or acquisitions it has entered into with third-parties. These contingent payments include royalty payments with respect to Angiomax under the Company's license agreements with Biogen Idec and HRI, royalty and milestone payments with respect to Cleviprex, contingent cash payments up to approximately \$85.1 million that would be owed to former Targanta shareholders under the Company's merger agreement with Targanta and contingent payments with respect to cangrelor, oritavancin, MDCO-157, MDCO-2010, MDCO-216 and ready-to-use Argatroban. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. These contingent payments have not been included in the table above. Further, the timing of any future payment is not reasonable estimable. In 2011, 2010 and 2009, the Company incurred aggregate royalties to Biogen Idec and HRI of \$108.2 million, \$85.5 million and \$77.4 million, and royalties to AstraZeneca with respect to Cleviprex of \$0.8 million, \$0.7 million and \$0.4 million.

Teva API, Inc.

Contemporaneously with entering into the settlement and license agreements with Teva on September 30, 2011, the Company and Teva API entered into a supply agreement under which the Company agrees to purchase from Teva API certain minimum quantities of the active pharmaceutical ingredient bivalirudin for the Company's commercial supply at agreed upon specified prices. The initial term of the supply agreement ends December 31, 2015 and will

automatically be renewed for up to two successive three-year periods unless terminated by the Company with at least six-month written notice or by Teva API with at least 24-months written notice prior to the expiration of the initial term or either renewal term. The Company has the right to terminate the supply agreement, effectively immediately, if a generic form of bivalirudin is launched after January 1, 2013. The Company and Teva API may terminate the supply agreement in the event of a material breach by the other party, unless the material breach is cured within 30 days of a written notice, and the Company may terminate the supply agreement upon breach of the settlement agreement and certain breaches of the license agreement. During 2011 the Company recorded \$11.0 million in costs related to Teva API's production of active pharmaceutical ingredient bivalirudin.

F - 34

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Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

**Eagle Pharmaceuticals Arbitration.** The Company received a Demand for Arbitration filed by Eagle dated October 25, 2011. In the Demand for Arbitration, Eagle claims that the Company failed to meet its obligations under the license and development agreement between the Company, Eagle and certain other parties relating to the development of a new formulation Angiomax, and to the Company's efforts to seek and obtain regulatory approval, market and sell that new formulation. As a result, Eagle alleges that it has been damaged in an amount it believes exceeds \$200 million. The Company believes it has valid defenses to Eagle's claims and intend to defend itself vigorously. The Company believes that any potential liability is not estimable at this time.

In addition, the Company is currently party to the legal proceedings described in Part I, Item 3 of this annual report, which are principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability can be reasonably estimated. As a result, the Company did not record any loss contingencies. While it is not possible to determine the outcome of the matters described in Part I, Item 3 of this annual report, the Company believes that, the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to the Company's consolidated results of operations in any one accounting period.

## 17. Employee Benefit Plan

The Company has an employee savings and retirement plan which is qualified under Section 401(k) of the Internal Revenue Code. The Company's employees may elect to reduce their current compensation up to the statutorily prescribed limit and have the amount of such reduction contributed to the 401(k) plan. Effective March 2010, the Company agreed to make matching contributions of 50% of employee's contributions up to a maximum of 6% of an employee's eligible earnings.

## 18. Segment and Geographic Information

The Company manages its business and operations as one segment and is focused on advancing the treatment of acute and intensive care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. Revenues reported to date are derived primarily from the sales of Angiomax in the United States.

The geographic segment information provided below is classified based on the major geographic regions in which the Company operates.

	Years Ended December 31,								
	2011			2010			2009		
							(In thousands)		
Net revenue:									
United States	\$453,163	93.5	%	\$413,044	94.4	%	\$385,939	95.5	%
Europe	25,532	5.3	%	20,126	4.6	%	13,908	3.4	%
Other	6,037	1.2	%	4,475	1.0	%	4,394	1.1	%
Total net revenue	484,732			437,645			404,241		



Table of Contents

## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Years Ended December 31,					
	2011			2010		
	(In thousands)					
Long-lived assets:						
United States	\$ 126,513	99.0	%	\$ 117,095	98.8	%
Europe	1,069	0.8	%	1,213	1.0	%
Other	187	0.1	%	220	0.2	%
Total long-lived assets	\$ 127,769			\$ 118,528		

## 19. Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the years ended December 31, 2011 and 2010.

	Three Months Ended							
	Mar. 31,	June 30,	Sept. 30,	Dec. 31,	Mar. 31,	June 30,	Sept. 30,	Dec. 31,
	2011	2011	2011	2011	2010	2010	2010	2010
	(1)		(2)					(3)
	(In thousands, except per share data)							
Net revenue	\$ 112,137	\$ 119,591	\$ 120,773	\$ 132,231	\$ 102,088	\$ 110,135	\$ 105,743	\$ 119,679
Cost of revenue	35,570	37,830	39,459	44,007	28,769	33,568	31,568	35,394
Total operating expenses	61,720	67,956	71,903	68,218	62,998	59,984	52,464	68,485
Net income	24,241	11,440	72,614	19,582	9,432	15,426	21,205	58,572
Basic net income per common share	\$0.46	\$0.21	\$1.36	\$0.36	\$0.18	\$0.29	\$0.40	\$1.10
Diluted net income per common share	\$0.45	\$0.21	\$1.34	\$0.35	\$0.18	\$0.29	\$0.40	\$1.09

(1) Net income for the first quarter of 2011 includes income of \$18.0 million related to the settlement agreement entered into with WilmerHale in February 2011.

(2) Net income for the third quarter of 2011 includes a tax benefit of \$66.5 million from reducing our valuation allowance against our deferred tax assets.

(3) Net income for the fourth quarter of 2010 includes a tax benefit of \$45.2 million from reducing our valuation allowance against our deferred tax assets

## 20. Subsequent Events

On January 22, 2012, the Company and APP entered into a Settlement Agreement (the Settlement Agreement) and a License Agreement (the License Agreement, and together with the Settlement Agreement, the Settlement Documents). The Settlement Documents relate to The Medicines Company v. APP Pharmaceuticals, LLC., et al., an action for patent infringement in the U.S. District Court for the District of Delaware (the ANDA Litigation), and The Medicines Company v. Kappos, et al., an appeal before the U.S. Court of Appeals for the Federal Circuit relating to the August 2010 federal district court decision holding that the Company's application for Hatch Waxman patent term extension of the '404 patent, was timely filed (the Pending Appeal, and together with the ANDA Litigation, the Pending Litigations).

In the ANDA Litigation, the Company alleges that the ANDA for generic bivalirudin for injection filed by APP with the FDA infringes U.S. Patent Nos. 7,582,727 and 7,598,343 (the Litigated Patents), two patents of the Company that cover bivalirudin for injection. The Litigated Patents are currently due to expire on July 27, 2028.

Regarding the Pending Appeal, in the first quarter of 2010, the Company filed suit against the PTO, the FDA and HHS seeking to set aside the PTO's denial of the Company's application to extend the patent term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia ordered the PTO to consider the Company's patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in the Company's case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP appealed the denial of its motion, as well as the federal district court's August 3, 2010 order (and all related and underlying orders), to the U.S. Court of

F - 36

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Appeals for the Federal Circuit.

Contemporaneously with entering into the Settlement Documents, the Company and APP entered into the following agreements:

- a Contract Manufacturing Agreement (the Fill-Finish Manufacturing Agreement) under which APP has agreed to manufacture and supply Angiomax finished product to the Company,
- a License and Supply Agreement (the APP Generic Product License and Supply Agreement) under which APP has agreed to license and supply to the Company a portfolio of ten generic products, and
- an AG Supply Agreement (the AG Supply Agreement, and collectively with the Fill-Finish Manufacturing Agreement, APP Generic Product License and Supply Agreement and the Settlement Documents, the Agreements) under which the Company has agreed to supply APP with an authorized generic bivalirudin product (the AG Product) upon specified circumstances set forth in the License Agreement.

The following is a summary of the material terms of the Agreements.

**Settlement Agreement**

Under the Settlement Agreement, APP admits that the Litigated Patents are valid and enforceable and would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDA. APP has agreed that it will not make, use, sell, offer for sale or import generic bivalirudin for injection products under its ANDA except as provided in the License Agreement. The Company and APP agreed that they will not pursue litigation activities related to the Pending Litigations. Under the Settlement Agreement, the Company agreed to make a one-time payment to APP within five business days following the later of the court's entry of the consent judgment and order of permanent injunction with respect to the ANDA Litigation and the entry of the joint dismissal of the Pending Appeal with respect to the Pending Appeal, in recognition of the savings inuring to the Company in terms of the avoidance of costs, expenditure of time, disruption and burden associated with prosecuting the ANDA Litigation. On January 24, 2012, the district court entered a consent judgment and order of permanent injunction concluding the Company's patent infringement suits against APP. On February 2, 2012, the Federal Circuit entered an order dismissing the appeal. As a result, in February 2012, the Company made the one-time payment to APP. The Settlement Agreement terminates upon the earlier of the expiration of the Litigated Patents, including any statutory or regulatory extensions thereof, and the termination of the License Agreement. The Settlement Agreement provides that the Company and APP will submit the Agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice within ten business days following the date of the Settlement Agreement.

On February 1, 2012, the Company and APP submitted the Agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice.

**License Agreement**

Under the License Agreement, the Company grants APP a non-exclusive license under the Licensed Patents to sell in the United States a generic bivalirudin for injection product under an APP ANDA (an APP Product) beginning on May 1, 2019 or earlier under specified conditions, and, in certain limited circumstances, to sell a generic bivalirudin for injection product under the Company's NDA for Angiomax (an Authorized Generic Product) in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. APP's right under the License Agreement to sell an Authorized Generic Product is subject to the payment to the Company of a royalty on sales of the Authorized Generic Product. If APP has the right to sell an Authorized Generic Product, such right could extend for a period of as long as 180 days. The Licensed Patents include the Litigated Patents and any other present or future patents owned, licensed or controlled by the Company that cover or would cover an APP Product or an Authorized Generic Product other than the '404 patent.

Under the License Agreement, the Company and APP have also agreed to negotiate an agreement under which the Company would supply APP with bivalirudin bulk drug substance for use by APP in the manufacture of APP Product to be sold under the License Agreement.

The License Agreement will remain in effect until the later of the expiration of all of the Licensed Patents, and the date six months after the expiration of the '404 patent. Each of the Company and APP may terminate the License Agreement in the event of a material breach by the other party, unless the material breach is cured within 60 days of written notice. Either party may also terminate the License Agreement if the other party undergoes bankruptcy events. The Company may terminate the License Agreement, effectively immediately, upon specified breaches by APP of the License Agreement, including if APP challenges the validity or enforceability of the Licensed Patents or markets a generic bivalirudin for injection product outside the License Agreement.

Fill-Finish Manufacturing Agreement

Under the Fill-Finish Manufacturing Agreement, the Company has agreed to purchase from APP a specified minimum

F - 37

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Table of Contents

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

percentage of the Company's requirements for Angiomax finished product for the sale of the Angiomax product in the United States. The Company has agreed to pay APP a fixed price per vial supplied and to reimburse APP for specified development costs and capital expenditures made by APP. The term of the Fill-Finish Manufacturing Agreement ends on May 1, 2019, but may be extended, at the Company's sole option, for an additional term of two years. If a generic form of bivalirudin for injection is marketed by APP or another third party during the term of the Fill-Finish Manufacturing Agreement, the Company has the right to renegotiate the price and minimum quantity terms of the Fill-Finish Manufacturing Agreement and, if such terms cannot be agreed to by the parties, the Company will have the right to terminate the Fill-Finish Manufacturing Agreement upon 90 days written notice. Each of the Company and APP may terminate the Fill-Finish Manufacturing Agreement in the event of a material breach by the other party, effective immediately in the case of a non-curable breach and effective upon 60 days written notice in the case of a curable breach if such breach is not cured within such 60-day period. Either party may also terminate the Fill-Finish Manufacturing Agreement if the other party undergoes bankruptcy events. The Company may terminate the Fill-Finish Manufacturing Agreement upon at least 12 months written notice if the Company decides to discontinue marketing the Angiomax product in the United States or upon 30 days written notice in the event that any government or regulatory authority prevents the Company from purchasing or selling the Angiomax product in the United States.

**APP Generic Product License and Supply Agreement**

Under the APP Generic Product License and Supply Agreement, APP grants the Company a non-exclusive license under APP's marketing authorizations and intellectual property to sell ten specified generic products to hospitals and integrated delivery networks in the United States. The Company has agreed to purchase its entire requirements for these products from APP for a price equal to APP's cost of goods. Under the terms of this agreement, the Company made a one-time, upfront payment of \$30 million to APP.

The term of the APP Generic Product License and Supply Agreement ends January 22, 2022. Each of the Company and APP may terminate this agreement in the event of a material breach by the other party, unless the material breach is cured within 90 days of written notice or within 120 days of written notice if the breach is incapable of being cured within the 90-day period. Either party may also terminate this agreement if the other party undergoes bankruptcy events. APP may terminate this agreement upon 60 days written notice if the Company fails to pay in full any invoice that is past due unless such payment is the subject of a dispute set forth in writing by the Company. The Company may terminate this agreement if, with respect to two purchase orders in a calendar year, APP has failed to supply at least the aggregate quantity of conforming product specified in the purchase order or failed to deliver the product prior to the applicable delivery date specified in the purchase order and APP has failed to cure these breaches in the manner specified in the APP Generic Product License and Supply Agreement.

In addition, either party may terminate the APP Generic Product License and Supply Agreement on a product-by-product basis, effective immediately, upon written notice to the other party in the event the FDA takes any action the result of which is to permanently prohibit the manufacture of the product in the United States. APP may also terminate the APP Generic Product License and Supply Agreement on a product-by-product basis upon 180 days written notice if APP has determined that it will discontinue the marketing authorization for the product in the United States. The Company may terminate the APP Generic Product License and Supply Agreement on a product-by-product basis upon 180 days written notice if the total market value of a product falls below a specified percentage of the total market value of the product as of the effective date of the agreement. In the event that this agreement is terminated with respect to a product, the parties shall agree upon a substitute product.

**AG Supply Agreement**

Under the AG Supply Agreement, the Company has agreed to supply APP with the AG Product in the event APP has the right to market the AG Product under the License Agreement. The Company agrees to use commercially reasonable efforts to supply the AG Product during the period during which APP can market the AG Product (the Supply Period). APP shall purchase the AG Product from the Company at a price based on the costs paid by the Company to third parties in connection with the manufacture of the AG Product. The AG Supply Agreement

terminates upon the earlier of the end of the Supply Period or December 27, 2019. In addition, each of the Company and APP may terminate the AG Supply Agreement upon the termination of the License Agreement or the Fill-Finish Manufacturing Agreement or in the event of a material breach by the other party, unless the material breach is cured within 60 days of written notice. Either party may terminate the AG Supply Agreement if the other party undergoes bankruptcy events.

The Agreements also contain provisions including indemnification, confidentiality, dispute resolution and other customary provisions for agreements of these kinds.

The foregoing descriptions of the Agreements do not purport to be complete and are qualified in their entirety by reference to the complete texts of the Agreements, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as exhibits to the Company's Quarterly Report on Form 10-Q for the period ending on March 31, 2012.



Table of Contents

INDEX TO EXHIBITS

Number Description

- 2.1† Sale and Purchase Agreement, dated August 4, 2008, between The Medicines Company (Leipzig) GmbH and Curacyte AG (filed as Exhibit 2.1 of the registrant's current report on Form 8-K/A, filed on November 10, 2008)
- 2.2 Agreement and Plan of Merger among the registrant, Boxford Subsidiary Corporation, and Targanta Therapeutics Corporation, dated as of January 12, 2009 (filed as Exhibit 2.1 of the registrant's current report on Form 8-K, filed on January 14, 2009)
- 2.3† Amendment to Sale and Purchase Agreement dated December 14, 2009 between The Medicines Company (Leipzig) GmbH and Curacyte AG (filed as Exhibit 2.3 to the registrant's annual report on Form 10-K for the year ended December 31, 2009)
- 3.1 Third Amended and Restated Certificate of Incorporation of the registrant, as amended (filed as Exhibit 4.1 to the Amendment No. 1 to the registrant's registration statement on Form 8-A/A, filed July 14, 2005)
- 3.2 Amended and Restated By-laws of the registrant, as amended (filed as Exhibit 3.2 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
- 10.1 Amended and Restated Registration Rights Agreement, dated as of August 12, 1998, as amended, by and among the registrant and the other parties thereto (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2002)
- 10.2 Lease for 8 Campus Drive dated September 30, 2002 by and between Sylvan/Campus Realty L.L.C. and the registrant, as amended by the First Amendment and Second Amendment, (filed as Exhibit 10.15 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
- 10.3 Third Amendment to Lease for 8 Campus Drive dated December 30, 2004 by and between Sylvan/Campus Realty L.L.C. and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2004)
- 10.4 Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.32 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
- 10.5 Amendment to Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.40 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
- 10.6\* Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell (filed as Exhibit 10.12 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
- 10.7\* Letter Agreement dated March 2, 2006 by and between the registrant and Glenn P. Sblendorio, (filed as Exhibit 10.23 to the registrant's annual report on Form 10-K for the year ended December 31, 2005)
- 10.8\* Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Clive Meanwell and Glenn Sblendorio (filed as Exhibit 10.24 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
- 10.9\* Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Paul Antinori, William O'Connor and Leslie Rohrbacker (filed as Exhibit 10.25 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)

Table of Contents

Number Description

10.10*	Form of Lock-Up Agreement dated as of December 23, 2005 by and between the registrant and each of its executive officers and directors (filed as Exhibit 10.27 to the registrant's annual report on Form 10-K for the year ended December 31, 2005)
10.11*	1998 Stock Incentive Plan, as amended (filed as Exhibit 10.1 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.12*	Form of stock option agreement under 1998 Stock Incentive Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004)
10.13*	2000 Employee Stock Purchase Plan, as amended (filed as Exhibit 10.1 of the registrant's registration statement on Form S-8, filed on September 1, 2009)
10.14*	2000 Outside Director Stock Option Plan, as amended (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003)
10.15*	2001 Non-Officer, Non-Director Employee Stock Incentive Plan (filed as Exhibit 99.1 to the registration statement on Form S-8 filed December 5, 2001 (registration no. 333-74612))
10.16*	Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 99.1 to the registrant's registration statement on Form S-8, dated July 3, 2008)
10.17*	Form of stock option agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.22 to the registrant's annual report on Form 10-K for the year ended December 31, 2004)
10.18*	Form of restricted stock agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006)
10.19*	2007 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed January 11, 2008 (registration no. 333-148602))
10.20*	Form of stock option agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.34 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.21*	Form of restricted stock agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.35 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.22*	2009 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed February 24, 2009 (registration number 333-157499))
10.23*	Form of stock option agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.24*	Form of stock option agreement for employees in Italy under 2009 Equity Inducement Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.25*	Form of restricted stock agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.26*	Summary of Annual Cash Bonus Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008)
10.27*	Summary of Performance Measures under the registrant's Annual Cash Bonus Plan (filed in Item 5.02 of the registrant's current report on Form 8-K, filed on February 27, 2012)
10.28†	License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant (filed as Exhibit 10.6 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.29†	License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc. (filed as Exhibit 10.7 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.30†	License Agreement effective as of March 28, 2003 by and between AstraZeneca AB and the registrant
10.31†	Amendment No. 1 to License Agreement dated April 25, 2006 by and between AstraZeneca AB
10.32	Amendment No. 2 to License Agreement, dated October 22, 2008 by and between the registrant and AstraZeneca AB (filed as Exhibit 10.38 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)



Table of Contents

Number Description

10.33†	License Agreement dated as of December 18, 2003 by and between AstraZeneca AB and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
10.34†	Amendment to License Agreement dated July 6, 2007 between AstraZeneca AB and the registrant (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2007)
10.35	License Agreement, dated December 23, 2005 by and between Targanta Therapeutics Corporation (as successor to InterMune, Inc.) and Eli Lilly and Company (filed as Exhibit 10.11 to Targanta's registration statement on Form S-1 (registration no. 333-142842), as amended, originally filed with the SEC on May 11, 2007)
10.36	Contingent Payment Rights Agreement dated February 25, 2009 between the registrant and American Stock Transfer & Trust Company (filed as Exhibit 99.1 of the registrant's current report on Form 8-K, filed on March 2, 2009)
10.37†	License Agreement dated as of December 18, 2009 between the registrant and Pfizer Inc. (filed as Exhibit 10.41 to the registrant's annual report on Form 10-K for the year ended December 31, 2009)
10.38†	Consent and Release Agreement dated as of December 18, 2009 between the registrant and Washington Cardiovascular Associates, LLC, HDLT LLC, H. Bryan Brewer, Silvia Santamarina-Fojo and Michael Matin (filed as Exhibit 10.42 to the registrant's annual report on Form 10-K for the year ended December 31, 2009)
10.39†	Chemilog Development and Supply Agreement, dated as of December 20, 1999, by and between the registrant and UCB Bioproducts S.A. (filed as Exhibit 10.5 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.40	Second Amendment to License Agreement dated as of June 1, 2010 between AstraZeneca AB and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2010)
10.41*	The Medicines Company's 2010 Employee Stock Purchase Plan (incorporated by reference to Appendix I to the registrant's definitive proxy statement, dated and filed with the Securities and Exchange Commission on April 30, 2010, for the registrant's 2010 Annual Meeting of Stockholders)
10.42*	The Medicines Company's 2004 Amended and Restated Stock Incentive Plan, as amended (incorporated by reference to Appendix II to the registrant's definitive proxy statement, dated and filed with the Securities and Exchange Commission on April 30, 2010, for the registrant's 2010 Annual Meeting of Stockholders)
10.43	First Amendment to lease for 400 Fifth Avenue, Waltham, MA, dated as of June 30, 2010 by and between ATC Realty Sixteen Inc. and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010)
10.44*	Form of restricted stock agreement under the registrant's Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010)
10.45*	Restricted stock agreement of Clive Meanwell under the registrant's Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 10.53 to the registrant's annual report on Form 10-K for the year ended December 31, 2010)

Table of Contents

Number	Description
10.46†	Second Amended and Restated Distribution Agreement effective as of October 1, 2010 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.54 to the registrant's annual report on Form 10-K for the year ended December 31, 2010)
10.47†	Settlement Agreement and Release, dated February 14, 2011, between registrant and Wilmer Cutler Pickering Hale and Dorr LLP (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2011)
10.48	Fourth Amendment to Lease, dated June 30, 2011, between registrant and Sylvan/Campus Realty L.L.C. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2011)
10.49†	Manufacturing Services Agreement, dated March 30, 2011, between registrant and Patheon International A.G. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
10.50†	Settlement Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
10.51†	License Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
10.52†	Supply Agreement, dated September 30, 2011, between registrant and Plantex USA Inc. (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
10.53†	First Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc. (filed as Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
10.54†	Second Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc. (filed as Exhibit 10.6 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011)
21	Subsidiaries of the registrant
23	Consent of Ernst & Young LLP, Independent Registered Accounting Firm
31.1	Chief Executive Officer — Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer — Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chief Executive Officer — Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer — Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	The following materials from The Medicines Company Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statement of Operations, (iii) the Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements

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Management contract or compensatory plan or arrangement filed as an exhibit to this form pursuant to Items 15(a) and 15(c) of Form 10-K

- † Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission Unless otherwise indicated, the exhibits incorporated herein by reference were filed under Commission file number 000-31191.
- + In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this annual report on Form 10-K shall be deemed to be “furnished” and not “filed.”