

MEDICINES CO /DE  
Form 10-K  
March 01, 2013  
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-K  
(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934  
For the fiscal year ended: December 31, 2012

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	Name of Each Exchange on Which Registered
Common Stock, \$.001 Par Value Per Share	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, 2012 was approximately \$1,208,307,104 based on the last reported sale price of the Common Stock on The NASDAQ Global Select Market on June 29, 2012 of \$22.94 per share.

Number of shares of the registrant’s class of Common Stock outstanding as of February 25, 2013: 54,618,122.

**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, 2012. 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;

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Part III, Item 11. Executive Compensation;

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 Accounting Fees and Services.

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The Medicines Company® name and logo, Angiomax®, Angiox®, Cleviprex® and IONSYS™ 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.

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### PART I

#### Item 1. Business

##### Our Company

##### Overview

We are a global biopharmaceutical company focused on saving lives, alleviating suffering and improving the economic efficiency of the world's leading hospitals. We have four marketed products, Angiomax<sup>®</sup> (bivalirudin), Recothrom<sup>®</sup> Thrombin, topical (Recombinant), 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 four late-stage development product candidates, cangrelor, oritavancin, MDCO-157 and IONSYS<sup>™</sup> (fentanyl iontophoretic transdermal system), and early stage development product candidates, MDCO-216 and ALN-PCS02 and ALN-PCSsc of our ALN-PCS program. 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 to these products and product candidates, we have a portfolio of ten generic drugs, which we refer to as our acute care generic products that we have the non-exclusive right to market in the United States. We expect to begin selling certain of our acute care generic products in the first quarter of 2013. We also co-promote the oral tablet antiplatelet medicine BRILINTA<sup>®</sup> (ticagrelor) in the United States, as part of our global collaboration agreement with AstraZeneca LP, or AstraZeneca.

During 2012 and the first quarter of 2013, we continued to build our acute and intensive care portfolio of hospital products.

On January 22, 2012, we entered into a license and supply agreement with APP Pharmaceuticals, LLC, or APP, in connection with the settlement of our Angiomax 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 the acute care generic products to hospitals and integrated delivery networks in the United States.

On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. The first activity agreed to under the global collaboration is a four year co-promotion arrangement for BRILINTA in the United States.

In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company, or BMS, we acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period, which we refer to as the collaboration term, and certain limited assets exclusively related to Recothrom, primarily the biologics license application, or BLA, for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom.

In January 2013, we acquired Incline Therapeutics, Inc., or Incline, a company focused on the development of IONSYS, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting.

In February 2013, we entered into a license and collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam, for the development and commercialization of Alnylam's ALN-PCS RNAi therapeutic program for the treatment of hypercholesterolemia.

Additionally, during this period, we have continued to progress our clinical trial programs, including in particular with respect to cangrelor and oritavancin.

- Cangrelor. In January 2013, we announced that data analysis of our Phase 3 CHAMPION PHOENIX clinical trial revealed that the protocol defined primary composite efficacy endpoint of death, myocardial infarction,

ischemia driven revascularization and stent thrombosis at 48 hours had been met, as cangrelor demonstrated statistically significant improvement for this endpoint as compared to clopidogrel. Safety outcomes from the trial were similar to those observed in prior trials. We expect that the trial results will be presented at the American College of Cardiology Scientific Session in March 2013.

Oritavancin. In December 2012, we announced that in the SOLO I trial, oritavancin had met all protocol-specified primary and secondary efficacy endpoints and was shown to be non-inferior to vancomycin in the efficacy analyses for the early clinical evaluation (48-72 hour) endpoints required by the FDA and the later (7-14 days after end of treatment)



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endpoint required by the EMA. The efficacy of oritavancin was similar in the overall population and in those patients with microbiologically confirmed MRSA infections. In addition, overall, safety profiles between oritavancin and vancomycin were similar. As a result of the positive SOLO I trial results, we have accelerated enrollment in the SOLO II clinical trial and expect to announce data from the trial in mid-2013.

## Products and Products in Development

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, except for Recothrom, IONSYS and ALN-PCSsc, are administered intravenously. Recothrom is a topical hemostat, IONSYS is being developed to be administered transdermally and ALN-PCSsc is being developed as a subcutaneous injectable. All of our acute care generic products are injectable products.

Product or Product in Development	Development Stage	Mechanism/Target	Clinical Indication(s)/Therapeutic Areas
Marketed Products			
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 For use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical
Recothrom	Marketed in the United States and Canada	Recombinant human thrombin	

			procedures
	Marketed in the United States		
Cleviprex	Approved in Australia, Austria, Canada, France, Germany, the Netherlands, New Zealand, Sweden, Switzerland and the United Kingdom	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
	Marketing Authorization Application, or MAA, submitted for other European Union countries		
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

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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
Products in Development			
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	Short-term management of acute postoperative pain Platelet inhibition in patients suffering from ACS or patients recently experiencing myocardial infarction, or MI, stroke, or peripheral arterial disease when oral therapy is not feasible or not desirable
IONSYS	Pre-registration stage	Patient-controlled analgesia system	Reversal cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events
MDCO-157 (IV clopidogrel)	Pre-registration stage	Platelet inhibitor	
MDCO-216	Phase 1	Naturally occurring variant of a protein found in high-density lipoprotein, or HDL	
ALN-PCS program: ALN-PCS02 and ALN-PCSsc	Phase 1	PCSK-9 gene antagonist addressing low-density lipoprotein, or LDL, cholesterol disease modification	Treatment of hypercholesterolemia
Marketed Products			
Angiomax			
Overview			

Angiomax is an intravenous direct thrombin inhibitor that is a peptide compound. We licensed Angiomax from Biogen Idec, Inc., or Biogen Idec, in 1997 and have exclusive license rights to develop, market and sell Angiomax worldwide. Angiomax is approved 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/HITTS.

Angiomax is approved in the European Union 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. In Europe, we market Angiomax under the tradename Angiox.

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Angiomax is also approved for sale in Australia, Canada, New Zealand, Russia, India and a number of countries in Central America, South America and the Middle East for PCI indications similar to those approved by the U.S. Food and Drug Administration, or the FDA. In addition, Angiomax is approved in Canada for the treatment of patients with HIT/HITTS undergoing cardiac surgery.

In 2012, our net sales of Angiomax totaled approximately \$548.2 million, including approximately \$501.7 million of net sales in the United States.

### 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.

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.

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.

We continue to develop Angiomax for use in additional patient populations, including patients with structural heart disease, patients undergoing peripheral interventions, including carotid angioplasty, cardiovascular surgery and

patients with or at risk of HIT/HITTS.

Recothrom

Overview

Recothrom is a topical human recombinant thrombin. In February 2013, pursuant to a master transaction agreement with BMS, we acquired the right to sell, distribute and market Recothrom on a global basis during the collaboration term, and BMS transferred to us certain limited assets exclusively related to Recothrom, primarily the BLA for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the

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expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom. Recothrom was approved by the FDA in January 2008 and by Health Canada in December 2010 for use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical procedures.

In 2012, BMS reported net sales of Recothrom totaling approximately \$67.0 million.

### Medical Need

Thrombin is a specific blood-clotting enzyme that converts the protein fibrinogen to fibrin, the primary protein contained in newly formed blood clots. Thrombin also promotes clot formation by activating Factor XIII, another blood clotting protein, to strengthen the newly forming clot. Topical thrombin is widely used to stop diffuse (non-arterial) bleeding occurring during surgical procedures, when control of bleeding by standard surgical techniques, such as direct pressure, ligation, or cautery, is ineffective or impractical. Minimizing bleeding during surgical procedures is important to maintain visibility in the operating field, limit the use of transfused blood products and reduce peri- and post-operative complications. Thrombin is generally sold as a lyophilized powder stored at room temperature, which is dissolved in saline and absorbed onto a surgical sponge, embedded onto a hemostatic pad or sprayed directly for topical application to wounds. Currently, there are three types of topical thrombin available in the United States: bovine (cattle) plasma-derived, human-plasma derived and recombinant human thrombin.

We believe that there are important advantages to recombinant human thrombin as compared to other topical thrombin products. Other topical thrombin products are derived from human or bovine (cattle) plasma and are associated with potential safety risks directly attributable to their source, as described in the product labels. Recothrom, which is human thrombin produced using recombinant DNA technology, is inherently free from these risks.

### Clinical Development

Recothrom was developed as an alternative to the plasma-derived thrombins. The primary clinical development program, including the Phase 4 post-marketing commitment studies, was completed in 2010. Recothrom was approved by the FDA and Health Canada based upon a small Phase 1 dose-finding study, four placebo-controlled Phase 2 studies conducted simultaneously in four surgical settings, and a single Phase 3 pivotal study comparing Recothrom to Thrombin-JMI (bovine thrombin), a product currently marketed by Pfizer Inc., or Pfizer, in the same four surgical settings. In addition, a Phase 2 study of Recothrom applied using a spray applicator was conducted. Following the approval of Recothrom, a Phase 3b study in patients with known or highly likely prior exposure to bovine thrombin, as well as two Phase 4 post-marketing commitment studies regarding the safety and immunogenicity of Recothrom in patients re-exposed to the product and in pediatric patients were completed. These trials developed clinical data regarding Recothrom in patients undergoing various surgical procedures, including spinal surgery, peripheral arterial bypass, arteriovenous graft, hepatic resection and skin graft after burn wound excision.

The Phase 3 study was a comparability study, and Recothrom demonstrated similar efficacy to Thrombin-JMI, based on the incidence of hemostasis within 10 minutes after application. In addition, in the Phase 3 study, the overall incidence of adverse events was similar between the treatment groups, and Recothrom demonstrated statistically significantly lower immunogenicity (anti-product antibody formation) than Thrombin-JMI. The results of each study have been published, including an integrated safety and immunogenicity manuscript that was published in November 2012.

### Cleviprex

Cleviprex is an intravenous small molecule calcium channel blocker. We licensed Cleviprex from AstraZeneca AB, or AstraZeneca in March 2003 and 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.

In addition to the United States, Cleviprex is approved for sale in Australia, Austria, Canada, France, Germany, the Netherlands, New Zealand, Sweden, Switzerland and the United Kingdom with indications for blood pressure control in perioperative settings. However, 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. We have submitted MAAs for Cleviprex to member states of the European Union, pursuant to the European Union's decentralized procedure and are continuing to pursue approval in those countries.

In June 2011, the FDA approved a supplemental new drug application, or sNDA, that we submitted for an improved formulation of Cleviprex. The improved formulation triples the maximum allowable infusion time per vial, commonly referred to in hospitals as "hang time", to 12 hours compared to the four-hour hang time of the formulation approved by the FDA in 2008. We re-launched Cleviprex in October 2011 with the new formulation.



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In 2012, our net sales of Cleviprex totaled approximately \$3.0 million.

### 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 GlaxoSmithKline in a concentrated formulation and by Sandoz, a Novartis company, in two ready-to-use formulations, 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 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 ready-to-use Argatroban due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

In 2012, our net sales of ready-to-use Argatroban totaled approximately \$7.3 million.

### 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 certain of the acute care generic products in the first quarter of 2013.

### BRILINTA Co-promotion

On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca, pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, the first joint activity agreed upon by the parties under the global collaboration was a four-year co-promotion arrangement for BRILINTA in the United States. BRILINTA is approved for the reduction of the rate of thrombotic cardiovascular events in patients with ACS.

Our sales force began supporting promotion activities for BRILINTA in May 2012 under the collaboration agreement. In 2012, we recognized \$10.0 million in co-promotion income in 2012 under the collaboration agreement.

### Products in Development

#### 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. We plan to submit applications for marketing approval in the United States in the second quarter of 2013 and the European Union in the second half of 2013.

##### 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 also now available in various generic formulations.

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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 is recommended in treatment guidelines, no randomized controlled study has been conducted to show superiority in improvement of ischemic outcomes in coronary angioplasty. In addition, there are several other efficacy and safety issues with the use of this agent in acute and intensive care practice, including that the effect of clopidogrel can be delayed and variable because clopidogrel requires absorption from the gut and liver metabolism to form the active agent and such metabolism can be influenced by other medications.

Oral agents like clopidogrel have impaired bioavailability in patients in the acute and intensive care setting due to several issues, including nausea, impaired absorption and inability to swallow oral drugs because they received pre-procedural sedatives, are intubated or are in shock. This need for clopidogrel to be swallowed is particularly problematic when there is a need for patients to swallow multiple tablets in a restricted period of time.

In addition, there is currently no short-acting platelet inhibitor available that allows 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 coronary artery bypass grafts, or 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 and cardiovascular surgeons, we believe that the importance of reducing the possibility of ischemic events, including stent thrombosis, through platelet inhibition combined with the limitations of current oral therapy in acute and intensive care settings 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

We have evaluated cangrelor in 18 studies in approximately 13,800 patients and healthy volunteers since we licensed it from AstraZeneca in 2003. We plan to submit our applications for marketing approval of cangrelor on the basis of our CHAMPION PHOENIX and BRIDGE clinical trials.

**CHAMPION Program.** In October 2010, we commenced the CHAMPION PHOENIX Phase 3 clinical trial of cangrelor to evaluate the use of cangrelor in patients undergoing PCI. The trial was a double-blind parallel group randomized study, which compared cangrelor to a clopidogrel loading dose of 300mg or 600mg administered as soon as possible after it is determined that the patient will undergo PCI. In the trial, cangrelor was infused for at least two hours and up to four 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 at 48 hours after the procedure. The primary endpoint of the trial is measured by the composite incidence of death, MI, ischemia driven revascularization and stent thrombosis.

In October 2012, we completed enrollment of approximately 10,900 patients in the trial. Data analysis of the trial revealed that the protocol defined primary composite efficacy endpoint of death, myocardial infarction, ischemia driven revascularization and stent thrombosis at 48 hours was met, as cangrelor demonstrated statistically significant improvement for this endpoint as compared to clopidogrel. Safety outcomes from the trial were similar to those observed in prior trials. We expect that the trial results will be presented at the American College of Cardiology Scientific Session in March 2013.

Prior to conducting the CHAMPION PHOENIX trial, we had conducted two earlier Phase 3 trials of cangrelor. The CHAMPION-PCI and CHAMPION PLATFORM trials were 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. In May 2009, we discontinued enrollment in the trials prior to completion 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. 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.

In November 2009, the results of the CHAMPION-PCI and CHAMPION PLATFORM 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

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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. On this basis, in our PHOENIX study, we changed the process of endpoint evaluation as compared to the CHAMPION-PCI and CHAMPION PLATFORM clinical trials 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 prior to randomization.

**BRIDGE.** In the fourth quarter of 2008, we commenced a clinical trial, which we refer to as the BRIDGE trial, to assess 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 of establishing the dosage level of cangrelor that achieves inhibition of platelet aggregation at levels below the threshold needed for prevention of ischemia 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. 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, which originally discovered and developed oritavancin. 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. 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 European Medicines Agency, or 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.

We worked with the FDA and the EMA 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, as described below. We recently announced the results for the SOLO I trial and expect to have data from the SOLO II trial in mid-2013.

#### 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, as a result, are only effective against some serious pathogens but not others;

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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 reduce 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. In clinical trials, oritavancin has demonstrated 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

**SOLO.** The SOLO I and SOLO II clinical trials are identical multicenter, double-blind, randomized clinical trials in which a single 1,200 mg intravenous dose of oritavancin is compared with seven to 10 days of intravenous vancomycin treatment. The trials are designed 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. Additionally, the trials are designed to meet EMA drug approval requirements. 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. In October 2012, we completed enrollment in the SOLO I clinical trial. As of February 25, 2013, we had enrolled 939 of the expected 1,020 patients in the SOLO II clinical trial.

In December 2012, we announced that in the SOLO I trial, oritavancin had met all protocol-specified primary and secondary efficacy endpoints and was shown to be non-inferior to vancomycin in the efficacy analyses for the early clinical evaluation (48-72 hour) endpoints required by the FDA and the later (7-14 days after end of treatment) endpoint required by the EMA. The efficacy of oritavancin was similar in the overall population and in those patients with microbiologically confirmed MRSA infections and, overall, safety profiles between oritavancin and vancomycin were similar. As a result of the positive SOLO I trial results, we have accelerated enrollment in the SOLO II clinical trial and expect to announce data from the trial in mid-2013. If the results of the trials warrant, we would expect to submit an NDA in mid-2013.

**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 ABSSSI. 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 Studies.** 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. In the first quarter of 2013, we conducted a double-blind, randomized, placebo-controlled, parallel-design, study with an open-label positive-control, to assess the cardiac safety of oritavancin in 149 healthy volunteers. The trial is designed to assess the effect of the supratherapeutic 1600 mg dose of oritavancin on cardiac repolarization as assessed by the

QT interval corrected for pulse rate (QTcF). We expect to announce data from the trial in the first half of 2013. 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.



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

### IONSYS

IONSYS (fentanyl iontophoretic transdermal system) is a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting. In January 2013, we completed our acquisition of Incline Therapeutics, Inc., or Incline, a company focused on the development of IONSYS.

IONSYS was originally developed and evaluated in an extensive clinical program, including seven Phase III clinical trials. IONSYS was approved by the FDA in the United States in 2006 but was never launched. IONSYS was approved by the EMA in Europe in 2006 and launched in Europe in 2008. However, due to device stability issues, IONSYS was voluntarily recalled later that year. The MAA was suspended and subsequently expired in 2011. In 2010, ALZA Corporation, or ALZA, licensed IONSYS to Incline and Incline developed an enhanced version of the system to address the device stability issues while further increasing reliability and improving usability.

Current patient-controlled pain management systems, known as IV PCAs, are controlled infusions pumps that deliver a prescribed amount of an opioid intravenously when a patient activates a button connected to the pump. Although IV PCAs are commonly used during hospitalization after surgery, IV PCAs have been associated with programming, medication, and pump errors, IV line complications, limited patient mobility, and consumption of significant amounts of hospital resources.

We expect key results from a pharmacokinetic study and usability study of IONSYS in the second quarter of 2013.

The objective of the pharmacokinetic study is to demonstrate bioequivalence of fentanyl absorbed between the enhanced IONSYS system and the previously approved IONSYS system in healthy volunteers. The objective of the usability study is to assess potential errors or operational difficulties with the enhanced IONSYS system in post-operative patients experienced by nurses, pharmacists and the patients themselves. We anticipate that, if positive, these results will form the basis for submission of a sNDA in the United States and an MAA in Europe.

### MDCO-157

MDCO-157 is a Captisol®-enabled intravenous formulation of clopidogrel bisulfate. 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 and to related know-how.

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 commenced, in the third quarter of 2012, a pharmacokinetic and pharmacodynamic study of several doses of MDCO-157 and oral clopidogrel in healthy volunteers. We expect to have data from this study in the first half of 2013. In addition, we are conducting commercial assessments of the market for MDCO-157, including the market needs, value proposition and decision making on formulary access and pricing.

### 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 in December 2009. In multiple non-clinical studies, MDCO-216 rapidly removed excess cholesterol from artery walls, thereby stabilizing and regressing atherosclerotic plaque. In a Phase 2 study conducted from 2001 through 2003 in 57 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, following our license with Pfizer, we completed a technology transfer program with Pfizer related to improved manufacturing methodologies developed by Pfizer since the Phase 2 trial of MDCO-216. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in preclinical and clinical 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 commenced a Phase 1 single ascending dose study of MDCO-216 in February 2013 to investigate the safety and tolerability of escalating single doses of MDCO-216 in healthy volunteers and in patients with stable coronary artery disease. This study will also characterize the single dose pharmacokinetics and pharmacodynamics of MDCO-216.

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### ALN-PCS Program

The ALN-PCS program is a development program which includes ALN-PCS02, an intravenously administered RNA interference, or RNAi, therapeutic, and ALN-PCSsc, a subcutaneously administered RNAi therapeutic. In February 2013, we entered into a license and collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam, to develop, manufacture and commercialize RNAi therapeutics targeting the proprotein convertase subtilisin/ kexin type 9, or PCSK9, gene for the treatment of hypercholesterolemia and other human diseases. RNAi is a naturally occurring biological pathway within cells for selectively silencing and regulating the expression of specific genes. PCSK9 is a gene involved in the regulation of LDL receptor levels on hepatocytes and the metabolism of LDL cholesterol, which is commonly referred to as “bad” cholesterol.

Under our agreement with Alnylam, we and Alnylam are collaborating in the development of ALN-PCS02 or ALN-PCSsc. Alnylam is responsible for the development of these product candidates until Phase 1 completion. We have assumed all other responsibility for the development and commercialization of all product candidates under our agreement with Alnylam. Initially, we are focusing on the development of both ALN-PCS02 and ALN-PCSsc in parallel. We and Alnylam intend to select one of ALN-PCS02 or ALN-PCSsc for ongoing development at a specified development stage, in accordance with the terms of the agreement.

### Sales and Distribution

We market and sell Angiomax, Cleviprex and our ready-to-use Argatroban in the United States with a sales force experienced in selling to hospital customers. As of December 31, 2012, our sales force consisted of 120 representatives, whom we refer to as engagement partners, associate engagement partners and engagement managers. We are also using our sales force to sell BRILINTA under our collaboration agreement with AstraZeneca and we expect to use our sales force to sell the acute care generic products. In February 2013, in connection with our arrangement with BMS with respect to Recothrom, we hired 51 sales persons from BMS. We expect such sales persons to sell Recothrom and possibly other of our products. In support of our sales efforts, we focus

- our Angiomax and BRILINTA sales efforts in the United States on hospital systems, individual hospitals, and health care providers, including interventional cardiologists in cardiac catheterization laboratories;
- our Cleviprex sales efforts on hospital systems, individual hospitals, and health care providers; and
- our ready-to-use Argatroban sales efforts on hospital systems, including hospital pharmacies.

We expect to focus our Recothrom sales efforts on the top 1,300 accounts where surgical procedures, including orthopedic, burn, trauma, plastic, vascular, cardiothoracic, neurosurgical and general surgery, are performed in the United States. 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 our ready-to-use Argatroban in the United States through a sole source distribution model with Integrated Commercialization Solutions, or ICS. Under this model, we currently sell Angiomax, Cleviprex and ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax, Cleviprex and 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 and, commencing in the second quarter of 2013, Recothrom, through the same sole source distribution model.

Our agreement with ICS, which we initially entered into in 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 connection with a reduction in marketing, sales and distribution fees payable to ICS, in October 2010 we amended our agreement with ICS to extend 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

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accounts receivable. We expect to enter into an amendment to our agreement with ICS to include the acute generic products and Recothrom under the agreement.

In Europe, we market and sell Angiomax, which we market under the trade name Angiox, with a sales force that is experienced in selling to hospital customers. As of December 31, 2012, our sales force in Europe consisted of 31 engagement partners and engagement managers. Our European sales force targets hospitals with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. 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, which has a sales force of one engagement partner and three engagement managers. We also have agreements with other third parties for other countries outside of the United States, including Israel, Russia and certain countries in the Middle East. In January 2012, we reacquired our rights to sell Angiomax in Australia and New Zealand from CSL Limited and are now marketing and selling Angiomax in those two countries with a sales force consisting of, as of December 31, 2012, two engagement partners and three engagement managers in those countries. 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 additional countries.

To support the commercialization and distribution efforts of Angiomax outside the United States, 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, Hong Kong, 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, Turkey and the Middle East. We believe that by establishing operations outside the United States for Angiomax, we will be positioned to commercialize Cleviprex, Recothrom and our products in development, if and when they are approved outside 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., or Lonza Braine, 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 2016, 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-months' 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, effective immediately, if a generic form of bivalirudin is launched. 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

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breaches of the license agreement entered into by us with Teva API on September 30, 2011 in connection with the settlement of our Angiomax patent litigation.

**Drug Product.** 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 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. Recothrom

In connection with our master transaction agreement with BMS, BMS has agreed that either BMS or one of its affiliates will supply us with Recothrom during the collaboration term at specified purchase prices under a supply agreement we entered into with BMS in December 2012. The supply agreement expires upon the completion or earlier termination of the collaboration term in accordance with the master transaction agreement, unless the parties mutually agree, at least one month prior to the expiration of the term, to extend the term for a period of 12 months. Either we or BMS may terminate the supply agreement due to the material breach of the terms of the agreement by the other party, if the material breach is not cured within 30 days after receipt of written notice of such breach, if the breach reasonably cannot be cured within such 30 day-period or, if the breaching party does not commence and diligently continue actions to cure such default during such 30 day-period. If a sub-contractor of BMS is the cause of the breach, we are entitled to terminate the supply agreement only with respect to those complete products or components of products that are produced by the breaching sub-contractor.

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 manufactured according to the original formulation for the intravenous treatment of primarily peri-operative hypertension using its proprietary formulation technology. Under this agreement, Hospira supplied us with the formulation of Cleviprex that was originally approved by the FDA.



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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 improved formulation of Cleviprex drug product that the FDA approved in June 2011. 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.

### Ready-to-Use Argatroban

In connection with our license of the marketing rights to Eagle's formulation of Argatroban, Eagle has agreed to supply us with ready-to-use Argatroban at a specified price for certain initial lots and then at the lower of the specified price or a price equal to Eagle's costs, under a supply agreement we entered into with Eagle in September 2009 and amended in September 2012. The supply agreement expires at the earlier of the termination of our license agreement with Eagle or September 24, 2019.

### Acute Care Generic Products

APP, a division of Fresenius Kabi USA, LLC, has agreed to supply and we have agreed to purchase from APP, our entire requirement for the acute care generic products under the license and supply agreement we entered into with APP in January 2012. Under the terms of this agreement, we are required pay APP's cost of goods for the supply of the acute care generic products on an ongoing basis. The term of the license and supply agreement ends January 22, 2022. Either 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.

### 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 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 January 2013, Abbott separated into two independent

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companies, Abbott and AbbVie Inc. As a result of the separation, our development and supply agreement regarding oritavancin is now with AbbVie Inc.

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

Drug Product. 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.

### IONSYS

Bulk Drug Substance. Prior to our acquisition of Incline, Incline entered into an agreement with Johnson Matthey for the supply of fentanyl hydrochloride, the drug delivered by the IONSYS system, for development, clinical and initial commercial production. We expect to enter into a long term commercial supply agreement for fentanyl hydrochloride with Johnson Matthey.

Drug Unit Manufacturing. In February 2011, Incline entered into agreements with DPT Laboratories, or DPT, for the transfer and management of the process equipment used for to manufacture the drug unit part of the IONSYS system. In January 2012, Incline entered into an agreement for the manufacture, testing and supply of product for development and clinical trial use. We expect to enter into a supply agreement with DPT for commercial drug unit manufacture and testing and final product packaging.

Controller Manufacturing. The electronic component of the IONSYS system, referred to as the controller, is manufactured by Sanmina Corporation, or Sanmina. In January 2011, Incline entered into an agreement with Sanmina for manufacturing process development and supply of controllers for development, clinical trial and design verification testing use. We expect to enter into a supply agreement with Sanmina for commercial supply of the controller for the IONSYS system.

The controller uses an application specific integrated circuit, or ASIC, manufactured by On Semiconductor. In November 2010, Incline entered into an agreement with On Semiconductor for the development and qualification of the ASIC, and supply of components for development, clinical trial and design verification testing. We expect to enter into a supply agreement with On Semiconductor for commercial supply of ASICs for the controller of the IONSYS system.

### MDCO-157

We currently obtain our supply of MDCO-157 bulk drug substance and drug product for our clinical trials from third-party manufacturers in Israel and Canada 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 our licensing agreement with Ligand. Either party may terminate the agreement for the other's material breach on the same terms as those of the license agreement with Ligand.

### 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 ongoing 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. In February 2013, we entered into an agreement with Lonza Ltd. for manufacturing processing development and the production of certain quantities of MDCO-216 drug product.

### ALN-PCS Program

Under our agreement with Alnylam, Alnylam has agreed to use commercially reasonable efforts to supply the quantity of finished product reasonably required for the conduct of the first Phase 1 clinical trial and for the first Phase 2 clinical trial of a product candidate. Alnylam will bear the costs of these activities, subject to certain agreed upon caps. After such time, we will have the sole right and responsibility to manufacture and supply licensed product for development and commercialization under our development plan. We and Alnylam intend to enter into a development supply agreement under which Alnylam will supply us with the finished product for the first Phase 2 clinical trial and will transfer the manufacturing technology for the product to us or our third-party manufacturers.

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### Business Development Strategy

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 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 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.

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### Recothrom

Recothrom is a surgical hemostat that is applied topically during surgery to stop bleeding. There are a number of different classes of topical hemostats including:

- the Gelfoam Plus hemostasis kit marketed by Baxter Healthcare Corporation;
- mechanical hemostats, such as absorbable gelatin sponge, collagen, cellulose, or polysaccharide-based hemostats applied as sponges, fleeces, bandages, or microspheres, which do not contain thrombin or any other active biologic compounds;
- active hemostats, which are thrombin products that may be derived from bovine or human pooled plasma purification or human recombinant manufacturing processes;
- flowable hemostats, which consist of granular collagen or gelatin component that is mixed with saline or reconstituted thrombin to form a semi-solid, flowable putty; and
- fibrin sealants, which consist of thrombin and fibrinogen that can be sprayed or applied directly to the bleeding surface.

The choice of a surgical hemostat depends on the surgical procedure, type and strength of bleeding, surgeon preference, price and availability of products within the operating room or hospital.

Recothrom competes with each of these types of surgical hemostats as well as other active hemostats. Recothrom is the only active hemostat that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or in combination with a variety of other currently available mechanical and flowable hemostat products that are labeled for use with thrombin. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, THROMBIN-JMI®, a bovine derived thrombin marketed by Pfizer, and EVITHROM®, a human pooled plasma thrombin marketed by Ethicon, Inc., a subsidiary of Johnson & Johnson. In addition, Baxter International, Inc. markets the GELFOAM Plus Hemostasis Kit, which is Pfizer Inc.'s GELFOAM sterile sponge co-packaged with human plasma-derived thrombin. Further, a number of companies, including Johnson & Johnson, Pfizer and Baxter International, Inc., currently market other hemostatic agents that may compete with RECOTHROM, including passive agents such as gelatin and collagen pads and flowable hemostats, as well as fibrin sealants and tissue glues. Many of these alternative hemostatic agents are relatively inexpensive and have been widely used for many years.

### Cleviprex

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.

### Ready-to-Use Argatroban

Our ready-to-use formulation of Argatroban that we license from Eagle competes with marketed versions of Argatroban promoted by GlaxoSmithKline and by Sandoz. In the first quarter of 2013, Sandoz launched a second generic version of ready-to-use Argatroban with the same size specifications as our ready-to-use formulation. In addition, we expect our ready-to-use Argatroban to compete with other potential generic versions of a ready-to-use formulation or other innovative forms of the product. We believe that our infrastructure and relationships with customers are our competitive strengths in competing with the other generic versions of Argatroban.

### 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. We believe that our infrastructure and relationships with customers are our competitive strengths in competing with respective brand name reference products and other equivalent generic products of the acute care generic products.

### 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 (clopidogrel) from Bristol Meyers Squibb/Sanofi Pharmaceuticals

Partnership and generic formulations of clopidogrel, Effient (prasugrel), an anti-platelet agent from Eli Lilly and Daiichi Sankyo, and BRILINTA. We believe that cangrelor, if approved, will compete with these products on the basis of its profile which addresses the needs in acute intensive care setting by combining its bioavailability with platelet inhibition to prevent thrombotic events and achieve fast offset of effect to prevent bleeding risk during and after surgery.



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### 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. In addition, there are a number of new drugs that address serious gram positive infection in late stage development that could compete with oritavancin if both products receive marketing approval. 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.

### IONSYS

We believe that IONSYS, if approved, will compete with a number of injectable opioid delivery systems, including nurse-administered bolus injections, epidurals, and IV PCA. The primary competition for IONSYS is the IV PCA pump, which is widely used in the post-operative setting. Leading manufacturers of IV PCA pumps include Hospira Inc., CareFusion Corporation, Baxter International Inc., Curlin Medical, Inc. and Smiths Medical. An additional potential patient-controlled competitor for IONSYS is an oral sufentanil dispensing system, NanoTab, which is in Phase 3 development by AcclRx, Inc. We believe that IONSYS has advantages over other patient-controlled systems due to its reduced potential for medication errors, a smaller overall opioid-related adverse event burden, improved postoperative mobility, fewer analgesic gaps, and reduced labor requirements.

### 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 (clopidogrel) from Bristol Meyers Squibb/Sanofi Pharmaceuticals Partnership and generic formulations of clopidogrel, Effient (prasugrel), an anti-platelet agent from Eli Lilly and Daiichi Sankyo, and BRILINTA. We believe that MDCO-157, if approved, will compete with these products on the basis of improved bioavailability and faster onset of effect required in acute intensive care setting.

### 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.

The principal U.S. patents covering Angiomax include U.S. Patent No. 5,196,404, or the '404 patent, U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent. The '404 patent covers the composition of matter of Angiomax. The '404 patent is set to expire in December 2014. 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.

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. In

September 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. The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva), license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents. In January 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,

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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 patent infringement litigation involving the '727 patent and '343 patent are described in more detail in Part I, Item 3, Legal Proceedings, of this annual report.

In Europe, the principal patent covering Angiomax expires in 2015. This patent covers the composition of matter of Angiomax.

Recothrom. We have exclusively licensed from BMS rights to patents and patent applications covering Recothrom's pharmaceutical compositions, formulations and methods of manufacturing. The expiration dates of these patents range from 2013 to 2030 in the United States. BMS has also filed and is currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. As a biologic, we believe Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020.

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. The '346 patent was set to expire in January 2016, but the term was extended to January 2021 by the PTO under the Hatch-Waxman Act. 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. 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.

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.

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 issued patents directed to cangrelor pharmaceutical compositions which expire in 2017 and 2018 if no patent term extension is obtained. 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 issued patents directed to the process of making oritavancin. These patents are set to expire in 2017 if no patent term extension is obtained. In February 2013, the PTO issued to us an allowance for a patent application covering the use of oritavancin in treating certain skin infections. Upon its issuance, the resulting patent will expire in August 2029 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.

IONSYS. As a result of our acquisition of Incline, we acquired a portfolio of patents and patent applications covering the IONSYS device and its uses. Some of these patents and patent applications were exclusively licensed from ALZA. The expiration dates of patents covering the IONSYS device and its use range from September 2014 to September 2031 in the United States. In Europe, the expiration date of patents covering the IONSYS device range from June 2015 to January 2021. We are also currently prosecuting patent applications relating to IONSYS in the United States and in certain foreign countries.

MDCO-157. We have exclusively licensed from Ligand rights to patents and patent applications covering MDCO-157 formulations and its uses. The principal U.S. patent, U.S. Patent No. 8,343,995, or the '995 patent, is set to expire in April 2028 if no patent term extension is obtained. The corresponding patent application is pending in Europe, and if issued, will expire in April 2028. We are also prosecuting a number of patent applications relating to MDCO-157 in the United States and in certain foreign countries.

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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 if not patent term extension is obtained. 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. As a biologic, we believe MDCO-216 is entitled to receive 12 years of regulatory exclusivity as a "reference product" 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.

ALN-PCS Program. We have exclusively licensed from Alnylam patents and patent applications covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases. These patents generally expire between 2015 and 2023 both in the United States and in certain foreign countries. In addition, Alnylam has filed and is prosecuting patent applications that are specifically directed to PCSK9 product. 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®, Cleviprex® and IONSYSTM 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 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.

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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 2012, we incurred approximately \$119.4 million in royalties related to Angiomax under our agreement with Biogen Idec. In August 2012, we and Biogen Idec amended the license agreement providing, among other things, that effective solely for the period from January 1, 2013 through and including December 15, 2014, each of the royalty rate percentages payable by us as set forth in the license agreement would be increased by one percentage point.

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. During 2012, we incurred approximately \$2.8 million in royalties related to Angiomax under the agreement with HRI.

Recothrom. In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company, or BMS, we acquired the right to sell, distribute and market Recothrom on a global basis for a two year period, which we refer to as the collaboration term, and certain limited assets exclusively related to Recothrom, primarily the BLA for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom. Under the master transaction agreement, we paid to BMS a one-time collaboration fee equal to \$105.0 million and a one-time option fee equal to \$10.0 million. We did not assume, and if we exercise the option, we will not assume, any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and we did not acquire, and if we exercise the option, we will not acquire, any significant tangible assets related to the Recothrom business. Under the master transaction agreement, we agreed to pay to BMS quarterly tiered royalty payments during the two year collaboration term equal to a percentage of worldwide net sales of Recothrom.

If we exercise the option, we would acquire such assets and assume certain liabilities of BMS and its affiliates related to those assets and to pay to BMS a purchase price equal to the net book value of inventory included in the acquired

assets, plus either:

a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase of the assets to be acquired in connection with exercising the option (unless such closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding such closing); or if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by us under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.

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



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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 2012, we incurred \$1.0 million in royalties related to Cleviprex under our agreement with AstraZeneca.

**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, which has been reduced to \$5 million as certain milestones have not been achieved by specified dates, 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 settlement documents with APP, including 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 settlement documents, we made a one-time, upfront payments of \$32 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.

BRILINTA. On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, a joint development and research committee and a joint commercialization committee have been established to prepare and deliver a global development plan and a country-by-country collaboration and commercialization plan, respectively, related to BRILINTA and Angiomax and cangrelor. Implementation of these plans is subject to agreement between both parties. The first joint activity agreed upon by the parties under the global collaboration was a four-year co-promotion arrangement for BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. Under the terms of the agreement, AstraZeneca agreed to pay us \$2.5 million for conducting BRILINTA co-promotion activities during the period from the effective date of the agreement through June 30, 2012, \$7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from July 1, 2012 to December 31, 2012, plus up to \$2.5 million in additional consideration for the same period, contingent upon the number of new prescriptions written during that period, \$15.0 million in base consideration per year from 2013 through 2015 for conducting BRILINTA co-promotion activities,

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plus up to an additional \$5.0 million per year from 2013 to 2015 if certain performance targets with respect to new prescriptions are achieved and \$7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from January 1, 2016 until June 30, 2016, plus up to an additional \$2.5 million in additional consideration for the same period if certain performance targets with respect to new prescriptions are achieved. We and AstraZeneca have not agreed as to any development and commercialization activities to be performed with respect to Angiomax and cangrelor or as to any terms under which such activities would be performed.

Either party may terminate the agreement upon an uncured material breach of the agreement by the other party. In addition, either party may terminate the agreement upon the occurrence of certain events, including the withdrawal of BRILINTA from the market, and the entry into the market of a generic version of BRILINTA which achieves a specified market share. Either party may terminate the agreement if a change of control of us occurs involving certain companies described and identified in the agreement and we may terminate the agreement if AstraZeneca transfers its rights in BRILINTA to any of such companies.

At the end of the second year of the agreement, AstraZeneca may terminate the agreement if performance targets for the second year are not achieved. Conversely, we may terminate the agreement at such time if the performance targets for the second year are achieved. Either party may terminate the agreement at the end of the third year of the agreement. If AstraZeneca elects to terminate the agreement at the end of the third year and the performance targets for the third year have been achieved, AstraZeneca must pay us a termination fee of \$5 million.

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 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. IONSYS. As a result of our acquisition of Incline, we are a party to a license agreement with ALZA through our Incline subsidiary. Under the terms of the agreement, Incline acquired from ALZA certain rights to the IONSYS product and ALZA transferred to Incline specified trademarks, know-how, domain names and tangible assets relating to the IONSYS product. ALZA also granted Incline worldwide licenses under specified patent rights and know-how to develop, manufacture and commercialize iontophoretic transdermal systems providing delivery under the influence of an electric current which is from a source external to the human body

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of specified fentanyl analogs. The licenses granted by ALZA under the agreement are exclusive with respect to specified patent rights and know-how and nonexclusive under other specified patent rights.

We, through our subsidiary, Incline have the sole responsibility for the development and commercialization of licensed products under the agreement, and are required to use commercially reasonable efforts to develop and commercialize at least one licensed product in the United States, United Kingdom, Germany, France, Italy and Spain. In addition to the other rights and licenses granted to Incline under the ALZA Agreement, if, at any time during the 10-year period following the date of the agreement, ALZA wishes to grant a license under specified licensed patents to a third party, other than in connection with the settlement of litigation, to develop, manufacture and/or commercialize specified systems that deliver opioid compounds or combinations of opioid compounds with fentanyl analogs or generic compounds, in each case that do not contain any active compound that is proprietary to, licensed by or otherwise controlled by the third party or, except for specified fentanyl analogs, by ALZA, then we will have a right of first negotiation to obtain the proposed license.

If, at any time during the 10-year period following the date of the agreement, we wish to obtain from ALZA a license under specified licensed patents to develop, manufacture and/or commercialize specified systems that deliver generic compounds, combinations of generic compounds with fentanyl analogs or compounds exclusively owned, licensed or otherwise controlled by Incline, alone or in combination with generic compounds or specified fentanyl analogs, in each case that do not contain any active compound, other than specified fentanyl analogs, that is proprietary to, licensed by or otherwise controlled by ALZA or that is a generic drug owned, licensed or controlled by ALZA, then upon notice to ALZA of our desire to obtain the license, ALZA will be obligated to negotiate in good faith with Incline to grant the proposed license.

Under the ALZA Agreement, Incline paid ALZA an upfront payment and we will be obligated to pay ALZA up to an aggregate of \$32.5 million in regulatory and commercial launch milestone payments and up to an aggregate of \$86.0 million in sales milestone payments. ALZA is also entitled to specified royalties based on net sales of licensed products, on a licensed product-by-licensed product and country-by-country basis, during the period commencing on the first commercial sale of the licensed product in the applicable country and ending on the latest of the expiration of the licensed patents covering the licensed product, the expiration of applicable regulatory exclusivity or the 20th anniversary of the first commercial sale of the licensed product in the applicable country. We will also be required to pay amounts that become payable, if any, under specified ALZA third party licenses as a result of our development and commercialization of licensed products.

Either ALZA or we may terminate the agreement due to the other party's material breach of the agreement if such breach is not cured within 60 days of notice of the breach except that if the breach relates solely to the United States, any country in Europe or any other country in the world, the termination right shall apply to the United States, applicable countries in Europe or the rest of the world (other than the US and Europe), as the case may be. ALZA may also terminate the agreement due to our bankruptcy. Neither party has any discretionary right to terminate the agreement. If not terminated earlier pursuant to its terms, the agreement terminates upon the expiration and satisfaction of all payment obligations under the agreement.

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 an 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

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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 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.

**ALN-PCS Program.** In February 2013, we entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize therapeutic products targeting the human PCSK-9 gene based on certain of Alnylam's RNAi technology. Under the terms of the agreement, we obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. We paid Alnylam \$25 million in an initial license payment and agreed to pay up to \$180 million in success-based development and commercialization milestones. In addition, Alnylam will be eligible to receive scaled double-digit royalties based on annual worldwide net sales of PCSK-9 products by us or our affiliates and sublicensees. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country. The royalties are subject to reduction in specified circumstances. We are also responsible for paying royalties, and in some cases milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products.

The agreement expires when the last royalty term expires under the agreement, unless earlier terminated. We may terminate the agreement at any time with four months prior written notice to Alnylam. Either party may terminate the agreement on 60 days (10 days in the event of a payment breach) prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period. Such cure period may be extended in certain circumstances. Alnylam may terminate the agreement upon 30 days prior written notice to us if a lead product has not been designated by the joint steering committee prior to the earlier of (a) the date 30 days after the date Alnylam reaches the development costs cap unless we have agreed to pay the relevant extra costs and (b) June 30, 2015. If the agreement is terminated by us for convenience, by Alnylam for our uncured material breach or challenge of the patents licensed from Alnylam, or by Alnylam if the lead product is not designated prior to the deadlines set forth above, we have agreed to grant a license to Alnylam under certain of its technology developed in the course of our activities under the Agreement, subject to a royalty to be negotiated between the parties, and we will provide certain other assistance to Alnylam to continue the development and commercialization of the products. The exclusivity restrictions imposed on us will survive termination of the agreement for specified periods of time if we terminate the agreement for convenience or if Alnylam terminates the agreement for cause or for a patent challenge by us.

### 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 and ready-to-use Argatroban in September 2011. We expect to begin selling Recothrom to ICS in the second quarter of 2013. ICS accounted for 90% of our net revenue in 2012, 96% of our net revenue in 2011 and 94% of our net revenue in 2010. At December 31, 2012, amounts due from ICS represented approximately \$92.3 million, or 89%, of gross accounts receivable. 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.

#### 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



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and after approval is obtained, violations of regulatory requirements may result in various adverse consequences, including, among other things, clinical holds, untitled letters, warning letters, fines and other monetary penalties, the FDA's 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 generally 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 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

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

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.

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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 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.

### Marketing Approval

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. The submission of an NDA or BLA typically requires the payment of a significant user fee to FDA. 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.

The FDA regulates combinations of products that cross FDA centers, such as drug, biologic or medical device components that are physically, chemically or otherwise combined into a single entity, as a combination product. The FDA center with primary jurisdiction for the combination product will take the lead in the premarket review of the product, with the other center consulting or collaborating with the lead center, and often will require approval of only a single application, such as an NDA or BLA. The FDA's Office of Combination Products, or OCP, determines which center will have primary jurisdiction for the combination product based on the combination product's "primary mode of action." A mode of action is the means by which a product achieves an intended therapeutic effect or action. The primary mode of action is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. For example, our IONSYS product is considered to be a combination drug-device product, but because it has a primary mode of action of a drug, it has been approved under an NDA by FDA's Center for Drug Evaluation and Research, or CDER.

### Manufacturing Requirements

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 or modification 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.

#### Abbreviated New Drug Applications and Section 505(b)(2) New Drug Applications

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. 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,

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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 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, unless the exclusivity period protects an indication or other aspect of labeling that can be “carved out” of the labeling for the proposed generic product. 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

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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 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.

### Biologics Price Competition and Innovation Act

Under the Biologics Price Competition and Innovation Act, or BPCIA, enacted in the United States in 2010, the FDA now has the authority to approve biosimilar or interchangeable versions of previously-approved 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, also known as a reference product, 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 reference product. The FDA, however, has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA provisions, including the exclusivity provisions for reference products. 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.

### Patient Protection and Affordable Care Act

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 other than the BPCIA provisions of PPACA discussed above. 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.

### GAIN Provisions of Food and Drug Administration Safety and Innovation Act

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act, or FDASIA. Under the “Generating Antibiotic Incentives Now,” or GAIN, provisions of FDASIA, the FDA may designate a product as a qualified infectious disease product, or QIDP. A QIDP is defined as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or a so-called “qualifying pathogen” found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. The GAIN provisions describe several examples of “qualifying pathogens,” including methicillin-resistant *Staphylococcus aureus*, or MRSA, and *Clostridium difficile*. Upon the designation of a drug by the FDA as a QIDP, any non-patent exclusivity period awarded to the drug will be extended by an additional five years. This extension is in addition to any pediatric exclusivity extension awarded.

We are currently developing oritavancin for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of oritavancin for other indications, including for the treatment of Clostridium difficile, prosthetic joint infections, anthrax and other Gram-positive bacterial infections. We believe that oritavancin may qualify as a QIDP and intend to request that oritavancin be designated as a QIDP. If we are successful in having oritavancin designated as a QIDP by the FDA under the GAIN provisions of the new FDASIA legislation, we expect the non-patent exclusivity awarded to oritavancin upon approval of an NDA to be extended by an additional five years.

Pharmaceutical Coverage, Pricing and Reimbursement

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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 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

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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 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 \$126.4 million in 2012, \$110.2 million in 2011 and \$85.2 million in 2010.

## Employees

As of February 25, 2013, we employed 538 persons worldwide, which included 26 employees added in connection with our January 2013 acquisition of Incline and 72 employees added in connection with our February 2013 agreement with BMS. 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 February 2013, we commenced implementation of a workforce reduction plan intended to improve efficiency and better align our costs and employment structure with our strategic plans. As a result of the workforce reduction, we reduced our personnel by 66 employees. Affected employees will be eligible to

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receive reduction payments in specified amounts and fully paid health care coverage and outplacement services for specified periods. 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

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. We expect revenue from Angiomax to account for the significant majority of our revenue in 2013. The commercial success of Angiomax depends upon:

our ability to maintain market exclusivity for Angiomax in the United States through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of 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.

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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/HITTS. We may not be successful in developing Angiomax and obtaining marketing approval of Angiomax for these additional patient populations. However, even if we are successful in obtaining approval for the use of Angiomax in additional patient populations, our ability to sell Angiomax for use in these additional patient populations may not result in higher revenue or income on a continuing basis.

As of December 31, 2012, our inventory of Angiomax was \$75.6 million, and we had inventory-related purchase commitments totaling \$29.9 million for 2013, \$26.6 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 products and our products in development. We also will require cash to pay interest on the \$275.0 million aggregate principal amount of our 1.375% convertible senior notes due 2017, or the Notes, and to make principal payments on the Notes at maturity or upon conversion. Our sources of funding to meet these requirements will 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 through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

- the extent to which Cleviprex, ready-to-use Argatroban, Recothrom 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 our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

- the extent to which we are successful in our efforts to establish 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, MDCO-157, IONSYS 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 and Recothrom outside the United States 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,



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products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the \$275 million in outstanding principal amount of the Notes. 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 additional 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. Moreover, our ability to obtain additional debt financing may be limited by the \$275 million in outstanding principal amount of the Notes. 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 from sales of our products is completely dependent on our sole source distributor, Integrated Commercialization Solutions, or 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, Cleviprex and ready-to-use Argatroban in the United States through a sole source distribution model. Under this model, we currently sell Angiomax, Cleviprex and ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax, Cleviprex and 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 Recothrom and the acute care generic products through the same sole source distribution model. Our revenue from sales of Angiomax, Cleviprex, ready-to-use Argatroban in the United States is exclusively from sales to ICS pursuant to our agreement with them. We anticipate that our revenue from sales of Recothrom and the acute care generic products that we sell will be exclusively from sales to ICS. In connection with a reduction in marketing, sales and distribution fees payable to ICS, in October 2010 we amended our agreement with ICS to extend 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 material and adverse effect on our revenue in periods in which such purchase reductions occur.

We may not realize the anticipated benefits of past or future acquisitions or product licenses and integration of these acquisitions and any products and product candidates acquired or licensed may disrupt our business and management

We have in the past and may in the future acquire or license additional development-stage compounds, clinical-stage product candidates, approved products, technologies or businesses. For example, recently we acquired Incline, obtained the exclusive right to promote, market and sell Recothrom from BMS and entered into a license and collaboration agreement with Alnylam, to develop, manufacture and commercialize RNAi therapeutics targeting the PCSK9 gene for the treatment of hypercholesterolemia

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and other human diseases. We may not realize the anticipated benefits of an acquisition or license, each of which involves numerous risks. These risks include:

- difficulty in integrating the operations, products or product candidates and personnel of an acquired company;

- entry into markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;

- failure to successfully further develop the acquired or licensed business, product, compounds, programs or technology or to achieve strategic objectives, including commercializing and marketing successfully the development stage compounds and clinical stage candidates that we acquire or license;

- disruption of our ongoing business and distraction of our management and employees from other opportunities and challenges;

- inability to retain personnel, key customers, distributors, vendors and other business partners of the acquired company, or acquired or licensed product or technology;

- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges of an acquired company, or acquired or licensed product or technology, including but not limited to, problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, revenue recognition or other accounting practices, employee, customer or partner disputes or issues and other legal and financial contingencies and known and unknown liabilities;

- liability for activities of the acquired company or licensor before the acquisition or license, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities, and other known and unknown liabilities;

- exposure to litigation or other claims in connection with, or inheritance of claims or litigation risk as a result of, an acquisition or license, including but not limited to, claims from terminated employees, customers, former stockholders or other third-parties; and

- difficulties in the integration of the acquired company's departments, systems, including accounting, human resource and other administrative systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, controls, including internal control over financial reporting required by the Sarbanes–Oxley Act of 2002 and related procedures and policies.

Acquisitions and licensing arrangements are inherently risky, and ultimately, if we do not complete an announced acquisition or license transaction or integrate an acquired business, or an acquired or licensed product or technology successfully and in a timely manner, we may not realize the benefits of the acquisition or license to the extent anticipated and the perception of the effectiveness of our management team and our company may suffer in the marketplace. If we cannot successfully integrate acquired businesses, or acquired or licensed products or technologies we may experience material negative consequences to our business, financial condition or results of operations. Future acquisitions or licenses could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, or amortization expenses, or impairment of goodwill, and restructuring charges, any of which could harm our business, financial condition or results of operations.

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

We have incurred net losses in many years and on a cumulative basis since our inception. As of December 31, 2012, we had an accumulated deficit of approximately \$60.4 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 marketed 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, 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 stock may decline.

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### Risks Related to Our Notes

Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the Notes

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek such refinancing. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Notes or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change, as defined in the indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the Notes, which we refer to as the Indenture, at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the Indenture. In addition, upon conversion of the Notes, we will be required to make with respect to each \$1,000 in principal amount of Notes converted cash payments of at least the lesser of \$1,000 and the sum of the daily conversion values as described in the Indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes or to pay cash upon conversions of Notes. In addition, our ability to repurchase Notes or to pay cash upon conversions of Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the Indenture or to pay any cash payable on future conversions of the Notes as required by the Indenture would constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results

Holders of the Notes are entitled to convert the Notes at any time during specified periods at their option upon the occurrence of certain conditions, which are set forth in the Indenture. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash

Settlement)", which has subsequently been codified as Accounting Standards Codification 470-20, "Debt with Conversion and Other Options", which we refer to as ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component is treated as original issue discount for purposes of accounting for the liability component of the Notes. As a result, we will be required to record non-cash interest expense in current periods presented as a result of the amortization of the excess of the principal amount of the liability component of the Notes over its carrying amount over the term of the Notes. We will report lower net income in our financial results because ASC 470-20 will require interest expense to include the current period's amortization of the debt discount and transaction costs, as well as the Notes' contractual interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Notes.

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In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our diluted earnings per share would be adversely affected.

We have incurred substantial indebtedness, and our leverage and maintenance of high levels of indebtedness may adversely affect our business, financial condition and results of operations

As a result of the sale of the Notes, we have a greater amount of debt than we have maintained in the past. Our maintenance of higher levels of indebtedness could have adverse consequences including:

- impacting our ability to satisfy our obligations;

- increasing our vulnerability to general adverse economic and industry conditions;

- limiting our ability to obtain additional financing in the future;

- increasing the portion of our cash flows that may have to be dedicated to interest and principal payments and may not be available for operations, research and development, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete, and

- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

## Risks Related to Commercialization

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, Recothrom, ready-to-use Argatroban and our acute care generic products are approved for 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 markets a branded formulation of Argatroban and Sandoz markets generic formulations of

ready-to-use 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, Recothrom 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.



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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. 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 procedures 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 our inability to enforce our 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.

Recothrom faces significant competition from all classes of topical hemostats and related sealant products, which may limit the use of Recothrom and adversely affect our revenue

Recothrom is a surgical hemostat that is applied topically during surgery to stop bleeding. There are a number of different classes of topical hemostats including:

- the Gelfoam Plus hemostasis kit marketed by Baxter Healthcare Corporation;
- mechanical hemostats, such as absorbable gelatin sponges;
- collagen, cellulose, or polysaccharide-based hemostats applied as sponges, fleeces, bandages, or microspheres which do not contain thrombin or any other active biologic compounds;
- active hemostats, which are thrombin products that may be derived from bovine or human pooled plasma purification or human recombinant manufacturing processes;
- flowable hemostats, which consists of granular collagen or gelatin component that is mixed with saline or reconstituted thrombin to form a semi-solid, flowable putty; and
- fibrin sealants, which consists of thrombin and fibrinogen that can be sprayed or applied directly to the bleeding surface.

The choice of a surgical hemostat depends on the surgical procedure, type and strength of bleeding, surgeon preference, price and availability of products within the operating room or hospital.

Recothrom competes with each of these types of surgical hemostats as well as other active hemostats. Recothrom is the only active hemostat that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or in combination with a variety of other currently available mechanical and flowable hemostat products that are labeled for use with thrombin. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, Thrombin-JMI, a bovine derived thrombin marketed by Pfizer, and Evithrom, a human pooled plasma thrombin marketed by Ethicon, Inc., a subsidiary of Johnson & Johnson. In addition, Baxter International, Inc. markets the GELFOAM Plus Hemostasis

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Kit, which is Pfizer Inc.'s GELFOAM sterile sponge co-packaged with human plasma-derived thrombin. Further, a number of companies, including Johnson & Johnson, Pfizer and Baxter International, Inc., currently market other hemostatic agents that may compete with Recothrom, including passive agents such as gelatin and collagen pads and flowable hemostats, as well as fibrin sealants and tissue glues. Many of these alternative hemostatic agents are relatively inexpensive and have been widely used for many years, and hospital purchasers continue to seek to limit growth of expenditures. Consequently, some physicians and hospital formulary decision-makers may be hesitant to adopt Recothrom. The active hemostat class has seen minor usage contraction recently while the flowable hemostats and fibrin sealants have shown growth. If physicians do not accept the potential advantages of Recothrom or resist the use of Recothrom due to either custom or cost containment measures, or the active hemostat class continues to decline, our revenues could be adversely affected.

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. For example, in October 2012, we voluntarily discontinued our clinical trials and further development of MDCO-2010, which we had acquired in connection with our acquisition of Curacyte Discovery in August 2008, in response to serious unexpected patient safety issues encountered during a clinical trial.

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 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 and sell the drug may be limited or denied. For example, 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

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

The commercial success of Angiomax depends, in part, on the overall number of PCI procedures performed. 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.

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, 2012, we had \$46.5 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:

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- 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;
- 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



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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.

Use or misuse of our products may result in serious injuries or even death to patients and may subject 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 or study.

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.

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.

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. Eagle, as a result, alleges that it is entitled to an amount of damages totaling \$306 million. In January 2013, an arbitration hearing took place and in

February 2013, we and Eagle submitted post-hearing briefs. 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 and other third parties for bulk substance and to carry out fill-finish activities for our products

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and products in development. We expect to continue this manufacturing arrangement for Angiomax, Recothrom and all of our other approved products and products in development for the foreseeable future.

In the event that any third-party 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 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 of Angiomax and Cleviprex on a timely basis.

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.

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Our reliance on third-party manufacturers and suppliers 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 and suppliers 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 or supply 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 were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

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 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 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 generated revenue from three products that we sell: 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 2013, for instance, we acquired Curacyte Discovery, Targanta and Incline, licensed marketing rights to the ready-to-use formulation of Argatroban, licensed development and commercialization rights to MDCO-216, MDCO-157 and the ALN-PCS program, licensed the non-exclusive rights to sell and distribute ten acute care generic products and entered into a collaboration arrangement with BMS with respect to the commercialization of Recothrom. 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

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research capabilities that we acquired in our acquisitions of Curacyte Discovery, Targanta and Incline, 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.

### 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 non-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. 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, an 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.



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

In order to market our products 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, 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. 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. If we are unsuccessful in expanding the product label of our products, the size of the commercial market for our products will be limited.

For example, 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 October 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which we were developing to reduce blood loss during surgery, in response to serious unexpected patient safety issues encountered during the trial. Further, in November 2009, we discontinued enrollment in our Phase 3 clinical trials of cangrelor prior to completion 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.

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, ethics committees 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

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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 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 the contract manufacturers manufacturing our products and product candidates 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 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 promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

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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

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 our inability to enforce our 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

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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 the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. 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. 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 by a number of parties 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 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 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 our inability to enforce our U.S. patents covering Angiomax, Angiomax could become subject to generic competition in the United States earlier than May 1, 2019. 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.

Following our settlements with Teva and APP, we submitted the settlement documents for each settlement to the U.S. Federal Trade Commission, or the 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.

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. 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 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.

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 protecting our intellectual property depends significantly on our ability to:



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- 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, for which we own the patents and patent applications, and we license on a non-exclusive basis the acute care generic products from APP 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 patent, was set to expire in March 2010, but the term was extended to December 15, 2014 by the PTO under the Hatch-Waxman Act. 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.

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. In

September 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. The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva), license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents. In January 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.

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

Recothrom. We have exclusively licensed from BMS rights to patents and patent applications covering Recothrom's pharmaceutical compositions, formulations and methods of manufacturing. The expiration dates of these patents range from 2013 to 2030 in the United States. BMS has also filed and is currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. As a biologic, we believe Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020. The FDA, however, has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA provisions enacted in 2010 under the BPCIA, including the exclusivity provisions for reference products. It is thus possible that the FDA will decide to interpret the provisions in such a way that our products are not considered to be reference products for purposes of the statute or to be entitled to any period of data or marketing exclusivity. Even if our products are considered to be reference products eligible for exclusivity, such exclusivity will not prevent other companies marketing competing versions of Recothrom, including competing recombinant thrombin product, if such companies can complete, and FDA permits the submission of and approves, full BLAs with complete human clinical data packages for such products.

Cleviprex. The principal U.S. patent for Cleviprex is U.S. Patent No. 5,856,346, or the '346 patent, which was set to expire in January 2016, but the term has been extended to January 2021 by the PTO under the Hatch-Waxman Act. 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 will expire in November 2014 if no patent term extension is obtained. 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.

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.

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 issued patents directed to cangrelor pharmaceutical compositions which expire in 2017 and 2018 if no patent term extension is obtained. 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 will expire in November 2015 if no patent term extension is obtained. We have issued patents directed to the process of making oritavancin. These patents are set to expire in 2017 if no patent term extension is obtained. In February 2013, the PTO issued to us an allowance for a patent application covering the use of oritavancin in treating certain skin infections. Upon its issuance, the resulting patent will expire in August 2029 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.

IONSYS. As a result of our acquisition of Incline, we acquired a portfolio of patents and patent applications covering the IONSYS device and its uses. Some of these patents and patent applications were exclusively licensed from ALZA. The expiration dates of patents covering the IONSYS device and its use range from September 2014 to September 2031 in the United States. In Europe, the expiration date of patents covering the IONSYS device range from June 2015 to January 2021. We are also currently prosecuting patent applications relating to IONSYS in the United States and in certain foreign countries.

MDCO-157. We have exclusively licensed from Ligand Pharmaceuticals rights to patent and patent applications covering MDCO-157 formulations and its uses. The principal U.S. patent, the '995 patent, is set to expire in April 2028 if no patent term extension is obtained. The corresponding patent application is pending in Europe, and if issued, will expire in April 2028. We are also prosecuting a number of patent applications relating to MDCO-157 in the United States and in certain foreign countries.

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 if not patent term extension is obtained. 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. As a biologic, we believe MDCO-216 is entitled to receive 12 years of regulatory exclusivity as a "reference product" 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.

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ALN-PCS Program. We have exclusively licensed from Alnylam patents covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases. These patents generally expire between 2015 and 2023 both in the United States and in certain foreign countries. In addition, Alnylam has filed and is prosecuting patent applications that are specifically directed to PCSK9 product being developed under the license.

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 2016, 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 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

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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.

The warrant transactions and the derivative transactions entered into by the Hedge Counterparties in connection with the convertible note hedge and warrant transactions may affect the price of our common stock

In connection with sale of the Notes, we entered into convertible note hedge and warrant transactions with the Hedge Counterparties. Upon settlement, the warrants could have a dilutive effect on our earnings per share and the market price of our common stock to the extent that the market price per share of our common stock exceeds the then applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

In connection with establishing their hedges of the convertible note hedge and warrant transactions, the Hedge Counterparties or their affiliates entered into various derivative transactions with respect to our common stock. These parties may modify their hedge positions in the future by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so during any observation period related to a conversion of the Notes). These activities could cause a decrease or avoid an increase in the market price of our common stock.

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, 2010 to February 25, 2013, the last reported sale price of our common stock ranged from a high of \$32.57 per share to a low of \$7.00 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, NDAs or BLAs for products competitive with ours;



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• 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;

• 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 through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of 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;

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• 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 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 also lease small offices and other facilities in Waltham and Cambridge, Massachusetts, U.S.; Redwood City, California, U.S.; Seattle, Washington, U.S.; Montreal, Canada; Milton Park, Abingdon, United Kingdom; Basel, Switzerland; Zurich, Switzerland; Paris, France; Rome, Italy; Munich, 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; New Delhi and 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.

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'727 Patent and '343 Patent Litigations

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. The Hospira action was consolidated for discovery purposes with the then pending and now settled cases against Teva and APP. The case was reassigned back to the U.S. District Court for the District Court of Delaware. A Markman hearing was held on December 5, 2012. The Court has yet to issue a decision. The Court set a schedule for the case including a September 23, 2013 trial date.

Mylan Pharmaceuticals, Inc.

In January 2011, we were notified that Mylan Pharmaceuticals, Inc. had submitted an ANDA seeking permission to market 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 to add counterclaims and affirmative defenses of inequitable conduct and unclean hands. Following motion practice, the Court granted Mylan's request to add counterclaims and affirmative defenses of inequitable conduct and to add affirmative defenses of unclean hands. On March 7, 2012, we filed a reply denying these counterclaims. A Markman hearing was held on July 30, 2012. The Court issued a Markman Order on August 6, 2012. The parties are conducting discovery and other pre-trial matters. 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. On May 11, 2012, Dr. Reddy's filed a motion for summary judgment. On October 2, 2012, the Court held oral argument on Dr. Reddy's summary judgment motion and conducted a Markman hearing. On October 15, 2012, the Court denied Dr. Reddy's summary judgment motion. A Markman decision was issued by the Court on January 2, 2013. On January 25, 2013, Dr. Reddy's filed a second summary judgment motion this time for non-infringement. A trial date has been set for June 3, 2013.

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 set an initial case scheduling conference for June 7, 2012. At the conference, the Court set a pretrial schedule. No trial date has been set.

#### Eagle Pharmaceuticals, Inc. 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

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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. Eagle, as a result, alleges that it is entitled to an amount of damages totaling \$306 million. In January 2013, an arbitration hearing took place and in February 2013, we and Eagle submitted post-hearing briefs. 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.

	Common Stock	
	Price High	Low
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
Year Ended December 31, 2012		
First Quarter	\$ 22.82	\$ 18.06
Second Quarter	23.45	19.37
Third Quarter	26.95	22.39
Fourth Quarter	26.75	20.04

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on February 25, 2013, we had 173 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, 2007 to December 31, 2012. The stock price performance included in this graph is not necessarily indicative of future stock price performance.





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\* Fiscal year ended December 31.

	12/07	12/08	12/09	12/10	12/11	12/12
The Medicines Company	100.00	76.88	43.53	73.75	97.29	125.1
NASDAQ Composite	100.00	59.03	82.25	97.32	98.63	110.78
NASDAQ Biotechnology	100.00	93.4	103.19	113.89	129.12	163.33

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, 2012, 2011, 2010, 2009, and 2008. In 2012, 2011 and 2010, we computed diluted earnings per share by giving effect to options and restricted stock awards outstanding at December 31, 2012, December 31, 2011 and December 31, 2010, respectively. 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 annual 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 annual report.

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	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(In thousands, except per share data)				
Statements of Operations Data					
Net revenue	\$558,588	\$484,732	\$437,645	\$404,241	\$348,157
Operating expenses:					
Cost of revenue	177,339	156,866	129,299	118,148	88,355
Research and development	126,423	110,180	85,241	117,610	105,720
Selling, general and administrative	171,753	159,617	158,690	193,832	164,903
Total operating expenses	475,515	426,663	373,230	429,590	358,978
Income (loss) from operations	83,073	58,069	64,415	(25,349)	(10,821)
Legal settlement	—	17,984	—	—	—
Co-promotion income	10,000	—	—	—	—
Interest expense	(8,005)	—	—	—	—
Other income (expense)	1,140	1,790	(267)	(2,818)	5,235
Income (loss) before income taxes	86,208	77,843	64,148	(28,167)	(5,586)
(Provision for) benefit from income taxes	(35,038)	50,034	40,487	(48,062)	(2,918)
Net income (loss)	51,170	127,877	104,635	(76,229)	(8,504)
Net loss attributable to non-controlling interest	84	—	—	—	—
Net income (loss) attributable to The Medicines Company	\$51,254	\$127,877	\$104,635	\$(76,229)	\$(8,504)
Basic earnings per common share attributable to The Medicines Company	\$0.96	\$2.39	\$1.98	\$(1.46)	\$(0.16)
Diluted earnings per common share attributable to The Medicines Company	\$0.93	\$2.35	\$1.97	\$(1.46)	\$(0.16)
Shares used in computing basic earnings (loss) per common share	53,545	53,496	52,842	52,269	51,904
Shares used in computing diluted earnings (loss) per common share	55,346	54,407	53,184	52,269	51,904
	As of December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
Balance Sheet Data					
Cash and cash equivalents, available for sale securities and accrued interest receivable	\$570,669	\$340,886	\$247,923	\$177,113	\$217,542
Working capital	621,169	327,088	239,251	156,103	212,222
Total assets	972,182	692,647	474,124	374,776	387,404
Long-term liabilities	250,754	26,370	31,156	47,768	5,771
Accumulated deficit	(60,411)	(111,665)	(239,542)	(344,177)	(267,948)
Total stockholders' equity	586,222	511,642	357,598	240,389	298,025

**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.



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### Overview

### Our Business

We are a global biopharmaceutical company focused on saving lives, alleviating suffering and improving the economic efficiency of the world's leading hospitals. We have four marketed products, Angiomax<sup>®</sup> (bivalirudin), Recothrom<sup>®</sup> Thrombin, topical (Recombinant), 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 four late-stage development product candidates, cangrelor, oritavancin, MDCO-157 and IONSYS<sup>™</sup> (fentanyl iontophoretic transdermal system), and early stage development product candidates, MDCO-216 and ALN-PCS02 and ALN-PCSsc of our ALN-PCS program. 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 to these products and product candidates, we have a portfolio of ten generic drugs, which we refer to as our acute care generic products that we have the non-exclusive right to market in the United States. We expect to begin selling certain of our acute care generic products in the first quarter of 2013. We also co-promote the oral tablet antiplatelet medicine BRILINTA<sup>®</sup> (ticagrelor) in the United States, as part of our global collaboration agreement with AstraZeneca LP, or AstraZeneca.

Angiomax, Recothrom, 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.

Our revenues to date have been generated primarily from sales of Angiomax in the United States. We had net sales revenue from sales of Angiomax in 2012 of approximately \$548.2 million and net revenue from sales of Cleviprex and ready-to-use Argatroban of approximately \$10.4 million in the aggregate. We commenced sales of Recothrom in the first quarter of 2013. BMS reported net revenue from sales of Recothrom in 2012 of approximately \$67.0 million.

We continue to expand our sales and marketing efforts outside the United States. We believe that by establishing operations outside the United States, we can increase our sales of Angiomax outside of the United States and be positioned to commercialize Cleviprex and Recothrom and our products in development, if and when they are approved and ready to be marketed outside of the United States.

Research and development expenses represent costs incurred for licenses of rights to products, clinical trials, nonclinical and preclinical studies, 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.

### Angiomax Patent Litigation

The principal U.S. patents covering Angiomax include U.S. Patent No. 5,196,404, or the '404 patent, U.S. Patent No. 7,582,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent.

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 by a number of parties 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 '727 patent and '343 patent infringement litigation with Teva Pharmaceuticals USA, Inc. and its affiliates, which we collectively refer to 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.

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The license agreement also contains a grant by Teva to us of an exclusive (except as to Teva), license under Teva's bivalirudin patents and right to enforce Teva's bivalirudin patents.

On January 22, 2012, we settled our patent litigation with APP, including our litigation with respect to the extension of the patent term of the '404 patent and our patent infringement litigation with respect to the '727 patent and the '343 patent. 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 patent infringement litigation involving the '727 patent and '343 patent with other ANDA filers, as described in in Part I, Item 3, Legal Proceedings, of this annual report. 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

## Business Development Activity

ALN-PCS Program. In February 2013, we entered into a license and collaboration agreement with Alnylam to develop, manufacture and commercialize therapeutic products targeting the human PCSK-9 gene based on certain of Alnylam's RNAi technology. Under the terms of the agreement, we obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. We paid Alnylam \$25 million in an initial license payment and agreed to pay up to \$180 million in success-based development and commercialization milestones. In addition, Alnylam will be eligible to receive scaled double-digit royalties based on annual worldwide net sales of PCSK-9 products by us or our affiliates and sublicensees. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country. The royalties are subject to reduction in specified circumstances. We are also responsible for paying royalties, and in some cases milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products.

Recothrom. In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company, or BMS, we acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period, which we refer to as the collaboration term, and certain limited assets exclusively related to Recothrom, primarily the biologics

license application for Recothrom and certain related regulatory assets. BMS also granted to us, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom. Under the master transaction agreement, we paid to BMS a one-time collaboration fee equal to \$105.0 million and a one-time option fee equal to \$10.0 million. We did not assume, and if we exercise the option, we will not assume, any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and we did not acquire, and if we exercise the option, we will not acquire, any significant tangible assets related to the Recothrom business. Under the master transaction agreement, we agreed to pay to BMS quarterly tiered royalty payments during the two-year collaboration term equal to a percentage of worldwide net sales of Recothrom.

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If we exercise the option, we would acquire such assets and assume certain liabilities of BMS and its affiliates related to those assets and to pay to BMS a purchase price equal to the net book value of inventory included in the acquired assets, plus either:

a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase of the assets to be acquired in connection with exercising the option (unless such closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding such closing); or if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by us under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.

We expect to account for the transaction as a business combination and are in the process of determining the allocation of the purchase price to acquired assets and assumed liabilities.

Incline Therapeutics, Inc. In January 2013, we acquired Incline Therapeutics, Inc., or Incline, a company focused on the development of IONSYS, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting.

Under the terms of our agreement with Incline, we paid to Incline's equityholders and optionholders an aggregate of approximately \$156 million in cash, which is subject to a post-closing purchase price adjustment process. In addition, we paid approximately \$13 million to Cadence Pharmaceuticals, Inc., or Cadence, to terminate Cadence's option to acquire Incline pursuant to an agreement between Cadence and Incline and deposited \$18.5 million in cash into an escrow fund for the purposes of securing the indemnification obligations of the Incline equityholders to us for any and all losses for which we are entitled to indemnification pursuant to the agreement with Incline and to provide the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process.

Under the terms of our agreement with Incline, we agreed to pay up to \$205 million in cash in the aggregate, less certain related expenses, if we enter into a license agreement in Japan or achieve certain regulatory approval or sales milestones with respect to IONSYS.

We expect to account for the Incline transaction as a business combination and are in the process of determining the allocation of the purchase price to acquired assets and assumed liabilities.

Collaboration with AstraZeneca. On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca, LP, or AstraZeneca, pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. Under the terms of the collaboration agreement, a joint development and research committee and a joint commercialization committee have been established to prepare and deliver a global development plan and a country-by-country collaboration and commercialization plan, respectively, related to BRILINTA and Angiomax and cangrelor. Implementation of these plans is subject to agreement between both parties. The first joint activity agreed upon by the parties under the global collaboration is a four-year co-promotion arrangement for BRILINTA in the United States. Pursuant to the agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. Under the terms of the agreement, AstraZeneca paid us \$2.5 million for conducting BRILINTA co-promotion activities in the second quarter of 2012. In addition, under the terms of the agreement, AstraZeneca has agreed to pay us \$7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from July 1, 2012 to December 31, 2012, plus up to \$2.5 million in additional consideration for the same period, contingent upon the number of new prescriptions written during that period, \$15.0 million in base consideration per year from 2013 through 2015 for conducting BRILINTA co-promotion activities, plus up to an additional \$5.0 million per year from 2013 to 2015 if certain performance targets with respect to new prescriptions are achieved and \$7.5 million in base consideration for conducting BRILINTA co-promotion activities during the period from January 1, 2016 until June 30, 2016, plus up to an additional \$2.5 million in additional consideration for the same period if certain performance targets with respect to new prescriptions are achieved.



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. 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.

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**Curacyte Discovery Acquisition.** In August 2008, we acquired 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), €3.0 million in December 2010 (approximately \$4.3 million at the time of payment) and €4.0 million in February 2012 (approximately \$5.3 million at the time of payment) upon achievement of clinical milestones. We also agreed to pay 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. On October 4, 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010 and ended the development of MDCO-2010, as described below under “ - MDCO-2010 Clinical Trial Discontinuation”.

**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 an 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.

### **Convertible Senior Note Offering**

On June 11, 2012, we completed our private offering of \$275.0 million aggregate principal amount of our 1.375% convertible senior notes due 2017, or the Notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, or the Trustee, governing the Notes, which we refer to as the Indenture. The net proceeds from the offering were \$266.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The Notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year. We made our first payment of cash interest on the Notes on December 1, 2012 in the amount of \$1.8 million.

The Notes will mature on June 1, 2017. The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by us.

The Notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any of our secured indebtedness

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to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities, including trade payables, incurred by our subsidiaries.

Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under certain specified circumstances which are set forth in the Indenture. On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the Notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of our conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, in any, of our common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of our common stock per \$1,000 principal amount of Notes, which is equivalent to an initial conversion price of \$27.93 per share of our common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on our common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash dividends and certain issuer tender or exchange offers, as described in the Indenture.

We may not redeem the Notes prior to maturity and are not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change", as defined in the Indenture, subject to certain conditions, in lieu of converting their Notes, holders may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, we will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default, including our failure to make any payment of principal or interest on the Notes when due and payable, occurring and continuing, the Trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding Notes by notice to us and the Trustee, may, and the Trustee at the request of such holders, subject to the provisions of the Indenture, shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary of ours, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

### Convertible Note Hedge and Warrant Transactions

On June 5, 2012, we entered into convertible note hedge transactions and warrant transactions with several of the initial purchasers of the Notes, their respective affiliates and other financial institutions, which we refer to as the Hedge Counterparties. We used approximately \$19.8 million of the net proceeds from the offering of the Notes to pay the cost of the convertible note hedge transactions, after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions.

We expect the convertible note hedge transactions to reduce the potential dilution with respect to shares of our common stock upon any conversion of the Notes in the event that the market price per share of our common stock, as measured under the terms of the convertible note hedge transactions, is greater than the strike price of the convertible note hedge transactions, which initially corresponds to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The warrant transactions will have a dilutive effect with respect to our common stock to the extent that the market price per share of our common stock, as measured under the terms of the warrant transactions, exceeds the applicable strike price of the warrants. However, subject to certain conditions, we may elect to settle all of the warrants in cash.

#### Share Repurchase

We used approximately \$50.0 million of the net proceeds of the offering of the Notes to repurchase 2,192,982 shares of our common stock in a privately negotiated transaction with one of the purchasers of the Notes. We repurchased the shares of our common stock in this transaction at a price of \$22.80 per share, which was the last reported sale price per share of our common stock on June 5, 2012, the date that we priced the private offering of the Notes.

#### 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

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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 four-hour hang time of the formulation 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.

### Ready-to-Use Argatroban Recall

In December 2011, Eagle Pharmaceuticals, Inc., or Eagle, conducted a voluntary recall of ready-to-use Argatroban due to the presence of particulate matter in some vials. As a result, we were not able to sell ready-to-use Argatroban from December 2011 to April 2012. In April 2012, we re-commenced selling ready-to-use Argatroban to existing and new customers.

### Biogen Letter Agreement

On August 7, 2012, we and Biogen Idec MA Inc., or Biogen, entered into a letter agreement resolving a disagreement between the parties as to the calculation and amount of the royalties required to be paid to Biogen by us under our license agreement with Biogen. The letter agreement amends the license agreement providing, among other things, that effective solely for the period from January 1, 2013 through and including December 15, 2014, each of the royalty rate percentages payable by us as set forth in the license agreement shall be increased by one percentage point.

### MDCO-2010 Clinical Trial Discontinuation

On October 4, 2012, we voluntarily discontinued our Phase 2b dose-ranging study of MDCO-2010, a serine protease inhibitor which was being developed to reduce blood loss during surgery. This action we took in response to serious unexpected patient safety issues encountered during the trial, which at the time the trial was discontinued, had enrolled 44 of a planned 90 patients in the first stage of the study.

While we continue to investigate the cause of the safety issues and any potential link to the study drug, we decided to end the trial and further development of MDCO-2010 because of the evidence of risk to patients. We are conducting an assessment of patient data from the study. Once this evaluation is completed and reviewed with experts in the field, we plan to publish our findings.

### 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 other than the Biologics Price Competition and Innovation Act provisions of PPACA described in Part I, Item 1, Business - Government Regulations, of this annual report. However, the potential impact of the PPACA on our business and results of operations is inherently difficult to predict because many of the details regarding the implementation of this legislation have not been determined. In addition, the impact on our business and results of operations may change as and if our business evolves.

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act, or FDASIA. Under the “Generating Antibiotic Incentives Now,” or GAIN, provisions of FDASIA, the FDA may designate a product as a qualified infectious disease product, or QIDP. A QIDP is defined as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or a so-called “qualifying pathogen” found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. The GAIN provisions describe several examples of “qualifying pathogens,” including methicillin-resistant *Staphylococcus aureus*, or MRSA, and *Clostridium difficile*. Upon the designation of a drug by the FDA as a QIDP, any non-patent exclusivity period awarded to the drug will be extended by an additional five years. This extension is in addition to any pediatric exclusivity extension awarded.

We are currently developing oritavancin for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of oritavancin for other indications, including for the treatment of *Clostridium difficile*, prosthetic joint infections,

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anthrax and other Gram-positive bacterial infections. We believe that oritavancin may qualify as a QIDP and intend to request that oritavancin be designated as a QIDP. If we are successful in having oritavancin designated as a QIDP by the FDA under the GAIN provisions of the new FDASIA legislation, we expect the non-patent exclusivity awarded to oritavancin upon approval of an NDA to be extended by an additional five years.

## Results of Operations

Years Ended December 31, 2012 and 2011

## Net Revenue:

Net revenue increased 15.2% to \$558.6 million for the year ended December 31, 2012 as compared to \$484.7 million for the year ended December 31, 2011.

The following table reflects the components of net revenue for the years ended December 31, 2012 and 2011:

	Year Ended December 31,		Change	Change	
	2012	2011	\$	%	
	(In thousands)				
Angiomax	\$548,229	\$483,906	\$64,323	13.3	%
Cleviprex/Ready-to Use Argatroban	10,359	826	9,533	*	
Total net revenue	\$558,588	\$484,732	\$73,856	15.2	%

\*Represents an increase in excess of 100%

Net revenue increased by \$73.9 million, or 15.2%, to \$558.6 million in 2012 compared to \$484.7 million in 2011, reflecting increases of \$58.9 million or 13.0% in the United States, and \$15.0 million or 47.4% in international markets. The net revenue increase was comprised of revenue from net volume increases of \$38.6 million and revenue from price increases of \$33.1 million, as well as the favorable impact from foreign exchange of \$2.2 million.

Angiomax. Angiomax net revenue increased by \$64.3 million, or 13.3%, to \$548.2 million in 2012 compared to \$483.9 million in 2011, primarily due to a price increase in the United States and increased unit sales globally. Net revenue in the United States in both 2012 and 2011 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the Patient Protection and Affordable Care Act, or PPACA. Under this program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing percutaneous coronary intervention, or PCI, on an outpatient basis. Chargebacks related to the 340B Drug Pricing Program increased by \$5.4 million to \$47.6 million in 2012 compared to \$42.2 million in 2011, primarily due to increased usage by eligible hospital customers. Rebates related to the PPACA increased by \$0.6 million to \$1.3 million in 2012 compared to \$0.7 million in 2011 due to increased Medicaid rebates. Net revenue from sales of Angiomax outside the United States increased in 2012 compared to 2011 due to greater demand by existing hospital customers and the addition of new hospital customers in Russia, the United Kingdom, Italy, Denmark, France, Germany, the Netherlands, Switzerland and Australia.

Cleviprex/Ready-to-Use Argatroban. Net revenue from sales of Cleviprex was \$3.0 million in 2012 compared to \$0.9 million in 2011. Our lower revenue from sales of Cleviprex reflects the fact that we did not sell any Cleviprex in 2011 prior to April 2011 when we began to resupply existing customers with Cleviprex following the recalls of Cleviprex, and the re-launch of Cleviprex in October 2011 with the new 12-hour hang-time formulation. Net revenue from sales of ready-to-use Argatroban was \$7.3 million in 2012 compared to no sales in 2011. Ready-to-use Argatroban was not approved for sale by the FDA until July 2011 and not sold from December 2011 to April 2012 due to the voluntary recall of the drug by Eagle. Sales of ready-to-use Argatroban from July 2011 to December 2011 were completely offset by returns related to the recall.

We expect to begin selling Recothrom in the first quarter of 2013 and net revenue in the year ending December 31, 2013 will include revenue from the sales of Recothrom.

## Cost of Revenue:



Cost of revenue in 2012 was \$177.3 million, or 32% of net revenue, compared to \$156.9 million, or 32% of net revenue, in 2011.

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Cost of revenue during both periods consisted of expenses in connection with the manufacture of our products sold, royalty expenses under our agreements with Biogen and Health Research Inc., or HRI, related to Angiomax, our agreement with AstraZeneca related to Cleviprex, our agreement with Eagle related to ready-to-use Argatroban, amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions, 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,			Year Ended December 31,	
	2012	% of Total Cost		2011	% of Total Cost
	(In thousands)			(In thousands)	
Manufacturing/Logistics	\$50,506	28	%	\$47,787	31
Royalty	125,930	71	%	108,853	69
Amortization of product rights and intangible assets	903	1	%	226	—
Total cost of revenue	\$177,339	100	%	\$156,866	100

Cost of revenue increased by \$20.5 million during 2012 compared to 2011 primarily due to an increase in royalty expense to Biogen due to higher royalty sales under our agreement with Biogen triggered by higher sales of Angiomax. The increase in cost of revenue was also related to an increase in manufacturing and logistics expenses due to costs associated with our entry into an agreement with Patheon International A.G., or Patheon, in March 2011 under which Patheon agreed to be an additional supplier of Angiomax drug product.

We expect royalty expense to Biogen to increase beginning in the first quarter of 2013 due to the increase in royalty rates agreed to under the letter agreement we entered into with Biogen on August 7, 2012. We also expect our cost of revenue will increase in connection with the incurrence of cost of revenues associated with the promotion, marketing and sales of Recothrom.

## Research and Development Expenses:

Research and development expenses increased by 15% to \$126.4 million for 2012, from \$110.2 million in 2011. The increase primarily reflects additional costs incurred in connection with our ongoing Phase 3 clinical trials of cangrelor and oritavancin, including our acceleration of patient enrollment in our SOLO I Phase 3 trial of oritavancin, which was completed in October 2012. The increase also reflects costs incurred in preparation for a Phase 1 clinical trial of MDCO-216 that was commenced in February 2013, including the manufacturing of drug product for the anticipated Phase 1 trial and costs incurred with the commencement enrollment of healthy volunteers in a pharmacodynamic study of intravenous MDCO-157 comparing it with oral clopidogrel. These increases were offset by a decrease in administrative and headcount expenses related to MDCO-2010 associated with the closure of our facilities in Leipzig, Germany.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, MDCO-216 and MDCO-157 during 2013 and that our research and development expenses will increase in 2013 from their levels in 2012. We expect research and development expenses in 2013 to include costs associated with our ongoing Phase 3 clinical trials of oritavancin and cangrelor, global regulatory activities related to oritavancin and cangrelor, manufacturing development activities for Angiomax, Cleviprex, cangrelor and MDCO-216, our evaluation of data related to our Phase 2 clinical trial program for MDCO-2010, our planned Phase 1 clinical trial of MDCO-216, product lifecycle management activities and the development of MDCO-157. We also expect research and development expenses in 2013 to include costs associated with IONSYS and the ALN-PCS-program.

The following table identifies for each of our major research and development projects our spending for 2012 and 2011. Spending for past periods is not necessarily indicative of spending in future periods.

## Research and Development Spending

Year Ended December 31,

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	2012 (In thousands)	% of Total R&D	2011 (In thousands)	% of Total R&D	
Angiomax Clinical trials	\$6,894	5	% \$6,606	6	%

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Manufacturing development	73	—	% 288	—	%
Administrative and headcount costs	3,170	3	% 2,574	3	%
Total Angiomax	10,137	8	% 9,468	9	%
Cleviprex					
Clinical trials	228	—	% 1,492	1	%
Manufacturing development	1,029	1	% 295	—	%
Administrative and headcount costs	1,776	1	% 1,557	2	%
Total Cleviprex	3,033	2	% 3,344	3	%
Cangrelor					
Clinical trials	36,132	29	% 26,823	24	%
Manufacturing development	2,465	2	% 955	1	%
Administrative and headcount costs	8,918	7	% 6,671	6	%
Total Cangrelor	47,515	38	% 34,449	31	%
Oritavancin					
Clinical trials	26,942	21	% 21,944	20	%
Manufacturing development	5,085	4	% 3,454	3	%
Administrative and headcount costs	5,000	4	% 5,221	5	%
Total Oritavancin	37,027	29	% 30,619	28	%
MDCO-157					
Clinical trials	1,518	1	% —	—	%
Manufacturing development	744	—	% —	—	%
Administrative and headcount costs	2,034	2	% 1,072	1	%
Acquisition license fee	—	—	% 1,750	2	%
Total MDCO-157	4,296	3	% 2,822	3	%
MDCO-2010					
Clinical trials	910	1	% 713	1	%
Manufacturing development	852	1	% 416	—	%
Administrative and headcount costs	2,919	2	% 4,637	4	%
Clinical milestone	—	—	% 5,275	5	%
Government subsidy	—	—	% (222	) —	%
Total MDCO-2010	4,681	4	% 10,819	10	%
MDCO-216					
Clinical trials	1,205	1	% 692	1	%
Manufacturing development	2,028	2	% 2,364	2	%
Administrative and headcount costs	1,327	1	% 1,373	1	%
Total MDCO-216	4,560	4	% 4,429	4	%
Ready-to-Use Argatroban					
Manufacturing development	—	—	% —	—	%
Administrative and headcount costs	—	—	% 491	—	%
Total Ready-to-Use Argatroban	—	—	% 491	—	%
Other	15,175	12	% 13,739	12	%
Total	\$126,424	100	% \$110,180	100	%

## Angiomax

Research and development spending related to Angiomax during 2012 increased by approximately \$0.7 million compared to 2011. Clinical trial costs increased by \$0.3 million, primarily due to increased expenditures in connection with our EUROMAX trial, and increased administrative and headcount related expenses.



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We are conducting our EUROMAX trial at sites in seven European countries 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 glycoprotein IIb/IIIa receptor inhibitor, or GP IIb/IIIa inhibitor. We commenced enrollment in our EUROMAX clinical trial in March 2010. We expect to enroll approximately 2,200 patients in the EUROMAX trial and to complete enrollment in 2013.

We expect that our total research and development expenses relating to Angiomax will increase in 2013 as compared to 2012 levels in connection with our efforts to further develop Angiomax for use in additional patient populations, including our EUROMAX trial, as well as continued research and development expenses related to our product lifecycle management activities.

### **Cleviprex**

Research and development expenditures for Cleviprex decreased by approximately \$0.3 million during 2012 compared to 2011. The decrease in costs during 2012 was primarily due to lower clinical costs in 2012 associated with our PRONTO trial. These decreased costs were partially offset by an increase in manufacturing development costs related to product lifecycle activities.

Our PRONTO trial, which we commenced in 2009, evaluated 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 completed enrollment of patients in our PRONTO trial. In November 2012, data from the trial was presented at the American Heart Association Scientific Sessions 2012. We expect total research and development expenses relating to Cleviprex will increase in 2013 as compared to 2012 levels in connection with our efforts to obtain marketing approval of Cleviprex outside the United States and an increase in product life-cycle activities.

### **Cangrelor**

Research and development expenditures related to cangrelor increased by approximately \$13.1 million in 2012 compared to 2011. The increase primarily reflects increased clinical trial expenses related to our Phase 3 CHAMPION PHOENIX clinical trial, as well as an increase in manufacturing development expenses.

We expect total research and development expenses relating to cangrelor will decrease in 2013 compared to 2012 levels, primarily due to completion research and development activities in connection with the CHAMPION PHOENIX clinical trial.

### **Oritavancin**

Research and development expenditures related to oritavancin increased by approximately \$6.4 million in 2012 compared to 2011. The increase primarily reflects increased costs incurred relating to our SOLO I and SOLO II Phase 3 clinical trials.

In October 2012, we completed patient enrollment in the SOLO I clinical trial. As of February 25, 2013, we had enrolled 939 of the expected 1,020 patients in the SOLO II clinical trial. As a result of the positive SOLO I trial results, we plan to accelerate enrollment in the SOLO II clinical trial and expect to announce data from the trial in mid-2013. If the results of the trials warrant, we would expect to file an NDA in mid-2013.

We expect to incur increased research and development expenses relating to oritavancin in 2013 as compared to 2012 in connection with data analysis of the SOLO I clinical trial, the completion of the SOLO II clinical trial, the QT study conducted in the first quarter of 2013 and preparation of regulatory submissions for marketing approval.

### **MDCO-157**

Research and development expenses related to MDCO-157 increased by \$1.5 million in 2012 due to our increased clinical trial expenses related to our pharmacodynamic study of MDCO-157 that we commenced during the third quarter of 2010, as well as increased, administrative and headcount related expenses and manufacturing development. Costs incurred during 2011 were primarily related to the acquisition of the licensing agreement that we entered into with Ligand in May 2011. Under the license agreement, we have agreed to spend at least \$2.5 million annually on the development of MDCO-157.

The progress and results of our clinical development of MDCO-157 will dictate the level of our 2013 research and development expenses relating to the product candidate.

MDCO-2010

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Research and development expenditures related to MDCO-2010 decreased by approximately \$6.1 million in 2012 compared to 2011. Costs incurred during 2012 primarily related to the Phase 2b dose ranging trial of MDCO-2010, which we commenced in the first quarter of 2012 and which we voluntarily discontinued in October 2012 in response to serious unexpected patient safety issues encountered during the trial. Costs incurred during 2011 primarily related to our Phase 2a clinical trial of MDCO-2010, which we commenced in November 2010 and completed in the third quarter of 2011 and costs associated with the 2011 closure of our facilities in Leipzig, Germany. Research and development costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid during 2011.

We expect that our total research and development expenses relating to MDCO-2010 will decrease in 2013 as compared to 2012, as a result of the discontinuation of the Phase 2b dose ranging trial and further development of MDCO-2010 in October 2012. We still expect to incur limited costs in 2013 as we are conducting an assessment of patient data from the study.

### MDCO-216

Research and development expenditures related to MDCO-216 increased by approximately \$0.1 million in 2012 as compared to 2011. Costs incurred during 2012 primarily related to manufacturing development in connection with preparation for the commencement of a Phase 1 study of MDCO-216 which we commenced in the first quarter of 2013 and administrative and headcount expenses. Costs incurred during 2011 were primarily manufacturing development expenses related to preclinical activities, the costs in preparation for the Phase 1 study of MDCO-216 and administrative and headcount expenses.

We expect that our total research and development expenses relating to MDCO-216 will increase in 2013 as compared to 2012, as we prepare to submit an IND for MDCO-216 to the FDA,

### Ready-to-Use Argatroban

Research and development expenditures related to ready-to-use Argatroban decreased by \$0.5 million in 2012 compared to 2011 as we did not incur any research and development expenses with respect to ready-to-use Argatroban in 2012. The costs incurred during 2011 primarily related to administrative and headcount related expenses incurred prior to FDA approval of our ready-to-use Argatroban in June 2011.

We do not expect to incur any research and development expenses relating to ready-to-use Argatroban in 2013.

### 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 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 \$1.4 million during 2012 compared to 2011, primarily due to an increase in personnel and headcount related 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. In addition, we cannot 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, the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, the timing and estimated costs of obtaining marketing approvals for Angiomax in additional countries and additional patient populations, the timing and estimated costs of obtaining marketing approvals for Cleviprex outside the United States, or the timing and estimated costs of 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:

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;

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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
	2012	2011	\$	%
	(In thousands)			
Selling, general and administrative expenses	\$ 171,753	\$ 159,617	\$ 12,136	(7.6 )%

The increase in selling, general and administrative expenses of \$12.1 million in 2012 as compared to 2011 reflects a \$7.1 million increase in selling, marketing and promotional expense primarily related to Angiomax, higher stock-based compensation costs of \$3.5 million, higher amortization of intangible costs of \$1.2 million and a \$3.5 million increase in costs related to a smaller reduction in the fair value of our contingent consideration obligations to the former Targanta shareholders recognized in 2012 compared to 2011. These increases were partially offset by a \$3.2 million decrease in general corporate and administrative spending primarily driven by a decrease in site costs as 2011 included lease termination costs associated with vacating our previous office facility in New Jersey.

We expect our selling, general and administrative expenses will increase in 2013 in connection with our recent acquisitions of Incline and Recothrom.

## Legal Settlement:

	Year Ended December 31,		Change	Change
	2012	2011	\$	%
	(In thousands)			
Legal settlement	\$—	\$ 17,984	\$ (17,984	) (100.0 )%

During 2011, 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 2012.

## Co-promotion Income:

	Year Ended December 31,		Change	Change
	2012	2011	\$	%
	(In thousands)			
Co-promotion income	\$ 10,000	\$—	\$ 10,000	*

\*Represents an increase in excess of 100%

During 2012, we recorded income of approximately \$10.0 million in connection with our collaboration agreement with AstraZeneca for the co-promotion of BRILINTA in the United States. Pursuant to the collaboration agreement, our sales force began supporting promotion activities for BRILINTA in May 2012. We did not record any co-promotion income in 2011.

Interest Expense:

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	Year Ended December 31, 2012	2011	Change \$	Change %
	(In thousands)			
Interest expense	\$ (8,005	) \$ —	\$ (8,005	) *

\*Represents a decrease in excess of 100%

During 2012, we recorded approximately \$8.0 million in interest expense related to the Notes. We did not record any interest expense in 2011. We issued the Notes on June 11, 2012 and have recorded interest from that date. We expect our interest expense from the Notes to increase in future periods as we record non-cash interest expense as a result of the amortization of the excess of the principal amount of the liability component of the Notes over its carrying amount over the term of the Notes.

## Other Income:

	Year Ended December 31, 2012	2011	Change \$	Change %
	(In thousands)			
Other income	\$ 1,140	\$ 1,790	\$ (650	) 36.3 %

Other income, which is comprised of interest income, gains and losses on foreign currency transactions, decreased by \$0.7 million to \$1.1 million of income for 2012, from \$1.8 million for 2011. This decrease was primarily due to higher losses on foreign currency transactions in 2012, but was partially offset by increased interest associated with investment of higher levels of cash.

## (Provision) Benefit for Income Tax:

	Year Ended December 31, 2012	2011	Change \$	Change %
	(In thousands)			
(Provision) benefit for income tax	\$ (35,038	) \$ 50,034	\$ (85,072	) *

\*Represents an increase in excess of 100%

We recorded a \$35.0 million provision for income taxes and a \$50.0 million benefit for income taxes for 2012 and 2011, respectively, based on income before taxes for such periods of \$86.2 million and \$77.8 million. Our effective income tax rates for 2012 and 2011 were approximately 40.6% and (64.3)%, respectively. During 2012 we recorded a non-cash charge of \$3.6 million related to a change in the New Jersey income tax laws. In addition to the \$66.5 million reduction in the valuation allowance against its deferred tax assets, our income tax benefit for 2011 includes the effect of a \$2.5 million income tax benefit resulting from the tax impact of the settlement from the law firm WilmerHale and a change in the New Jersey income tax law treated as discrete events. Both the 2012 and 2011 effective tax rates include the non-cash tax impact arising from purchase accounting for in-process R&D acquired in the Targanta acquisition. The U.S. research and development tax credit expired on December 31, 2011 and was retroactively reinstated in the first quarter of 2013. The tax benefit of our 2012 research credit will be recorded in the first quarter of 2013. This change in tax law does not have a significant impact on our income tax provisions. At December 31, 2012, we maintained a \$2.4 million valuation allowance against \$82.2 million of deferred tax assets compared to a \$4.2 million valuation allowance against \$110.4 million of deferred tax assets at 2011. A significant portion of this reduction in valuation allowance occurred during the third quarter of 2011 after considering all available positive and negative evidence regarding our future ability to realize our deferred tax assets.

We will continue to evaluate our future ability to realize our deferred tax assets on a periodic basis in light of changing facts and circumstances. These include but are not limited to projections of future 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 ability to achieve future anticipated revenues.

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Years Ended December 31, 2011 and 2010

Net Revenue:

Net revenue increased 10.8% to \$484.7 million for the year ended December 31, 2011 as compared to \$437.6 million for the year ended December 31, 2010.

The following table reflects the components of net revenue for the years ended December 31, 2011 and 2010:

Net Revenue

	Year Ended December 31,		Change	Change	
	2011	2010	\$	%	
	(In thousands)				
Angiomax	\$483,906	\$436,872	\$47,034	10.8	%
Cleviprex/Ready-to-Use 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. 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/Ready-to-Use 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 recalls. 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 by the FDA 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 and HRI, related to Angiomax, our agreement with AstraZeneca, related to Cleviprex, and our agreement with Eagle related 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

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	Year Ended December 31,				
	2011	% of Total Cost	2010	% of Total Cost	
	(In thousands)		(In thousands)		
Manufacturing/Logistics	\$47,787	31	% \$43,081	33	%
Royalty	108,853	69	% 86,218	67	%
Amortization of product rights and intangible assets	226	—	% —	—	%
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 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 closure of our facilities in Leipzig, Germany. 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 workforce reductions that we effected in 2010 and a payment made to AstraZeneca in connection with a June 2010 amendment to our cangrelor license agreement with AstraZeneca.

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

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	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





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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, which was designed to study utilization patterns of patients in Europe receiving Angiox and collect descriptive outcome and safety data of patients.

### 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.

### 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.

### 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.

### MDCO-157

Research and development expenditures relating to MDCO-157 incurred during 2011 primarily related to the acquisition of the license agreement with Ligand that we entered into in May 2011 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 a pro rata portion of the \$2.5 million in 2011 on MDCO-157.

### 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 a Phase 2a clinical trial and preparation for our Phase 2b clinical trial, 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. Costs related to our Phase 2 clinical trials include headcount related costs and manufacturing expenses related to the production of drug product for the trials. Costs related to MDCO-2010 were partially offset by a German government research and development subsidy paid in both 2011 and 2010.

### 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.

### Ready-to-Use Argatroban

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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.

**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.

**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 reduction in force that we conducted in the first quarter of 2010 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	*

\*Represents an increase in excess of 100%

We recorded approximately \$18.0 million in legal settlement income in connection with the settlement agreement we entered into with WilmerHale in February 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	*

\*Represents an increase in excess of 100%

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.

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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, 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 the U.S. Department of Health and Human Services, or 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;

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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

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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 \$110.4 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 \$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.

## 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, convertible promissory notes and warrants and interest income. We had \$570.3 million in cash, cash equivalents and available for sale securities as of December 31, 2012. In the first quarter of 2013, in connection with our transactions with Incline, BMS and Alnylam, we paid a total of \$309 million in cash.

### Cash Flows

As of December 31, 2012, we had \$519.4 million in cash and cash equivalents, as compared to \$315.4 million as of December 31, 2011. The increase in cash and cash equivalents was primarily due to \$46.3 million of net cash provided by operating activities and \$220.9 million in net cash provided by financing activities, which were partially offset by \$63.5 million in net cash used in investing activities.

Net cash provided by operating activities was \$46.3 million in 2012, compared to net cash provided by operating activities of \$96.4 million in 2011. The decrease was primarily due to the timing of changes in working capital. The cash provided by operating activities in 2012 included net income of \$51.2 million and non-cash items of \$55.7 million consisting primarily of stock-based compensation expense and depreciation and amortization, which were offset by a \$60.6 million decrease resulting from changes in working capital items. The changes in working capital items reflect a decrease in accounts payable and accrued expenses of \$21.3 million primarily due to payments related to inventory of active pharmaceutical ingredient bivalirudin and payment of certain corporate expenses, an increase in accounts receivable of \$11.1 million, which was due in part to the timing of receipts and related sales volume, and an increase in inventory of \$31.2 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.

Net 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 of certain minimum quantities of the active pharmaceutical ingredient bivalirudin for our commercial supply, an



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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.

During 2012, \$63.5 million in net cash was used in investing activities, which reflected \$65.4 million used to purchase available for sale securities and \$36.7 million used to acquire intangible assets related to our acute care generic products in connection with our settlement with APP and the reacquisition of our rights to sell Angiomax in Australia and New Zealand from CSL Limited. These amounts were offset by \$38.9 million in proceeds from the maturity and sale of available for sale securities and a \$3.1 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices.

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.

Net cash provided by financing activities was \$220.9 million in 2012, which reflected \$275.0 million in proceeds from the issuance of the Notes, \$38.4 million in proceeds from the issuance of warrants in connection with the issuance of the Notes and \$22.9 million of proceeds from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan. These were partially offset by the \$58.2 million purchase of a convertible note hedge, \$50.0 million for the purchase of treasury shares and \$8.8 million in issuance costs in connection with our convertible note offering.

We received \$16.1 million in 2011 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. We also will require cash to pay interest on the Notes and to make principal payments on the Notes at maturity or upon conversion. Our sources of funding to meet these requirements will 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 through the enforcement of the '727 patent and the '343 patent during the period following the expiration of the patent term of the '404 patent on December 15, 2014 and the six month pediatric exclusivity on June 15, 2015 through at least May 1, 2019, the date on which we agreed APP may sell a generic version of Angiomax;

- the extent to which Cleviprex, ready-to-use Argatroban, Recothrom 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 our global collaboration with AstraZeneca, including our four-year co-promotion arrangement for BRILINTA in the United States, is successful;

- the extent to which we are successful in our efforts to establish a commercial infrastructure outside the United States;

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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, MDCO-157, IONSYS 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 and Recothrom outside the United States and of our products in development globally;

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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.

We believe that our cash on hand and the cash we generate from our operations will be sufficient to meet our ongoing funding requirements. We may need to seek additional funds to engage in any material acquisition activity and to repay the \$275.0 million aggregate principal amount of the Notes at maturity or upon conversion. 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, Cleviprex, Recothrom, ready-to-use Argatroban and the acute generic products for which we acquired the non-exclusive right to sell and distribute from APP or higher than anticipated costs globally, we may need to sell additional 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. Moreover, our ability to obtain additional debt financing may be limited by the Notes. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. Further, we may seek additional financing to fund our acquisitions of development stage compounds, clinical stage product candidates and approved products and/or the companies that have such products, and we may not be able to obtain such financing on terms acceptable to us or 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 at the earliest date at which we deem that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated.

**Eagle Pharmaceuticals, Inc. 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. Eagle, as a result, alleges that it is entitled to an amount of damages totaling \$306 million. In January 2013, an arbitration hearing took place and in February 2013, we and Eagle submitted post-hearing briefs. We believe we have valid defenses to Eagle's claims and intend to defend ourselves vigorously. We believe that potential liability, if any, is not estimable at this time.

Currently, we are party to other legal proceedings as described in Part I, Item 3, Legal Proceedings, 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 obligations 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. These obligations also include our obligations under the Notes. Future estimated contractual obligations as of December 31, 2012 are:

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Contractual Obligations (in thousands) <sup>(1)</sup>	Total	Less Than		More Than	
		1 Year	1 - 3 Years	4 - 5 Years	5 Years
Inventory related commitments	\$78,141	\$40,753	\$36,678	\$710	—
Long-term debt obligations	292,015	3,781	7,562	280,672	—
Research and development	7,046	6,266	780	—	—
Operating leases	54,823	7,412	11,817	17,068	18,526
Selling, general and administrative	3,539	2,550	989	—	—
Unrecognized tax benefits	2,433	2,433	—	—	—
Total contractual obligations	\$437,997	\$63,195	\$57,826	\$298,450	\$18,526

(1) 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 totaling \$29.9 million for 2013, \$26.6 million for 2014 and \$7.5 million for 2015 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$6.8 million is non-cancellable.

Our long-term debt obligations reflect our obligations under the Notes to pay interest on the \$275.0 million aggregate principal amount of the Notes and to make principal payments on the Notes at maturity or upon conversion.

We lease our principal offices in Parsippany, New Jersey. The lease covers 173,146 square feet and expires January 2024. 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 86% 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 \$5.8 million in 2012, \$7.3 million in 2011 and \$5.8 million in 2010.

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 and HRI, royalty and milestone payments under our agreement with AstraZeneca with respect to Cleviprex, contingent cash payments to former Targanta shareholders under our merger agreement with Targanta and royalty and milestone payments with respect to cangrelor, MDCO-157, MDCO-2010, MDCO-216 and ready-to-use Argatroban. Each of these payments is contingent upon the occurrence of certain future events and, given the nature of those events, it is unclear when, if ever, we may be required to make such payments and with respect to royalty payments, what the total amount of such payments will be. Further, the timing of any of the foregoing future payments is not reasonably estimable. For those reasons, these contingent payments have not been included in the table above. The arrangements that are excluded from the table above include the following:

- Under our license agreement with Biogen related to Angiomax, we are obligated to pay up to \$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. In connection with entering into the Biogen license, Biogen assigned to us a license agreement with HRI under which we are obligated to pay royalties to HRI on sales of Angiomax and on any sublicense income we

earn.

- Under our license agreement with AstraZeneca related to Cleviprex, we are obligated to pay up to an additional \$2.0 million upon reaching agreed upon regulatory milestones. 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.

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- In connection with our acquisition of Targanta, we are obligated to pay contingent cash payments up to \$85.1 million in the aggregate upon reaching specified milestones. In addition, as a result of the Targanta acquisition, we are a party to a license agreement with Eli Lilly through our Targanta subsidiary. We are required to make payments to Eli Lilly upon reaching specified regulatory and sales milestones. In addition, we are obligated to pay royalties to Eli Lilly 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. In addition, we are required 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.
- Under our license agreement with AstraZeneca related to cangrelor, we are obligated to make additional payments of up to \$54.5 million in the aggregate upon reaching agreed upon regulatory and commercial milestones. 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 our license agreement with Ligand related to MDCO-157, we are obligated 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.
- In connection with our acquisition of Curacyte Discovery, we agreed to pay 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.
- Under our license agreement with Pfizer Inc. related to MDCO-216, we agreed to pay Pfizer up to an aggregate of \$410.0 million upon achievement of specified clinical, regulatory and sales milestones. We also agreed to make royalty payments to Pfizer on the sale of MDCO-216, 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 to these obligations to Pfizer, in connection with the license, we also agreed to make payments to third parties of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments on sales of MDCO-216.
- Under the license agreement with Eagle related to the ready-to-use formulation of Argatroban, we are obligated to make additional payments of up to \$5.0 million in the aggregate upon the achievement of certain regulatory and commercial milestones and royalties on net sales of the ready-to-use formulation of Argatroban.
- In connection with our acquisition of Incline , we agreed to pay contingent payments of up to \$205 million, less certain expenses, upon achievement of specified regulatory and sales milestones with respect to IONYS. We also agreed to make payments to third parties of up to \$2.5 million upon achievement of specified development milestones.
- Under the license agreement with BMS, we have an option whereby upon exercise we would acquire certain assets and assume certain liabilities of BMS and its affiliates related to the assets and to pay BMS a purchase price equal to the net it would at the closing we agreed net book value of inventory included in the acquired assets, plus either:
  - a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase (unless the purchase closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding the purchase closing); or
  - if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by us under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.
- Under the license agreement with Alnylam, we agreed to pay contingent payments of up to \$180 million upon achievement of specified regulatory and sales milestones for the PCSK-9 products. We have also agreed to pay to Alnylam specified royalties on net sales of the PCSK-9 products. In addition to these obligations to Alnylam, in connection with the license, we also agreed to make payments to third parties on sales of the PCSK-9 products. In 2012 and 2011, we incurred and paid aggregate royalties to Biogen and HRI of \$122.2 million and \$108.2 million, respectively and royalties to AstraZeneca with respect to Cleviprex of \$1.0 million and \$0.8 million, respectively.

The above table also excludes obligations to make potential future payments in connection with our arrangements with Incline, BMS and Alnylam and under the license with ALZA, which we acquired as part of our acquisition of Incline.

Recent Accounting Pronouncements



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In July 2012, the FASB issued ASU 2012-02, "Testing Indefinite-Lived Intangible Assets for Impairment" (ASU 2012-02). ASU 2012-02 amended the procedures for testing the impairment of indefinite-lived intangible assets by permitting an entity to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible assets are impaired. An entity's assessment of the totality of events and circumstances and their impact on the entity's indefinite-lived intangible assets will then be used as a basis for determining whether it is necessary to perform the quantitative impairment test as described in Accounting Standard Codification (ASC) 350-30, "Intangibles – Goodwill and Other – General Intangibles Other than Goodwill." ASU 2012-02 will be effective for us on January 1, 2013, with early adoption permitted. The adoption of this guidance is not expected to have a significant effect on our consolidated financial statements.

### 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 our ready-to-use Argatroban in the United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax, Cleviprex and ready-to-use Argatroban to our sole source distributor, ICS. ICS then sells Angiomax, Cleviprex and, 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 and, commencing in the second quarter of 2013, Recothrom, through the same sole source distribution model.

Our agreement with ICS, which we initially entered into in 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 connection with a reduction in marketing, sales and distribution fees payable to ICS, in October 2010, we amended our agreement with ICS to extend 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.

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 \$0.8 million as of December 31, 2012 and \$0.4 million as of December 31, 2011 associated with sales of Angiomax to wholesalers outside of the United States. We recognize revenue from such sales when hospitals purchase the product.

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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. We recognized \$3.0 million, \$0.9 million and \$0.8 million of revenue associated with Cleviprex during 2012, 2011 and 2010, 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 require 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, 2012 and December 31, 2011, our accrual for product returns was \$1.1 million and \$3.9 million, respectively. A 10% change in our accrual for product returns would have had an approximately \$0.1 million effect on our reported net revenue for the year ended December 31, 2012.

**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.

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.

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Our allowance for chargebacks was \$14.8 million and \$15.6 million at December 31, 2012 and December 31, 2011, respectively. A 10% change in our allowance for chargebacks would have had an approximate \$1.5 million effect on our reported net revenue for the year ended December 31, 2012. Our accrual for rebates was \$1.2 million at December 31, 2011. We did not have any significant allowance for rebates at December 31, 2012.

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 \$3.6 million and \$3.3 million at December 31, 2012 and December 31, 2011, respectively. A 10% change in our fee-for-service accruals and allowances would have had an approximately \$0.4 million effect on our net revenue for the year ended December 31, 2012.

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 2012, 2011 and 2010 (amounts in thousands):

	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for- Service
Balance at January 1, 2010	\$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
Allowances for sales during 2012	12,240	854	68,179	—	9,914
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,849)	(3,612)	(9,673)	(1,170)	(2,885)
Actual credits issued for sales during 2012	(10,230)	—	(59,303)	—	(6,721)
Balance at December 31, 2012	\$2,010	\$1,113	\$14,843	\$—	\$3,577

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 2012, 2011 and 2010 was \$5.8 million, \$6.0 million and \$4.5 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 packaging against specific product batches.



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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.

As of December 31, 2012, our inventory of Angiomax was \$75.6 million, and we had inventory-related purchase commitments totaling \$29.9 million for 2013, \$26.6 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, which could negatively impact our results of operations and our financial condition.

### 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.



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On a periodic basis, we evaluate the realizability of 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.

### 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, 2012, we held \$570.3 million in cash, cash equivalents and available for sale securities, which had an average interest rate of approximately 0.33%. A 10 basis point change in such average interest rate would have had an approximate \$0.2 million impact on our interest income. At December 31, 2012, all cash, cash equivalents and available for sale securities were due on demand or within one year and 94% 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, 2012, we had receivables denominated in currencies other than the U.S. dollar. A 10.0% change would have had an approximate \$1.5 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, 2012. 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, or the Exchange Act, 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, 2012,

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.

**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.

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## 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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information

## 2013 Base Salaries and 2012 Cash Bonuses

On February 19, 2013, the compensation committee of our board of directors established the following 2013 base salaries for our named executive officers, effective as of January 1, 2013, and awarded the following annual cash bonus payments to the following named executive officers for 2012. The bonus payments were paid in February 2013.

Name and Title	2013 Annual Base Salary	2012 Annual Cash Bonus Payments
Clive A. Meanwell Chief Executive Officer	\$ 793,272	\$ 795,143
Glenn P. Sblendorio President and Chief Financial Officer	\$ 569,296	\$ 480,344
Paul M. Antinori Senior Vice President and General Counsel	\$ 427,849	\$ 203,019
William B. O'Connor Senior Vice President and Chief Accounting Officer	\$ 375,000	\$ 169,257

The rationale and benchmarking for the named executive officers' 2013 base salaries and the method of calculation of the 2012 cash bonus payments to our named executive officers will be discussed in our Proxy Statement to be filed in connection with our 2013 Annual Meeting of Stockholders.

## Reduction in Force

On February 27, 2013, we commenced implementation of a workforce reduction plan intended to improve efficiency and better align our costs and employment structure with our strategic plans. As a result of the workforce reduction, we reduced our personnel by 66 employees, or roughly 12% of our workforce. Affected employees will be eligible to receive reduction payments in specified amounts and fully paid health care coverage and outplacement services for specified periods. We expect to complete the workforce reduction by the end of first quarter of 2013.

We expect to record, in the aggregate, a one-time charge of approximately \$7 million associated with the workforce reduction, which will be recognized in the first quarter of 2013. Substantially all of this charge is expected to represent cash expenditures. We expect to realize estimated annualized cost savings from the workforce reduction in the range of \$13.0 million to \$14.0 million starting in the first quarter of 2013.

## 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, 2012 in connection with our 2012 annual meeting of stockholders. We refer to such proxy statement herein as our 2013 Proxy Statement.

Item 10. Directors, Executive Officers and Corporate Governance

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The information required by this item will be contained in our 2013 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 2013 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 2013 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 2013 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 Accounting Fees and Services

The information required by this item will be contained in our 2013 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.

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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:

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<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>
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<u>Consolidated Statements of Cash Flows</u>	<u>F - 10</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F - 12</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.

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## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 1, 2013.

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)	March 1, 2013
/s/ Glenn P. Sblendorio Glenn P. Sblendorio	President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer); Director	March 1, 2013
/s/ William W. Crouse William W. Crouse	Director	March 1, 2013
/s/ Robert J. Hugin Robert J. Hugin	Director	March 1, 2013
/s/ John C. Kelly John C. Kelly	Director	March 1, 2013
/s/ Armin M. Kessler Armin M. Kessler	Director	March 1, 2013
/s/ Robert G. Savage Robert G. Savage	Director	March 1, 2013
/s/ Hiroaki Shigeta Hiroaki Shigeta	Director	March 1, 2013
/s/ Melvin K. Spigelman Melvin K. Spigelman	Director	March 1, 2013
/s/ Elizabeth H.S. Wyatt Elizabeth H.S. Wyatt	Director	March 1, 2013

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APPENDIX A

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THE MEDICINES COMPANY

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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, 2012. 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, 2012, 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 March 1, 2013

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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, 2012 and 2011, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey

March 1, 2013

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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, 2012, 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, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2012 consolidated financial statements of The Medicines Company and our report dated March 1, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey

March 1, 2013

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CONSOLIDATED BALANCE SHEETS

	December 31,	
	2012	2011
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$519,446	\$315,382
Available for sale securities	50,875	25,130
Accrued interest receivable	348	374
Accounts receivable, net of allowances of approximately \$17.7 million and \$18.1 million at December 31, 2012 and 2011	85,893	74,559
Inventory	76,355	45,145
Deferred tax assets	13,881	9,395
Prepaid expenses and other current assets	9,577	11,738
Total current assets	756,375	481,723
Fixed assets, net	16,100	17,979
Intangible assets, net	119,576	87,329
Goodwill	14,671	14,671
Restricted cash	1,571	4,714
Deferred tax assets	46,625	78,441
Other assets	17,264	7,790
Total assets	\$972,182	\$692,647
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$25,378	\$6,587
Accrued expenses	107,453	147,382
Deferred revenue	2,375	666
Total current liabilities	135,206	154,635
Contingent purchase price	18,971	20,431
Convertible senior notes (due 2017)	226,109	—
Other liabilities	5,674	5,939
Total liabilities	385,960	181,005
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; 56,153,140 issued and 53,960,158 outstanding at December 31, 2012 and 54,313,107 issued and outstanding at December 31, 2011	56	54
Additional paid-in capital	697,427	623,801
Treasury stock, at cost; 2,192,982 and 0 shares at December 31, 2012 and December 31, 2011, respectively	(50,000)	) —
Accumulated deficit	(60,411)	) (111,665)
Accumulated other comprehensive (loss)	(766)	) (548)
Total The Medicines Company stockholders' equity	586,306	511,642
Non-controlling interest in joint venture	(84)	) —
Total stockholders' equity	586,222	511,642
Total liabilities and stockholders' equity	\$972,182	\$692,647

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See accompanying notes to consolidated financial statements.

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Table of ContentsTHE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF INCOME

	Year Ended December 31,		
	2012	2011	2010
	(In thousands, except per share amounts)		
Net revenue	\$558,588	\$484,732	\$437,645
Operating expenses:			
Cost of revenue	177,339	156,866	129,299
Research and development	126,423	110,180	85,241
Selling, general and administrative	171,753	159,617	158,690
Total operating expenses	475,515	426,663	373,230
Income from operations	83,073	58,069	64,415
Legal settlement	—	17,984	—
Co-promotion income	10,000	—	—
Interest expense	(8,005	) —	—
Other income (loss)	1,140	1,790	(267
Income before income taxes	86,208	77,843	64,148
(Provision) benefit for income taxes	(35,038	) 50,034	40,487
Net income	51,170	127,877	104,635
Net loss attributable to non-controlling interest	84	—	—
Net income attributable to The Medicines Company	\$51,254	\$127,877	\$104,635
Basic earnings per common share attributable to The Medicines Company	\$0.96	\$2.39	\$1.98
Diluted earnings per common share attributable to The Medicines Company	\$0.93	\$2.35	\$1.97
Weighted average number of common shares outstanding:			
Basic	53,545	53,496	52,842
Diluted	55,346	54,407	53,184

See accompanying notes to consolidated financial statements.

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THE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
(in thousands)

	Year Ended December 31,		
	2012	2011	2010
Net income	\$51,170	\$127,877	\$104,635
Other comprehensive income (loss):			
Unrealized gain (loss) on available for sale securities	6	—	(26 )
Foreign currency translation adjustment	(224 )	(968 )	611
Other comprehensive (loss) income	(218 )	(968 )	585
Comprehensive income	\$50,952	\$126,909	105,220

See accompanying notes to consolidated financial statements.

THE MEDICINES COMPANY  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
For The Years Ended December 31, 2010, 2011 and 2012



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	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated (Loss) Income	Non-control Interest in JV	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income		
	(In thousands)								
Balance at January 1, 2010	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
Excess tax benefit from share-based compensation arrangements					292				292
Net loss						104,635			104,635
Currency translation adjustment							611		611
Unrealized loss on available for sale securities (net of tax)							(26 )		(26 )
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
Excess tax benefit from share-based compensation arrangements					9,393				9,393
Net income						127,877			127,877
Currency translation adjustment							(968 )		(968 )
Unrealized loss on available for sale securities (net of tax)							—		—
	54,312	\$54	—	\$—	\$623,801	\$(111,665)	\$ (548 )	\$ —	\$ 511,642

Balance at December 31, 2011									
Employee stock purchases	1,488	2			22,930				22,932
Issuance of restricted stock awards	352	—							—
Non-cash stock compensation					14,981				14,981
Excess tax benefit from share-based compensation arrangements					1,558				1,558
Equity component of the convertible notes, issuance, net					55,685				55,685
Purchase of convertible note hedges					(58,223 )				(58,223 )
Sale of warrants					38,425				38,425
Purchase of treasury stock			(2,193 )	(50,000 )					(50,000 )
Debt issuance costs					(1,730 )				(1,730 )
Net income					51,254		(84 )		51,170
Currency translation adjustment						(224 )			(224 )
Unrealized gain on available for sale securities (net of tax)						6			6
Balance at December 31, 2012	56,152	\$56	(2,193 )	\$(50,000)	\$697,427	\$(60,411 )	\$(766 )	\$(84 )	\$586,222

See accompanying notes to consolidated financial statements.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2012	2011	2010
	(In thousands)		
Cash flows from operating activities:			
Net income	\$51,170	\$127,877	\$104,635
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	7,270	6,231	6,124
Amortization of net premiums and discounts on available for sale securities	734	2,021	3,260
Amortization of long term debt financing costs	598	—	—
Amortization of debt discount	5,306	—	—
Unrealized foreign currency transaction (gains) losses, net	(573)	) 562	(1,217)
Non-cash stock compensation expense	14,981	11,017	8,336
Loss on disposal of fixed assets	69	299	293
Deferred tax provision (benefit)	30,376	(53,246)	) (43,592)
Excess tax benefit from share-based compensation arrangements	(1,558)	) (9,393)	) 292
Change in contingent consideration obligation	(1,460)	) (4,956)	) 1,720
Changes in operating assets and liabilities:			
Accrued interest receivable	26	905	(364)
Accounts receivable	(11,120)	) (28,086)	) (16,627)
Inventory	(31,152)	) (19,794)	) 701
Prepaid expenses and other current assets	1,516	(6,763)	) 5,031
Accounts payable	18,903	(2,203)	) 165
Accrued expenses	(40,160)	) 71,608	(736)
Deferred revenue	1,685	125	(616)
Other liabilities	(265)	) 171	62
Net cash provided by operating activities	46,346	96,375	67,467
Cash flows from investing activities:			
Purchases of available for sale securities	(65,354)	) (33,583)	) (128,240)
Proceeds from maturities and sales of available for sale securities	38,881	126,713	108,640
Purchases of fixed assets	(1,005)	) (1,269)	) (340)
Acquisition of intangible assets	(36,678)	) (7,000)	) —
Other investments	(2,500)	) (7,500)	) —
Adjustment to goodwill	—	—	263
Decrease in restricted cash	3,148	1,049	1,278
Net cash (used in) provided by investing activities	(63,508)	) 78,410	(18,399)
Cash flows from financing activities:			
Proceeds from issuances of common stock, net	22,935	6,725	3,361
Purchase of treasury stock	(50,000)	) —	—
Proceeds from the issuance of convertible senior notes	275,000	—	—
Proceeds from issuance of warrants	38,425	—	—
Purchase of convertible note hedge	(58,223)	) —	—
Debt issuance costs	(8,774)	) —	—
Excess tax benefit from share-based compensation arrangements	1,558	9,393	—
Net cash provided by financing activities	220,921	16,118	3,361
Effect of exchange rate changes on cash	305	(1,885)	) 1,710

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Increase in cash and cash equivalents	204,064	189,018	54,139
Cash and cash equivalents at beginning of period	315,382	126,364	72,225
Cash and cash equivalents at end of period	\$519,446	\$315,382	\$126,364
Supplemental disclosure of cash flow information:			
Taxes paid	\$1,709	\$6,850	\$1,699
Interest paid	\$1,786	\$—	\$—

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See accompanying notes to consolidated financial statements.

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### THE MEDICINES COMPANY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business

The Medicines Company (the Company) is a global biopharmaceutical company focused on saving lives, alleviating suffering and improving the economic efficiency of the world's leading hospitals. The Company has four marketed products, Angiomax<sup>®</sup> (bivalirudin), Recothrom<sup>®</sup> Thrombin, topical (Recombinant), Cleviprex<sup>®</sup> (clevidipine butyrate) injectable emulsion and its ready-to-use formulation of Argatroban. The Company also has a pipeline of acute and intensive care hospital products in development, including four late-stage development product candidates, cangrelor, oritavancin, MDCO-157 and IONSYS<sup>™</sup> (fentanyl iontophoretic transdermal system), and early stage development product candidates, MDCO-216, and ALN-PCS02 and ALN-PCSsc of its ALN-PCS program. 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 to these products and product candidates, the Company has a portfolio of ten generic drugs, which the Company refers to as its acute care generic products that the Company has the non-exclusive right to market in the United States. The Company expects to begin selling certain of its acute care generic products in the first quarter of 2013. The Company also co-promotes the oral tablet antiplatelet medicine BRILINTA<sup>®</sup> (ticagrelor), tablets, in the United States pursuant to its four-year co-promotion arrangement with AstraZeneca LP (AstraZeneca).

#### 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.

##### Loss Attributable to Noncontrolling Interest

In 2010, the Company and Windlas Healthcare Private Limited entered into a joint venture in India. Given the Company's majority ownership interest of approximately 74.0% of the joint venture company, the Medicines Company (India) Private Limited, the accounts of the Medicines Company (India) Private Limited have been consolidated with the Company's accounts, and a noncontrolling interest has been recorded for the noncontrolling investors' interests in the equity and operations of the Medicines Company (India) Private Limited. For the year ended December 31, 2012, the loss attributable to the noncontrolling interest in the Medicines Company (India) Private Limited was approximately \$0.1 million.

##### Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the Financial Accounting Standards Board (FASB) on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such

liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 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, 2012 and 2011, approximately \$14.7 million and \$25.2 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.

The Company currently sells Angiomax, Cleviprex and ready-to-use Argatroban in the United States to a sole source distributor, Integrated Commercialization Solutions, Inc. (ICS). ICS accounted for 90%, 96% and 94% of the Company's net revenue for 2012, 2011 and 2010, respectively. At December 31, 2012 and 2011, amounts due from ICS represented approximately \$92.3 million and \$85.1 million, or 89% and 92%, of gross accounts receivable, respectively. At December 31, 2012 and 2011, the Company did not maintain an allowance for doubtful accounts for its ICS accounts receivable.

## 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 \$504.7 million and \$290.2 million at December 31, 2012 and December 31, 2011, respectively. Cash and cash equivalents at December 31, 2012 and December 31, 2011 included investments of \$14.7 million and \$25.2 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 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 \$50.9 million at December 31, 2012 and \$25.1 million at December 31, 2011. These available for sale securities included various United States government agency notes, United States treasury notes and corporate debt securities. At December 31, 2012 and December 31, 2011, all of the \$50.9 million and \$25.1 million, respectively, of available for sale securities were due within one year. Available for sale securities, including carrying value and estimated fair values, are summarized as follows:

	As of December 31, 2012				As of December 31, 2011			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(In thousands)							
U.S. government agency notes	\$7,093	\$7,097	\$7,097	\$4	\$901	\$901	\$901	\$—
U.S. treasury notes	—	—	—	—	3,021	3,022	3,022	1
Corporate debt securities	43,772	43,778	43,778	6	21,204	21,207	21,207	3



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Total	\$50,865	\$50,875	\$50,875	\$10	\$25,126	\$25,130	\$25,130	\$4
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

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 \$1.6 million at December 31, 2012 and \$4.7 million at December 31, 2011, which is included in restricted cash on the consolidated balance sheets. Restricted cash of \$1.0 million and \$4.1 million at December 31, 2012 and December 31, 2011, 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. In addition, as a result of the acquisition of Targanta Therapeutics Corporation (Targanta) in 2009, the Company had at December 31, 2012 and December 31, 2011 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, 2012 restricted cash of \$0.3 million related to certain foreign tender requirements.

**Revenue Recognition**

**Product Sales.** The Company distributes Angiomax, Cleviprex and ready-to-use Argatroban, in the United States through a sole source distribution model with ICS. Under this model, the Company currently sells Angiomax, Cleviprex and ready-to-use Argatroban to its sole source distributor, ICS and records revenue upon shipment of Angiomax to ICS. ICS then sells Angiomax, Cleviprex and 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. The Company expects that it will also sell its acute care generic products through the same sole source distribution model. The Company's agreement with ICS, which it initially entered into February 2007, provides that ICS will be the Company's 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 the Company for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on the Company's customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to the Company's 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, the Company sells Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals. The Company had deferred revenue of \$0.8 million as of December 31, 2012 and \$0.4 million as of December 31, 2011 associated with sales of Angiomax to wholesalers outside of the United States. The Company recognizes revenue from such sales when hospitals purchase the product. 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.

The Company recognizes sales from Cleviprex and ready-to-use Argatroban under a deferred revenue model. Under its deferred revenue model, the Company does not recognize revenue upon product shipment to ICS. Instead, upon product shipment, the Company invoices ICS, records deferred revenue at gross invoice sales price, classifies the cost basis of the product held by ICS 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 currently recognizes the deferred revenue when hospitals purchase product and will do so until such time that the Company has

sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. The Company had deferred revenue of \$1.6 million as of December 31, 2012 and \$0.2 million as of December 31, 2011 associated with sales of Cleviprex and Argatroban in the United States. When such estimates are developed the Company expects to recognize Cleviprex revenue upon shipment to ICS in the same manner as the Company recognizes Angiomax revenue.

The Company recognized \$10.4 million, \$0.8 million and \$0.8 million of revenue associated with Cleviprex and ready-to-use Argatroban during 2012, 2011 and 2010, 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

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 require critical estimates, and the specific considerations the Company 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, 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, 2012 and December 31, 2011, the Company's accrual for product returns was \$1.1 million and \$3.9 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 \$14.8 million and \$15.6 million at December 31, 2012 and December 31, 2011, 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, 2012.

**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 \$3.6 million and \$3.3 million at December 31, 2012 and December 31, 2011, respectively.

The Company has adjusted its allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past 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 it believes actual experience may differ from its estimates.

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table provides a summary of activity with respect to the Company's sales allowances and accruals during 2012, 2011 and 2010 (amounts in thousands):

	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for- Service
Balance at January 1, 2010	\$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
Allowances for sales during 2012	12,240	854	68,179	—	9,914
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,849)	(3,612)	(9,673)	(1,170)	(2,885)
Actual credits issued for sales during 2012	(10,230)	—	(59,303)	—	(6,721)
Balance at December 31, 2012	\$2,010	\$1,113	\$14,843	\$—	\$3,577

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 2012, 2011 and 2010 was \$5.8 million, \$6.0 million and \$4.5 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 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 \$0.2 million, \$0.6 million and \$1.5 million for the years ended December 31, 2012, 2011, and 2010, 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**

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 2012.

**Treasury Stock**

Treasury stock is recognized at the cost to reacquire the shares. Shares issued from treasury are recognized utilizing the first-in first-out method.

**Research and Development**

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Milestone payments achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset.

**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 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

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 2009. 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 July 2012, the FASB issued ASU 2012-02, "Testing Indefinite-Lived Intangible Assets for Impairment" (ASU 2012-02). ASU 2012-02 amended the procedures for testing the impairment of indefinite-lived intangible assets by permitting an entity to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the indefinite-lived intangible assets are impaired. An entity's assessment of the totality of events and circumstances and their impact on the entity's indefinite-lived intangible assets will then be used as a basis for determining whether it is necessary to perform the quantitative impairment test as described in Accounting Standard Codification (ASC) 350-30, "Intangibles – Goodwill and Other – General Intangibles Other than Goodwill." ASU 2012-02 will be effective for the Company on January 1, 2013, with early adoption permitted. The adoption of this guidance is not expected to have a significant effect on the Company's consolidated financial statements.

**3. Inventory**

The major classes of inventory were as follows:

Inventory	2012	2011
	(In thousands)	
Raw materials	\$40,244	\$23,234
Work-in-progress	26,594	19,203
Finished goods	9,517	2,708
Total	\$76,355	\$45,145

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:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Estimated Life (Years)	December 31, 2012 (In thousands)	2011
Furniture, fixtures and equipment	3-7	\$ 10,437	\$ 11,647
Computer software	3	2,685	2,333
Computer hardware	3	2,130	2,282
Leasehold improvements	5-15	19,160	19,157
		34,412	35,419
Less: Accumulated depreciation		(18,312 )	(17,440 )
		\$ 16,100	\$ 17,979

Depreciation expense was approximately \$2.9 million, \$3.6 million and \$4.4 million for the years ended December 31, 2012, 2011 and 2010, respectively.

## 5. Investment

In December 2011, the Company made a non-controlling equity investment 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 investment as a cost method investment 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. At December 31, 2012 and 2011 the Company had a \$9.5 million and \$7.5 million investment in GeNO, respectively.

## 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.

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

For the Targanta transaction the Company defined an in-process research and development project by specific therapeutic treatment indication. The Company is pursuing four therapeutic treatment indications for oritavancin. 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 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, 2012			As of December 31, 2011		
	Weighted Average Useful Life (In thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets							
Customer relationships <sup>(1)</sup>	8 years	\$7,457	\$ (4,106 )	\$3,351	\$7,457	\$ (2,863 )	\$4,594
Distribution agreements <sup>(1)</sup>	5.7 years	9,125	(3,469 )	5,656	4,448	(1,708 )	2,740
Trademarks <sup>(1)</sup>	8 years	3,024	(1,665 )	1,359	3,024	(1,161 )	1,863
Product licenses <sup>(2)</sup>	8.8 years	39,000	(1,129 )	37,871	7,000	(226 )	6,774
Cleviprex milestones <sup>(3)</sup>	13 years	2,000	(161 )	1,839	2,000	(142 )	1,858
Total	8.3 years	\$60,606	\$ (10,530 )	\$50,076	\$23,929	\$ (6,100 )	\$17,829

(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.

In January 2012, the Company reacquired its rights to sell Angiomax in Australia and New Zealand from CSL Limited (CSL) and is now marketing and selling Angiomax in those countries with a sales force that as of December 31, 2012 consisted of two engagement partners and two engagement managers. The Company valued the

intangible assets related to Angiomax in those countries obtained from CSL at \$4.7 million, classified such assets as distribution agreements intangibles and commenced amortization of the assets using a 3.5 year expected useful life.

In January 2012, the Company acquired 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 valued the

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

intangible assets obtained from APP in the United States at \$32.0 million, classified such assets as product licenses intangibles and will amortize the assets using a 9 year expected useful life beginning in 2013.

Amortization expense was approximately \$4.4 million, \$2.6 million and \$1.8 million for the years ended December 31, 2012, 2011 and 2010, respectively. The Company expects annual amortization expense related to these intangible assets to be \$8.8 million, \$10.0 million, \$4.6 million, \$4.5 million and \$4.6 million for the years ending December 31, 2013, 2014, 2015, 2016 and 2017, respectively, with the balance of \$17.6 million being amortized thereafter. Amortization of customer relationships, distribution agreements and trademarks are recorded in selling, general and administrative expense on the consolidated statements of income. Amortization of product license and Cleviprex milestones are recorded in cost of revenue on the consolidated statements of income.

The following information details the carrying amounts of the Company's intangible assets not subject to amortization:

	As of December 31, 2012			As of December 31, 2011		
	Gross		Net	Gross		Net
	Carrying	Adjustments	Carrying	Carrying	Adjustments	Carrying
	Amount		Amount	Amount		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, 2012 and December 31, 2011 are as follows:

	December 31, 2012	December 31, 2011
	(In thousands)	
Balance at beginning of period	\$14,671	\$14,671
Adjustment to goodwill	—	—
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:

	2012	2011
	(In thousands)	
Royalties	\$39,169	\$32,183
Research and development services	16,728	25,133
Compensation related	23,773	23,424
Product returns, rebates and other fees	4,367	13,351
Legal, accounting and other	8,501	13,819
Manufacturing, logistics and related fees	12,529	38,336
Sales and marketing	2,071	1,136
Interest	315	—
	\$107,453	\$147,382

## 9. Convertible Senior Notes



In June 2012, the Company issued, at par value, \$275.0 million aggregate principal amount of the Notes. The Notes bear cash interest at a rate of 1.375% per year, payable semi-annually on June 1 and December 1 of each year. The Company made its first payment of cash interest on the Notes on December 1, 2012 in the amount of \$1.8 million. The Notes will mature on June 1, 2017.

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The net proceeds to the Company from the offering were \$266.2 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company.

The Notes are governed by an indenture dated as of June 11, 2012 (the Indenture), between the Company, as issuer, and Wells Fargo Bank, National Association, a national banking association, as trustee (the Trustee). The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness, or the issuance or repurchase of securities by the Company.

The Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any secured indebtedness of the Company to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding March 1, 2017 only under the following circumstances:

during any calendar quarter commencing on or after September 1, 2012 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price (described below) on each applicable trading day;

during the five business day period after any five consecutive trading day period (the Measurement Period) in which the trading price (as defined in the Indenture) per \$1,000 principal amount of Notes for each trading day of the Measurement Period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of the Company's assets.

On or after March 1, 2017, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the Notes to be converted and deliver shares of the Company's common stock in respect of the remainder, if any, of the Company's conversion obligation in excess of the aggregate principal amount of the Notes being converted, subject to a daily share cap, as described in the Indenture. Holders of Notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a Note, except in limited circumstances. Instead, accrued but unpaid interest will be deemed to be paid by the cash and shares, if any, of the Company's common stock, together with any cash payment for any fractional share, paid or delivered, as the case may be, upon conversion of a Note.

The conversion rate for the Notes was initially, and remains, 35.8038 shares of the Company's common stock per \$1,000 principal amount of Notes, which is equivalent to a conversion price of \$27.93 per share of the Company's common stock. The conversion rate and the conversion price are subject to customary adjustments for certain events, including, but not limited to, the issuance of certain stock dividends on the Company's common stock, the issuance of certain rights or warrants, subdivisions, combinations, distributions of capital stock, indebtedness, or assets, cash

dividends and certain issuer tender or exchange offers, as described in the Indenture.

The Company may not redeem the Notes prior to maturity and is not required to redeem or retire the Notes periodically. However, upon the occurrence of a "fundamental change" (as defined in the Indenture), subject to certain conditions, in lieu of converting their Notes, holders may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. Following certain corporate transactions that constitute a change of control, the Company will increase the conversion rate for a holder who elects to convert the Notes in connection with such change of control in certain circumstances.

The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the Notes when due and payable) occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may, and the Trustee at the request of such holders (subject to the provisions of the Indenture)

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. In case of an event of default involving certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable. Upon a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the Notes as a whole. The excess of the principal amount of the liability component over its carrying amount, referred to as the debt discount, is amortized to interest expense over the five-year term of the Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

In accounting for the transaction costs related to the issuance of the Notes, the Company allocated the total costs incurred to the liability and equity components of the Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the five-year term of the Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity. Additionally, the Company initially recorded a deferred tax asset of \$1.5 million in connection with the Notes. The Notes consisted of the following:

Liability component	December 31, December 31,	
	2012	2011
	(in thousands)	
Principal	\$275,000	\$ —
Less: Debt discount, net <sup>(1)</sup>	(48,891)	) —
Net carrying amount	\$226,109	\$ —

<sup>(1)</sup> Included in the condensed consolidated balance sheets within convertible senior notes (due 2017) and amortized to interest expense over the remaining life of the Notes using the effective interest rate method.

The fair value of the Notes was approximately \$240.9 million as of December 31, 2012. The Company estimates the fair value of its Notes utilizing market quotations for debt that have quoted prices in active markets. Since the Notes do not trade on a daily basis in an active market, the fair value estimates are based on market observable inputs based on borrowing rates currently available for debt with similar terms and average maturities (Level 2). As of December 31, 2012, the remaining contractual life of the Notes is approximately 4.4 years.

The following table sets forth total interest expense recognized related to the Notes:

	Years Ended December 31,		
	2012	2011	2010
	(in thousands)		
Contractual interest expense	2,101	—	—
Amortization of debt issuance costs	598	—	—
Amortization of debt discount	5,306	—	—
	\$8,005	\$—	\$—
Effective interest rate of the liability component	6.02	% —	% — %

Note Hedges. In June 2012, the Company paid an aggregate amount of \$58.2 million for the Note Hedges, which was recorded as a reduction of additional paid-in-capital in stockholders' equity. The Note Hedges cover approximately 9.8

million shares of the Company's common stock, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, have a strike price that corresponds to the initial conversion price of the Notes and are exercisable upon conversion of the Notes. The Note Hedges will expire upon the maturity of the Notes. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the Note Hedges, at the time of exercise is greater than the strike price of the Note Hedges. The Note Hedges are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the Notes or the Warrants. Holders of the Notes and Warrants will not have any rights with respect to the Note Hedges. As of December 31, 2012, the fair value of the Note Hedges was \$68.7 million.

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Warrants. The Company received aggregate proceeds of \$38.4 million from the sale to the Hedge Counterparties of the Warrants to purchase up to 9.8 million shares of the Company's common stock, subject to customary anti-dilution adjustments, at a strike price of \$34.20 per share, which the Company recorded as additional paid-in-capital in stockholders' equity. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash. The Warrants were anti-dilutive for the year ended December 31, 2012. The Warrants are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the Notes or Note Hedges. Holders of the Notes and Note Hedges will not have any rights with respect to the Warrants. The Warrants also meet the definition of a derivative under current accounting principles. Because the Warrants are indexed to the Company's common stock and are recorded in equity in the Company's consolidated balance sheets, the Warrants are exempt from the scope and fair value provisions of accounting principles related to accounting for derivative instruments.

10. 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 1,487,642 shares, 609,386 shares, and 557,725 shares of common stock during the years ended December 31, 2012, 2011 and 2010, 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 \$22.9 million, \$6.7 million, and \$3.4 million during the years ended December 31, 2012, 2011 and 2010, respectively, and are included within the financing activities section of the consolidated statements of cash flows. The Company issued 352,391 shares, 239,576 shares and 76,044 shares under restricted stock awards during the years ended December 31, 2012, 2011 and 2010, respectively.

Treasury Stock

On June 5, 2012, the Company's Board of Directors authorized the Company to use a portion of the net proceeds of the Notes offering to repurchase up to an aggregate of \$50.0 million of its common stock. The Company repurchased 2,192,982 shares of its common stock in the second quarter of fiscal 2012 for an aggregate cost of \$50.0 million.

As of December 31, 2012, there were 2,192,982 shares of the Company's common stock held in treasury.

11. 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).

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.

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2012, an aggregate of 112,626 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, 2012, an aggregate of 143,500 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:

- \$320 thousand value of options on the date of his or her initial election to the Board of Directors (the Initial Options); and

- \$215 thousand equity value split equally between stock options and restricted shares 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.

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 one installment 12 months 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, 2012, the Company had granted an aggregate of 11,374,782 shares as restricted stock or subject to issuance upon exercise of stock options under the 2004 Plan, of which 10,748,541 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, 2012, an aggregate of 1,111,241 shares had been issued under the 2001 Plan and options to purchase an aggregate of 77,937 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, 2012, an aggregate of 177,086 shares had been issued under the 2000 Directors Plan and options to purchase an aggregate of 61,667 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 Plan following adoption of an amendment to the 2004 Plan at its annual stockholders' meeting on May 25, 2006.

As of December 31, 2012, an aggregate of 5,068,910 shares had been issued under the 1998 Plan and options to purchase an aggregate of 492,979 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, 2012:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2010	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 )	17.3		
Outstanding, December 31, 2011	9,136,677	\$ 18.61		
Granted	1,619,702	22.28		
Exercised	(1,342,739 )	15.50		
Forfeited and expired	(301,608 )	17.62		
Outstanding, December 31, 2012	9,112,032	\$ 19.75	5.84	\$45,083,235
Vested and expected to vest, December 31, 2012	8,904,487	\$ 19.75	5.77	\$44,212,885
Exercisable, December 31, 2012	6,372,168	\$ 20.14	4.76	\$30,713,356
Available for future grant at December 31, 2012	2,014,721			

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, 2012, 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, 2012, 2011 and 2010 was \$8.95, \$7.38, and \$4.27, respectively. The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$10.4 million, \$3.0 million, and \$1.0 million, respectively.

In accordance with ASC 718-10, the Company recorded approximately \$15.0 million, \$11.0 million and \$8.3 million of stock-based compensation expense related to the options, restricted stock and ESPP for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, there was approximately \$15.1 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 1.30 years.

The Company recorded approximately \$9.6 million, \$7.5 million, and \$5.9 million in compensation expense related to options in the years ended December 31, 2012, 2011 and 2010.

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.

	Years Ended December 31,			
	2012	2011	2010	%
Expected dividend yield	—	% —	% —	%

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Expected stock price volatility	46.5	% 49	% 52	%
Risk-free interest rate	0.825	% 1.73	% 2.13	%
Expected option term (years)	4.95	4.75	5.17	

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 and 2010 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,			
	2012	2011	2010	
Expected dividend yield	—	% —	% —	%
Expected stock price volatility	32.65	% 38	% 65	%
Risk-free interest rate	0.14	% 0.1	% 0.19	%
Expected option term (years)	0.5	0.5	0.5	

The following table presents a summary of the Company's outstanding shares of restricted stock awards granted as of December 31, 2012:

	Number of Shares	Weighted Average Grant-Date Fair Value
Outstanding, January 1, 2010	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	14.70
Awarded	369,158	21.89
Vested	(188,541)	) 15.03
Forfeited	(16,767)	) 14.49
Outstanding, December 31, 2012	613,111	\$18.93

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 \$4.7 million, \$2.9 million and \$1.8 million was recognized related to restricted stock awards in the years ended December 31, 2012, 2011 and 2010, respectively. The remaining expense of approximately \$4.5 million will be recognized over a period of 1.24 years. The total fair value of the restricted stock that vested during the years ended December 31, 2012, 2011 and 2010 was \$4.0 million, \$3.0 million and \$1.9 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

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2012, the Company had issued 805,437 shares over the life of the 2000 ESPP. The Company canceled the 2000 ESPP upon approval of the 2010 ESPP.

**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 144,903 shares, and 157,786 shares under the 2010 ESPP during the year ended December 31, 2012 and 2011, and currently has 666,052 shares in reserve for future issuance under the 2010 ESPP. The Company recorded approximately \$0.7 million, and \$0.6 million in compensation expense related to the 2010 ESPP in the year ended December 31, 2012 and 2011.

**Common Stock Reserved for Future Issuance**

At December 31, 2012, there were 666,052 shares of common stock available for grant under the 2010 ESPP and 2,014,721 shares of common stock available for grant under the 2004 Plan.

**12. Earnings per Share**

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2012, 2011 and 2010.

	Years Ended December 31,		
	2012	2011	2010
	(In thousands, except per share amounts)		
Basic and diluted			
Net income attributable to The Medicines Company	\$51,254	\$127,877	\$104,635
Net weighted average common shares outstanding, basic	53,545	53,496	52,842
Plus: net effect of dilutive stock options and restricted common shares	1,801	911	342
Weighted average common shares outstanding, diluted	55,346	54,407	53,184
Income per common share attributable to The Medicines Company, basic	\$0.96	\$2.39	\$1.98
Income per common share attributable to The Medicines Company, diluted	\$0.93	\$2.35	\$1.97

Basic earnings 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, 2012, 2011 and 2010, options to purchase 3,171,163 shares, 6,970,991 shares, and 8,079,671 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, 2012, 2011 and 2010, 77,235 shares, 62,473 shares, and 6,375 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.



In June 2012, the Company issued, at par value, \$275.0 million aggregate principal amount of 1.375% convertible senior notes due June 1, 2017 (the Notes) (see note 9 "Convertible Senior Notes"). In connection with the issuance of the Notes, the Company entered into convertible note hedge transactions with respect to its common stock (the Note Hedges) with several of the initial purchasers of the Notes, their affiliates and other financial institutions (the Hedge Counterparties). The options that are part of

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the Note Hedges are not considered for purposes of calculating the total shares outstanding under the basic and diluted net income per share, as their effect would be anti-dilutive. The Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon any conversion of the Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the Note Hedges, is greater than the strike price of the Note Hedges, which initially corresponded to the conversion price of the Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the Notes. The shares of common stock issuable upon conversion of the Notes are not included for purposes of calculating the total shares outstanding under the basic and diluted net income per share, as the effect would be anti-dilutive.

In addition, in connection with the Note Hedges, the Company entered into warrant transactions with the Hedge Counterparties, pursuant to which the Company sold warrants (the Warrants) to the Hedge Counterparties to purchase, subject to customary anti-dilution adjustments, up to 9.8 million shares of the Company's common stock at a strike price of \$34.20 per share. For the year ended December 31, 2012, the warrants did not have a dilutive effect on earnings per share because the average market price during the periods presented was below the strike price. The Warrants will have a dilutive effect with respect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the Warrants, exceeds the applicable strike price of the Warrants. However, subject to certain conditions, the Company may elect to settle all of the Warrants in cash.

## 13. Income Taxes

The benefit from (provision for) income taxes in 2012, 2011 and 2010 consists of current and deferred federal, state and foreign taxes based on income and state taxes based on net worth as follows:

	2012	2011	2010
	(In thousands)		
Current:			
Federal	\$ (2,492 )	\$ (1,299 )	\$ (1,380 )
State	(1,309 )	(1,677 )	(1,433 )
Foreign	(863 )	(226 )	—
	(4,664 )	(3,202 )	(2,813 )
Deferred:			
Federal	(26,388 )	48,384	43,582
State	(3,920 )	5,077	(282 )
Foreign	(66 )	(225 )	—
	(30,374 )	53,236	43,300
Total benefit from (provision for) income taxes	\$ (35,038 )	\$ 50,034	\$ 40,487

The components of income before income taxes consisted of:

	2012	2011	2010
	(In thousands)		
Domestic	\$92,998	\$84,390	\$80,765
International	(6,790 )	(6,547 )	(16,617 )
Total	\$86,208	\$77,843	\$64,148

The difference between tax expense and the amount computed by applying the statutory federal income tax rate of 35% in 2012, 2011, and 2010 to income before income taxes is as follows:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Year Ended December 31,			
	2012	2011	2010	
	(In thousands)			
Statutory rate applied to pre-tax income	\$30,202	\$27,245	\$22,452	
Add (deduct):				
State income taxes, net of federal benefit	3,399	(2,210	) 1,115	
Foreign	2,136	(1,263	) 1,551	
Tax exempt portion of WilmerHale settlement	—	(4,344	) —	
Revaluation of Targanta contingent purchase price	(511	) (1,735	) 602	
Tax credits	(1,712	) (1,000	) —	
Lobbying costs	171	—	1,324	
Meals and entertainment	386	349	390	
Uncertain tax positions	542	—	510	
Other	425	(567	) 181	
Net operating loss utilization	—	—	(23,438	)
(Decrease) to valuation allowances	—	(66,509	) (45,174	)
Income tax provision (benefit)	\$35,038	\$(50,034	) \$(40,487	)

The significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2012	2011
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$23,501	\$32,437
Tax credits	13,581	24,072
Intangible assets	17,760	23,352
Stock based compensation	16,994	15,692
Other	10,386	14,841
Total deferred tax assets	82,222	110,394
Valuation allowance	(2,425	) (4,190
Total deferred tax assets net of valuation allowance	79,797	106,204
Deferred tax liabilities:		
Fixed assets	\$(1,192	) \$(979
Indefinite lived intangible assets	(18,099	) (17,389
Total deferred tax liabilities	(19,291	) (18,368
Net deferred tax assets	\$60,506	\$87,836

At December 31, 2012 and 2011, the Company's current net deferred tax asset was \$13.9 million and \$9.4 million, respectively, and its non-current net deferred tax asset was \$46.6 million and \$78.4 million, respectively.

At December 31, 2012 and 2011, none 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.

At December 31, 2012 and 2011, the Company recorded a valuation allowance of \$2.4 million and \$4.2 million, respectively, principally against net operating loss carryforwards in foreign jurisdictions. During the third quarter of 2011, the Company reduced its valuation allowance and recognized deferred tax assets of approximately \$66.5 million, because management believes these

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 was \$4.2 million, which relates to net operating losses in foreign jurisdictions.

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, 2012, 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:

Year of Expiration	Federal Net Operating Loss Carryforwards (In thousands)	Federal Research and Development Tax Credit Carryforwards
2018-2024	\$—	\$—
2025	—	224
2026	—	1,971
2027	16,507	1,028
2028	38,955	1,186
2029	4,755	899
2030	—	1,051
2031	—	2,170
	\$60,217	\$8,529

At December 31, 2012 the Company has the following additional carryforwards: Alternative Minimum Tax Credits of \$4.9 million with no expiration date and foreign net operating losses of approximately \$15.1 million expiring between 2013 and 2031.

The Company reduced its deferred tax asset attributable to certain tax credits by approximately \$0.5 million in 2012 to appropriately measure the amount of such deferred tax asset to be realized. 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 2009. However such taxing authorities can review and adjust any net operating losses and tax credit carryforwards utilized by the Company in years subsequent to 2008. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Gross Unrecognized Tax Benefits (In thousands)
Balance at January 1, 2011	\$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
Additions related to current year tax positions	—
Additions for prior year tax positions	542
Reductions for prior year tax positions	—
Settlements	—
Balance at December 31, 2012	\$2,433

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, 2012.

The Company provides income taxes on the earnings of foreign subsidiaries to the extent those earnings are taxable or are expected to be remitted. As of December 31, 2012, the Company's accumulated foreign unremitted earnings have been insignificant. The Company's policy is to leave its unremitted foreign earnings invested indefinitely outside the United States.

## 14. Fair Value Measurements

FASB 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 and U.S. treasury notes.
- 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 notes and corporate debt securities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- 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 based on management's assessment of the likelihood of achievement of certain development, regulatory and sales milestones.



The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at December 31, 2012 and 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:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	As of December 31, 2012				As of December 31, 2011			
	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, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2011
Assets and Liabilities								
Assets:								
Money market	\$ 14,751	\$ —	\$ —	\$ 14,751	\$ 25,240	\$ —	\$ —	\$ 25,240
U.S. treasury notes	—	—	—	—	3,022	—	—	3,022
U.S. government agency	—	7,097	—	7,097	—	901	—	901
Corporate debt securities	—	43,778	—	43,778	—	21,207	—	21,207
Total assets at fair value	\$ 14,751	\$ 50,875	\$ —	\$ 65,626	\$ 28,262	\$ 22,108	\$ —	\$ 50,370
Liabilities:								
Contingent purchase price	\$ —	\$ —	\$ 18,971	\$ 18,971	\$ —	\$ —	\$ 20,431	\$ 20,431
Total liabilities at fair value	\$ —	\$ —	\$ 18,971	\$ 18,971	\$ —	\$ —	\$ 20,431	\$ 20,431

## Level 3 Disclosures

The Company measures the contingent purchase price at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of contingent purchase price uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of contingent purchase price related to updated assumptions and estimates are recognized within the consolidated statements of income.

Contingent purchase price may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the market data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs:

Fair Value as  
of

	December 31, 2012  (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	\$18,971	Probability-adjusted discounted cash flow	Probabilities of success  Periods in which milestones are expected to be achieved Discount rate	20% - 60% (49%)  2013 - 2019  11%

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Fair Value as of December 31, 2011  (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
Targanta:				
Contingent purchase price	\$20,431	Probability-adjusted discounted cash flow	Probabilities of success  Periods in which milestones are expected to be achieved Discount rate	20% - 76% (58%)  2013 - 2018  12%

The fair value of the contingent purchase price represents the fair value of the Company's liability for all potential payments under the Company's agreement with Targanta. The significant unobservable inputs used in the fair value measurement of the Company's contingent purchase price are the probabilities of successful achievement of development, regulatory and sales milestones, which would trigger payments under the Targanta agreement, probabilities as to the periods in which the milestones are expected to be achieved and a discount rate. Significant changes in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement, respectively.

The changes in fair value of the Company's Level 3 contingent purchase price during the year ended December 31, 2012 and 2011 were as follows:

	December 31, 2012 (in thousands)	2011
Balance at beginning of period	\$20,431	\$25,387
Fair value adjustment to contingent purchase price included in net income	(1,460)	(4,956)
Balance at end of period	\$18,971	\$20,431

For the year ended December 31, 2012, the changes in the fair value of the contingent purchase price obligations resulted principally from a reduction in the probability of successfully obtaining regulatory approval by December 31, 2013 due to delays in enrollment in the Company's SOLO II trial. No other changes in valuation techniques or inputs occurred during the year ended December 31, 2012.

During 2011, the Company believed that the first contingent consideration payment, which related 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, was 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. This reduction in the fair value of the Company's liability was recognized as a gain in selling general and administrative expenses on the Consolidated Statements of Income 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, 2012.

15. Restructuring Costs and Other, Net

In September 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

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 statement of income. During 2012 the Company record charges of \$0.2 million relating to the 2011 Leipzig closure due the Saxony government in Leipzig recalling subsidies higher than originally estimated that were received by the Company during past three years. Of the \$2.4 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 \$0.8 million during 2012 and expects to pay out \$1.0 million during 2013. 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, 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 following table sets forth details regarding the activities described above during the year ended December 31, 2012 and 2011 are as follows:

	Balance as of January 1, 2012 (In thousands)	Expenses, Net	Cash	Noncash	Balance as of December 31, 2012
Employee severance and other personnel benefits:					
2011 Leipzig closure	\$697	\$—	\$(697)	) \$—	\$ —
Other associated costs	918	229	(138)	)	1,009
Total	\$1,615	\$229	\$(835)	) \$—	\$ 1,009

	Balance as of January 1, 2011 (In thousands)	Expenses, Net	Cash	Noncash	Balance as of December 31, 2011
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

## 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 royalties, milestone payments and other contingent payments due under the Company's licensing and acquisition agreements.

Future estimated contractual obligations as of December 31, 2012 are:

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Contractual Obligations <sup>(1)</sup>	2013	2014	2015	2016	2017	Later Years	Total
	(In thousands)						
Inventory related commitments	\$40,753	\$28,468	\$8,210	\$710	\$—	\$—	\$78,141
Long-term debt obligations	3,781	3,781	3,781	3,781	276,891	—	292,015
Research and development	6,266	780	—	—	—	—	7,046
Operating leases	7,412	6,172	5,645	5,378	11,690	18,526	54,823
Selling, general and administrative	2,550	850	139	—	—	—	3,539
Total contractual obligations	\$60,762	\$40,051	\$17,775	\$9,869	\$288,581	\$18,526	\$435,564

(1) 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 totaling \$29.9 million for 2013, \$26.6 million for 2014 and \$7.5 million for 2015 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$6.8 million is non-cancellable.

The Company's long-term debt obligations reflect its obligations under the Notes to pay interest on the \$275.0 million aggregate principal amount of the Notes and to make principal payments on the Notes at maturity or upon conversion. 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 expired January 2013. In the second half of 2010, 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 86% 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 \$5.8 million in 2012, \$7.3 million in 2011 and \$5.8 million in 2010.

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 and HRI, royalty and milestone payments with respect to Cleviprex, contingent cash payments up to approximately \$85.1 million that could 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-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 2012, 2011 and 2010, the Company incurred aggregate royalties to Biogen and HRI of \$122.2 million, \$108.2 million and \$85.5 million, respectively, and royalties to AstraZeneca with respect to Cleviprex of \$1.0 million, \$0.8 million and \$0.7 million, respectively.

Teva API, Inc.



Contemporaneously with entering into the settlement and license agreements with Teva Pharmaceuticals USA, Inc. and its affiliates 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

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

supply agreement upon breach of the settlement agreement and certain breaches of the license agreement. During 2012, Teva API's production of active pharmaceutical ingredient bivalirudin totaled \$26.5 million.

## 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. Eagle, as a result, alleges that it is entitled to an amount of damages totaling \$306 million. In January 2013, an arbitration hearing took place and in February 2013, the Company and Eagle submitted post-hearing briefs. The Company believes it has valid defenses to Eagle's claims and intends to defend itself vigorously. The Company believes that potential liability, if any, is not estimable at this time.

In addition, the Company is currently party to the other 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 for any of these matters. While it is not possible to determine the outcome of the matters described in Part I, Item 3, Legal Proceedings, 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. The Company made matching contributions in December 31, 2012 and 2011 of \$1.2 million and \$1.1 million, respectively.

## 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.

Company operations:									
	Years Ended December 31,								
	2012	2011			2010				
						(In			
						thousands)			
Net revenue:									
United States	\$512,044	91.7	%	\$453,163	93.5	%	\$413,044	94.4	%

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Europe	38,517	6.9	%	25,532	5.3	%	20,126	4.6	%
Other	8,027	1.4	%	6,037	1.2	%	4,475	1.0	%
Total net revenue	\$558,588			\$484,732			\$437,645		

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## THE MEDICINES COMPANY

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Years Ended December 31,					
	2012			2011		
	(In thousands)					
Long-lived assets:						
United States	\$ 166,129	99.1	%	\$ 126,513	99.0	%
Europe	1,243	0.7	%	1,069	0.8	%
Other	240	0.1	%	187	0.1	%
Total long-lived assets	\$ 167,612			\$ 127,769		

## 19. Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the years ended December 31, 2012 and 2011.

	Three Months Ended							
	Mar. 31, 2012	June 30, 2012	Sept. 30, 2012	Dec. 31, 2012	Mar. 31, 2011 (1)	June 30, 2011	Sept. 30, 2011 (2)	Dec. 31, 2011
	(In thousands, except per share data)							
Net revenue	\$ 126,610	\$ 135,702	\$ 136,786	\$ 159,490	\$ 112,137	\$ 119,591	\$ 120,773	\$ 132,231
Cost of revenue	38,663	42,681	43,767	52,228	35,570	37,830	39,459	44,007
Total operating expenses	75,964	73,429	77,932	70,851	61,720	67,956	71,903	68,218
Net income attributable to The Medicines Company	7,571	13,755	9,265	20,663	24,241	11,440	72,614	19,582
Basic net income per common share attributable to The Medicines Company	\$ 0.14	\$ 0.25	\$ 0.18	\$ 0.39	\$ 0.46	\$ 0.21	\$ 1.36	\$ 0.36
Diluted net income per common share attributable to The Medicines Company	\$ 0.14	\$ 0.25	\$ 0.17	\$ 0.38	\$ 0.45	\$ 0.21	\$ 1.34	\$ 0.35

(1) Net income for the first quarter of 2011 includes income of \$18.0 million related to the settlement agreement entered into with Wilmer Cutler Pickering Hale and Dorr LLP (WilmerHale) in February 2011.

(2) Net income for the third quarter of 2011 includes a tax benefit of \$66.5 million from reducing the Company's valuation allowance against its deferred tax assets.

## 20. Subsequent Events

## Incline Therapeutics, Inc.

In January 2013, the Company acquired Incline Therapeutics, Inc. (Incline), a company focused on the development of IONSYS, a compact, disposable, needleless patient-controlled system for the short-term management of acute postoperative pain in the hospital setting.

Under the terms of the Company's agreement with Incline, the Company paid to Incline's equityholders and optionholders an aggregate of approximately \$156 million in cash, which is subject to a post-closing purchase price adjustment process. In addition, the Company also paid approximately \$13 million to Cadence Pharmaceuticals, Inc. (Cadence) to terminate Cadence's option to acquire Incline pursuant to an agreement between Cadence and Incline and deposited \$18.5 million in cash into an escrow fund for the purposes of securing the indemnification obligations of the Incline equityholders to the Company for any and all losses for which the Company is entitled to indemnification pursuant to the merger agreement and to provide the source of recovery for any amounts payable to the Company as a result of the post-closing purchase price adjustment process.

Under the terms of the Company's agreement with Incline, the Company agreed to pay up to \$205 million in cash in the aggregate, less certain transaction expenses and taxes because of the milestone payments, upon its entering into a license agreement in Japan or achieving certain regulatory approval and sales milestones with respect to IONSYS.

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company expects to account for the transaction as a business combination and is in the process of determining the allocation of the purchase price to acquired assets and assumed liabilities.

Recothrom

In February 2013, pursuant to a master transaction agreement with Bristol-Myers Squibb Company (BMS), the Company acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period (the collaboration term), and BMS transferred to the Company certain limited assets exclusively related to Recothrom, primarily the biologics license application for Recothrom and certain related regulatory assets. BMS also granted to the Company, under the master transaction agreement, an option to purchase from BMS and its affiliates, following the expiration or earlier termination of the collaboration term, certain other assets, including certain patent and trademark rights, contracts, inventory, equipment and related books and records, held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, the Company paid to BMS a one-time collaboration fee equal to \$105 million and a one-time option fee equal to \$10 million. The Company did not assume, and if the Company exercises the option, it will not assume, any pre-existing liabilities related to the Recothrom business, contingent or otherwise, arising prior to the collaboration period, and the Company did not acquire, and if the Company exercises the option, it will not acquire, any significant tangible assets related to the Recothrom business. Under the master transaction agreement, the Company agreed to pay to BMS quarterly tiered royalty payments during the collaboration term equal to a percentage of worldwide net sales of Recothrom.

If the Company exercises the option, it would, at the closing of the purchase of the option assets, acquire such assets and assume certain liabilities of BMS and its affiliates related to the assets and to pay to BMS a purchase price equal to the net book value of inventory included in the acquired assets, plus either:

a multiple of average net sales over each of the two 12-month periods preceding the closing of the purchase (unless the purchase closing occurs less than 24 months after February 8, 2013, in which case the measurement period would be the 12-month period preceding the purchase closing); or

if BMS has delivered a valid notice terminating the collaboration term early as a result of a material breach by the Company under the master transaction agreement, the amount described above plus an amount intended to give BMS the economic benefit of having received royalty fees for a 24-month collaboration term.

In connection with the master transaction agreement, the Company also entered into a supply agreement with BMS. Under the supply agreement, BMS or one or more of its affiliates will manufacture Recothrom and serve as the exclusive supplier of the Recothrom to the Company during the collaboration term at specified purchase prices.

The Company expects to account for the transaction as a business combination and is in the process of determining the allocation of the purchase price to acquired assets and assumed liabilities.

ALN-PCS Program

In February 2013, the Company entered into a license and collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam) to develop, manufacture and commercialize therapeutic products targeting the proprotein convertase subtilisin/ kexin type 9 (PCSK9) gene, based on certain of Alnylam's RNA interference (RNAi) technology. Under the terms of the agreement, the Company obtained the exclusive, worldwide right under Alnylam's technology to develop, manufacture and commercialize PCSK-9 products for the treatment, palliation and/or prevention of all human diseases. The Company has paid Alnylam \$25 million in an initial license payment, which will be expensed in the first

quarter of 2013, and agreed to pay up to \$180 million in success-based development and commercialization milestones. In addition, the Company has agreed to pay specified royalties on net sales of these products. Royalties to Alnylam are payable on a product-by-product and country-by-country basis until the last to occur of the expiration of patent rights in the applicable country that cover the applicable product, the expiration of non-patent regulatory exclusivities for such product in such country, and the twelfth anniversary of the first commercial sale of the product in such country, subject to reduction in specified circumstances. The Company is also responsible for paying royalties, and in some cases, milestone payments, owed by Alnylam to its licensors with respect to intellectual property covering these products.

Workforce Reduction

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THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

On February 27, 2013, the Company commenced implementation of a workforce reduction plan intended to improve efficiency and better align the Company's costs and employment structure with its strategic plans. As a result of the workforce reduction, the Company reduced its personnel by 66 employees, or roughly 12%. Affected employees will be eligible to receive reduction payments in specified amounts and fully paid health care coverage and outplacement services for specified periods. The Company expects to complete the workforce reduction by the end of first quarter of 2013.

The Company expects to record, in the aggregate, a one-time charge of approximately \$7 million associated with the workforce reduction, which will be recognized in the first quarter of 2013. Substantially all of this charge is expected to represent cash expenditures. The Company expects to realize estimated annualized cost savings from the workforce reduction in the range of \$13 million to \$14.0 million starting in the first quarter of 2013.

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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)
- 2.4#† Agreement and Plan of Merger, dated December 11, 2012, by and among the registrant, Incline Therapeutics, Inc., Silver Surfer Acquisition Corp. and Fortis Advisors LLC (filed as Exhibit 2.1 to the registrant's current report on Form 8-K, filed January 10, 2013)
- 2.5#† Master Transaction Agreement, dated December 11, 2012, by and between the registrant and Bristol-Myers Squibb Company (filed as Exhibit 2.1 to the registrant's current report on Form 8-K, filed February 8, 2013)
- 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 3.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2012)
- 4.1 Indenture (including Form of Notes), dated as of June 11, 2012, by and between The Medicines Company and Wells Fargo Bank, National Association, a national banking association, as trustee (filed as Exhibit 4.1 to the registrant's current report on Form 8-K, filed June 14, 2012)
- 10.1† Supply Agreement, dated December 11, 2012, by and between the registrant and Bristol-Myers Squibb Company (filed as Exhibit 10.1 to the registrant's current report on Form 8-K, filed February 8, 2013)
- 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



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Number	Description
10.10*	Director Compensation Summary
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 June 30, 2010)
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
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 (filed as Exhibit 10.17 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
10.31†	Amendment No. 1 to License Agreement dated April 25, 2006 by and between AstraZeneca AB (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2006)
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)



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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)

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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)
10.55†	Settlement Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.56†	License Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.57†	Contract Manufacturing Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.58†	License and Supply Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.59†	AG Supply Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (filed as Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.60†	Amendment 1 to the Supply Agreement, dated February 13, 2012, between registrant and Teva API, Inc. (formerly known as Plantex USA Inc.) (filed as Exhibit 10.6 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012)
10.61†*	Severance Agreement and Full and Final Mutual General Release of Claims, dated April 16, 2012, between the registrant and Leslie C. Rohrbacker (filed as Exhibit 10.1 to the registrant's quarterly report on

Form 10-Q for the quarter ended June 30, 2012)

- 10.62† Global Collaboration Agreement, dated April 25, 2012, between the registrant and AstraZeneca LP (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2012)
- 10.63† Third Amendment to Second Amended and Restated Distribution Agreement, dated April 23, 2012, between registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2012)
- 10.64† Letter Agreement, dated August 7, 2012, by and between the registrant and Biogen Idec MA Inc. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2012)
- 10.65\* Consulting Agreement, dated July 6, 2012, by and between the registrant and Strategic Imagery, LLC (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2012)
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10.66*	Amendment to Consulting Agreement, effective as of July 6, 2012, by and between the registrant and Strategic Imagery, LLC
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, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statement of Income, (iii) the Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements

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# Schedules (and similar attachments) have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally copies of any of the omitted schedules (or similar attachments) to the Securities and Exchange Commission upon request.

\* 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.