

April 29, 2015

Dear Stockholders:

The Medicines Company remains committed to its purpose, which is to save lives, alleviate suffering and contribute to the economics of healthcare by focusing on 3,000 leading acute/intensive care hospitals worldwide. In doing this, we are confident in our expectation that we can create substantial stockholder value.

In 2014, we were able to execute on our strategic commercial and development plan by continuing to provide valuable solutions, such as Angiomax<sup>®</sup> (bivalirudin), Cleviprex<sup>®</sup> (clevidipine) injectable emulsion and Recothrom<sup>®</sup> Thrombin topical (Recombinant), by launching new solutions, such as Orbactiv<sup>®</sup> (oritavancin), and by advancing our product candidates through the development and regulatory approval processes.

Once again, this is a year of focused execution. The year has started with regulatory approval of Orbactiv, Kengrexal<sup>™</sup> (cangrelor) and Raplixa<sup>™</sup> (sealant powder) in the EU and Minocin<sup>®</sup> (minocycline) for Injection in the US. Looking ahead to the rest of 2015, we anticipate moving additional products through the regulatory approval process, including IONSYS<sup>®</sup> (fentanyl iontophoretic transdermal system), Raplixa and Kengreal (cangrelor) in the US. We continue to develop our capabilities in customer engagement – internally and through potential partnerships – to commercialize our current products and our product candidates upon their approval. In addition, we look forward to advancing our portfolio of significant development stage solutions, ABP-700, ALN-PCSSc, Carbavance<sup>™</sup> and MDCO-216, through further clinical development.

We thank you for your support and look forward to continuing to make meaningful contributions to our patients, customers and those in healthcare whose lives we impact. It is with great attention that we maintain the highest standards of moral, ethical and professional conduct so that we may continue to provide medical solutions that improve health outcomes for patients in leading hospitals worldwide.

Sincerely,



Clive A. Meanwell, MD, PhD  
Chairman and Chief Executive Officer



Glenn P. Sblendorio  
President and Chief Financial Officer

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, 2014

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, 2014 was approximately \$1,864,691,625 based on the last reported sale price of the Common Stock on The NASDAQ Global Select Market on June 30, 2014 of \$29.06 per share.

Number of shares of the registrant's class of Common Stock outstanding as of February 24, 2015: 65,645,458

**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, 2014. Portions of the proxy statement are incorporated herein by reference into the following parts of this Annual Report on Form 10-K:

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

Part III, Item 11. Executive Compensation;

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.

**THE MEDICINES COMPANY**  
**ANNUAL REPORT ON FORM 10-K**  
**For the Fiscal Year Ended December 31, 2014**  
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The Medicines Company® name and logo, Angiomax®, Angiox®, Cleviprex®, Carbavance™, Fibrocaps™, IONSYS®, Kengrexal™, Orbactiv®, PreveLeak™, Raplixa™ and Recothrom® 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, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. 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,” “will,” “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 Part II, Item 7. *Management Discussion and Analysis* of this Annual Report on Form 10-K and the factors set forth under the caption “Risk Factors” in Part I, Item 1A. of this Annual Report on Form 10-K. 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 on Form 10-K.

PART I

Item 1. Business.

Our Company

Overview

We are a global biopharmaceutical company focused on saving lives, alleviating suffering and contributing to the economics of healthcare by focusing on leading acute/intensive care hospitals worldwide. We market Angiomax<sup>®</sup> (bivalirudin), Cleviprex<sup>®</sup> (clevidipine) injectable emulsion, Minocin (minocycline) for injection, Orbactiv<sup>®</sup> (oritavancin), PreveLeak<sup>™</sup> and Recothrom<sup>®</sup> Thrombin topical (Recombinant). We also have a pipeline of acute and intensive care hospital products in development, including four registration stage product candidates for which we have submitted applications for regulatory approval in the United States, cangrelor, IONSYS<sup>®</sup> (fentanyl iontophoretic transdermal system), Raplixa<sup>™</sup>, formerly referred to as Fibrocaps<sup>™</sup>, and RPX-602, and four research and development product candidates, ABP-700, ALN-PCSsc, Carbavance<sup>™</sup> and MDCO-216. We refer to our registration stage product candidates and our research and development product candidates as our products in development. We have the right to develop, manufacture and commercialize ALN-PCSsc under our collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam. We believe that these 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 products in development, we sell a ready-to-use formulation of Argatroban and 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 are currently selling three of our acute care generic products, midazolam, ondansetron and rocuronium.

The following table 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, in each case. The table 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 ALN-PCSsc, IONSYS, PreveLeak, Raplixa and Recothrom, are administered intravenously. Each of PreveLeak and Recothrom is, and Raplixa is being developed as, 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
<b>Marketed Products</b>			
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/HITTS  Europe - for use as an anticoagulant in patients undergoing PCI, adult patients with acute coronary syndrome, or ACS, and for the treatment of patients with ST-segment elevation myocardial infarction, or STEMI, undergoing primary PCI

Cleviprex	Marketed in the United States, Australia, Germany, Spain and Switzerland  Approved in Austria, Belgium, Canada, France, Liechtenstein, Luxembourg, the Netherlands, New Zealand, Sweden and the United Kingdom  Marketing Authorization Application, or MAA submitted for other European Union countries	Calcium channel blocker	U.S. - Blood pressure reduction when oral therapy is not feasible or not desirable  Ex-U.S. - with various indications for blood pressure control in perioperative settings
Minocin IV	Marketed in the United States	Tetracycline-class antibiotic	Treatment of bacterial infections due to susceptible isolates of designated microorganisms, including Acinetobacter species.
Orbactiv	Marketed in the United States; MAA accepted for review in the European Union in the first quarter of 2014	Antibiotic	Treatment of adult patients with acute bacterial skin and skin structure infections, or ABSSSI, caused or suspected to be caused by susceptible isolates of the label-designated gram-positive microorganisms, including methicillin-resistant Staphylococcus aureus, or MRSA
PreveLeak	Approved in the United States; Marketed in the European Union	Mechanical vascular and surgical sealant	U.S. - for use as a vascular sealant Europe - for use in cardiac, vascular and soft tissue reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage
Ready-to-use Argatroban	Marketed in the United States	Direct thrombin inhibitor	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
Recothrom	Marketed in the United States	Recombinant human thrombin	For use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical procedures
Acute care generic products: Adenosine, Amiodarone, Esmolol and Milrinone	Approved in the United States	Various	Acute cardiovascular
Acute care generic products: Azithromycin and Clindamycin	Approved in the United States	Various	Serious infectious disease
Acute care generic products: Haloperidol, Midazolam, Ondansetron and Rocuronium	Approved in the United States; Midazolam, Ondansetron and Rocuronium marketed in the United States	Various	Surgery and perioperative

**Registration Stage**

Cangrelor	New Drug Application, or NDA, in the United States accepted for filing by the Food and Drug Administration, or FDA, in the third quarter of 2013; MAA accepted for review in the European Union in the fourth quarter of 2013	Antiplatelet agent	Prevention of platelet activation and aggregation when oral therapy is not feasible or not desirable
IONSYS	Supplemental New Drug Application, or sNDA, accepted for filing by the FDA in the third quarter of 2014; MAA accepted for review in European Union in the third quarter of 2014	Patient-controlled analgesia system	Short-term management of acute postoperative pain
Raplixa	Biologics License Application, or BLA, accepted for filing by the FDA in April 2014; MAA submission in the European Union accepted for review in the fourth quarter of 2013	Dry powder topical formulation of fibrinogen and thrombin	For use as an aid to stop bleeding during surgery
RPX-602	sNDA filed with the FDA in December 2014	Improved formulation of Minocin IV	Treatment of bacterial infections due to susceptible isolates of designated microorganisms, including Acinetobacter species.
<b>Research and Development Stage</b>			
ABP-700	Phase 1	Analogue of etomidate, an intravenous imidazole agent used for induction of general anesthesia	Sedative-hypnotic used to induce and maintain sedation for procedural care and general anesthesia for surgical care
ALN-PCSsc	Phase 1 being conducted by Alnylam	PCSK-9 gene antagonist addressing low-density lipoprotein cholesterol disease modification	Treatment of hypercholesterolemia
Carbavance	Phase 3 clinical trial commenced in the fourth quarter of 2014	Combination of RPX-7009, a proprietary, novel beta-lactamase inhibitor, with meropenem, a carbapenem antibiotic	Treatment of hospitalized patients with serious gram-negative bacterial infections
MDCO-216	Phase 1 completed	Naturally occurring variant of a protein found in high-density lipoprotein	Reversal cholesterol transport agent to reduce atherosclerotic plaque burden development and thereby reduce the risk of adverse thrombotic events

## 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 patients undergoing PCI, with provisional use of glycoprotein IIb/IIIa receptor inhibitors, or GP IIb/IIIa inhibitors, including patients with or at risk of HIT/HITTS.

Angiomax is approved in the European Union for use as an anticoagulant in adult patients undergoing PCI, including patients with STEMI undergoing primary PCI. The approval for ACS in Europe also includes treatment of adult 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.

Angiomax is also approved for use 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 FDA or European Medicines Agency, or EMA. In addition, Angiomax is approved in Canada for the treatment of patients with HIT/HITTS undergoing cardiac surgery.

In 2014, our net sales of Angiomax totaled approximately \$635.7 million, including approximately \$599.5 million of net sales in the United States.

#### Medical Need

Arterial thrombosis is a condition involving the formation of potentially occlusive blood clots in arteries and is associated with life-threatening conditions such as ischemic heart disease, peripheral vascular disease and stroke. When arterial thrombosis occurs in the coronary arteries, depending on the severity of the occlusion, a range of ACS may result.

The spectrum of ACS, from unstable angina to acute myocardial infarction, or AMI, results in chest pain, other ischemic symptoms, and potential damage to the heart muscle. Unstable angina and similar conditions are caused most often by a rupture of atherosclerotic 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. AMI occurs when coronary arteries, which supply blood to the heart, become completely blocked by a clot. AMI patients routinely undergo PCI as soon as possible as a primary treatment to unblock clogged arteries. Increasingly, patients with ACS are also undergoing early diagnostic angiography and receive PCI as soon as possible as treatment.

Coronary angioplasty procedures such as PCI or PTCA that are used to restore arterial blood flow inherently increase the risk of clot formation. Clots form as the body reacts to the manipulation of the artery as a result of, for example, the use of catheters, stents, and other devices as well as from mechanical plaque rupture during the angioplasty procedure. Accordingly, anticoagulation therapy is routinely administered to patients undergoing angioplasty to limit both the underlying thrombotic process of ACS, as well as the clotting process stimulated by the procedure itself.

Heparin has historically been used as an anticoagulant in the treatment of arterial thrombosis and during PCI or PTCA. However, heparin pharmacokinetics are non-linear, with intra- and interpatient variability. The result is that a patient's response to the drug is less predictable and standardized dosing is difficult. In some patients, especially patients with ACS, higher doses of heparin and adjunct therapy, such as GP IIb/IIIa inhibitors, may be required, which may increase the risk of bleeding complications. These shortcomings are significant because effective anticoagulation is important in patients being treated for ischemic heart disease to reduce the risk of further complications such as death, AMI or repeat revascularization.

Additionally, heparin has been associated with an immune syndrome known as HIT/HITTS. The most severe form, while rare, is a potentially devastating condition with a very high risk of morbidity and mortality.

#### 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 large clinical trials, Angiomax was compared to various drug regimens, including heparin and enoxaparin, a low-molecular weight heparin, which until relatively recently were the only injectable anticoagulants available for use in coronary angioplasty, and combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors. We have tested Angiomax against heparin or enoxaparin or combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors in comparative PCI and ACS trials. In these trials, compared with the comparator drug regimens, Angiomax use resulted in similar rates of ischemic complications, such as myocardial infarction, or MI, and in fewer bleeding events, including a reduction in the need for blood transfusion. 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 and patients undergoing peripheral endovascular intervention, or PEI.

## 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 June 2011, the FDA approved an 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. In October 2011, we re-launched Cleviprex in the United States with the new formulation.

In addition to the United States, the new formulation of Cleviprex is approved for sale in Australia, Austria, Belgium, Canada, France, Germany, Liechtenstein, Luxembourg, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom with various indications, including for short term treatment of hypertension when oral therapy is not feasible or desirable in Australia, for management of acute elevation of blood pressure in perioperative settings in Canada, and for the rapid reduction of blood pressure in perioperative settings in the European Union and Switzerland. The original formulation of Cleviprex is approved in New Zealand for the reduction of blood pressure when rapid and predictable control is desired. 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 2014, our net sales of Cleviprex totaled approximately \$6.8 million.

## Minocin IV

### Overview

As a result of our acquisition of Rempex in December 2013, we acquired and began to market Minocin (minocycline) for injection, or Minocin IV, in the United States. Minocin IV is an intravenous formulation of a tetracycline-class antibiotic that is approved in the United States for the treatment of infections due to susceptible strains of designated gram-negative bacteria, including those due to *Acinetobacter* spp, and designated gram-positive bacteria. Minocin IV is also approved for the treatment of infections caused by the following microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: skin and skin structure infections caused by *Staphylococcus aureus*, *Escherichia coli*, *Enterobacter aerogenes*. *Shigella* species, respiratory tract infections caused by *Haemophilus influenza* and respiratory tract and urinary tract infections caused by *Klebsiella* species.

In 2014, our net sales of Minocin IV totaled approximately \$1.4 million.

### Medical Need

*Acinetobacter* has recently emerged as a significant problem in many U.S. hospitals where it can cause serious infections in critically ill patients, particularly in intensive care units. Inadequate treatment of *Acinetobacter* is associated with high mortality. The U.S. Centers for Disease Control and Prevention, or CDC, recently classified multi-drug resistant, or MDR, *Acinetobacter* as a serious threat in the United States. According to the CDC, about 63% of *Acinetobacter* species are considered MDR. Recent studies of a large hospital database presented at ID Week in 2014 showed that infections due to MDR *Acinetobacter* were associated with a greater cost and increased hospital length of stay compared to non-MDR isolates. Surveillance data show a significant majority of isolates of *Acinetobacter baumannii* are susceptible to minocycline in vitro. In studies of large collections of isolates from U.S. hospitals, as well as hospitals worldwide, presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy in September 2013 and ID Week in October 2013, minocycline was one of the most active agents in vitro against this pathogen, including MDR strains. In view of the high mortality, drug resistance, and the poor economic and clinical outcomes associated with other drugs, we believe that Minocin IV would be a useful choice in patients infected with susceptible strains of *Acinetobacter*.

## Orbactiv

### Overview

Orbactiv is an intravenous antibiotic that has been approved by the FDA for the treatment of adult patients with acute bacterial skin and skin structure infections, or ABSSSI, caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms, including methicillin-resistant *Staphylococcus aureus*, or MRSA, with a single dose treatment. Orbactiv is synthetically modified from a naturally occurring compound. In August 2014, we received FDA approval of our NDA for Orbactiv, and in October 2014, we commercially launched Orbactiv in the United States. In January 2015, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA issued an opinion recommending marketing authorization for oritavancin in the European Union.

We obtained rights to Orbactiv as a result of our acquisition of Targanta Therapeutics Corporation, or Targanta, in February 2009. We have exclusive rights to develop, market, and sell Orbactiv worldwide under a license agreement with Eli Lilly, which originally discovered and developed Orbactiv. In November 2013, the FDA designated Orbactiv a qualified infectious disease product, or QIDP, under the "Generating Antibiotic Incentives Now," or GAIN, provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA. In August 2014, following Orbactiv's approval, the FDA informed us that Orbactiv met the criteria for an additional five years of non-patent exclusivity in the United States to be added to the five year exclusivity period already provided by the Food, Drug and Cosmetic Act. As a result, Orbactiv's non-patent regulatory exclusivity is scheduled to expire in August 2024.

In 2014, our net sales of Orbactiv totaled approximately \$0.8 million.

### Medical Need

Although there are a number of other approved antibiotics for the treatment of ABSSSI, these antibiotics have important shortcomings, including:

- bacteria are becoming non-susceptible or resistant to one or more of these existing antibiotics;
- some of these antibiotics, referred to as bacteriostatic drugs, inhibit the growth of pathogens and rely on the immune system to actually kill the bacteria. In contrast, bactericidal antibiotics, such as oritavancin kill bacteria independent of the immune system;
- many of the antibiotics used to treat ABSSSI are difficult or inconvenient to administer, as they must be administered intravenously more than once, and in some cases once or twice daily for seven or more days, and may require the insertion of a peripherally inserted central catheter (PICC line). As a result, patients receiving these antibiotics are typically either hospitalized or receive their antibiotics as an outpatient, either at an infusion center or at home, often once or twice a day; and
- therapeutic monitoring of blood levels is commonly utilized when the most frequently used intravenous antibiotic used for the treatment of ABSSSI due to MRSA is given to a patient.

We believe Orbactiv addresses many of the shortcomings of these antibiotics. Orbactiv is the first and only antibiotic approved by FDA to treat ABSSSI with a single, once-only administration. The pharmacokinetic and pharmacodynamic profile of Orbactiv includes concentration-dependent killing and a long half-life, which allows for the single dose therapy. We believe this single dose regimen, is beneficial because it assists patient compliance, offers physicians the option to treat patients as either an outpatient or inpatient, and does not require additional patient visits for repeat intravenous infusions.

### Clinical Development

In the fourth quarter of 2010, we commenced two independent, pivotal Phase 3 trials of Orbactiv, SOLO I and SOLO II, to evaluate the efficacy and safety of a single 1200 mg intravenous dose of Orbactiv compared to multiple doses of intravenous vancomycin, for the treatment of ABSSSI, including infections caused by MRSA. We designed these large, identically designed, global, randomized, double-blind studies in accordance with guidance from the FDA and the EMA to ensure accurate representation of the population requiring treatment with an antibacterial agent for ABSSSIs, including ABSSSIs caused by MRSA. The protocols were agreed to with the FDA following a special protocol assessment, or SPA, and with the EMA through Final Scientific Advice process.

*SOLO*. In the SOLO I and SOLO II clinical trials, we compared a single 1,200 mg intravenous dose of Orbactiv with seven to 10 days of intravenous vancomycin treatment given twice daily. The trials were 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. We enrolled 968 patients in the SOLO I clinical trial, and we enrolled 1,019 patients in the SOLO II clinical trial.

In both trials, non-inferiority to vancomycin was demonstrated for all protocol-specified primary and secondary efficacy endpoints, specifically for the Early Clinical Evaluation (48-72 hours after treatment initiation) endpoint required by the FDA and the Post Therapy Evaluation (7-14 days after end of treatment) endpoint required by the EMA. The most frequently reported adverse events associated with Orbactiv were nausea, headache, vomiting and diarrhea. Hypersensitivity reactions have been reported with the use of antibacterial agents including Orbactiv.

*QT Studies.* In the first quarter of 2013, we conducted a randomized, positive-, placebo-controlled thorough QTc study where 135 healthy subjects were administered a single 1600 mg dose of Orbactiv, placebo, and a positive control (moxifloxacin) by IV infusion over 3 hours. At a single 1600 mg dose of oritavancin, no significant effect on QTc interval was detected at peak plasma concentration or at any other time. We announced data from the trial in the second half of 2014.

*Other Clinical Studies.* Prior to our acquisition of Targanta, Targanta had completed a number of clinical studies of Orbactiv, including a Phase 2 clinical study evaluating 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 Orbactiv, in Arm B, patients received a 800 mg dose of Orbactiv on day 1 followed by an optional 400 mg dose of Orbactiv on day 5, and in Arm C, patients received a 200 mg dose of Orbactiv 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, Eli Lilly and InterMune, Inc., which transferred their rights for Orbactiv to Targanta in 2005, conducted two Phase 3 trials of Orbactiv, 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 Orbactiv to a control arm of vancomycin followed by an oral antibiotic, cephalexin, using a non-inferiority trial design. In both of the trials, Orbactiv met the primary endpoint.

*Additional development.* We are exploring the development of Orbactiv for other indications, including ABSSSI in children, uncomplicated bacteremia, endocarditis, prosthetic joint infections, and other gram-positive bacterial infections.

## **PreveLeak**

### *Overview*

PreveLeak is a mechanical vascular and surgical sealant that we acquired in our acquisition of Tenaxis Medical, Inc., or Tenaxis, in May 2014. PreveLeak is a polyaldehyde and albumin-based sealant that, when applied, creates an elastic biocompatible gel that bonds to native tissue and synthetic grafts and seals suture holes. PreveLeak received premarket approval from the FDA in March 2013 for use as a vascular sealant, but has not yet been commercialized in the United States. We expect to begin selling PreveLeak in the United States in 2015.

We began selling PreveLeak in the European Union after our acquisition of Tenaxis in April 2014. Prior to the acquisition, Tenaxis had been selling the product in the European Union since September 2008. In the European Union, the product is approved for sale with a European CE Mark as a surgical sealant indicated for vascular, cardiac and soft tissue reconstructions to achieve hemostasis by mechanically sealing areas of leakage.

In 2014, our net sales of PreveLeak, from and after the Tenaxis acquisition, totaled approximately \$0.3 million.

### *Medical Need*

When the natural process of blood clotting does not occur, surgeons employ other methods to stop the bleeding. Typically, surgeons will first use sutures and staples to close the bleeding site. Additionally, topical hemostatic agents, as adjuncts to hemostasis when sutures or staples are impractical or insufficient, have been in use for a number of years. Over the last decade, suture line bleeding has led to the widespread use and development of a variety of hemostats and sealants to seal suture lines and reinforce tissue not only when needed but also prophylactically. These sealants fill the needle or staple holes and seal the site preventing leakage of body fluids such as blood.

### *Clinical Development*

Prior to our acquisition of Tenaxis in April 2014, Tenaxis had completed three clinical trials of PreveLeak. The first was conducted in 2007 as an open-label, single-group trial performed in Germany. In this trial, PreveLeak demonstrated its sealing properties as well as its tolerability.

A pivotal clinical trial was conducted in 2010 to evaluate the safety and effectiveness of the use of PreveLeak in vascular surgical procedures to provide adjunctive hemostasis. This study was a prospective, randomized, controlled trial conducted in the United States. Safety and efficacy data from this clinical study were the primary basis for the premarket approval, or PMA, decision by the FDA.

A third clinical trial was completed in 2013 in order to collect data in support of publications and future product labeling revisions, to provide additional clinical information on use and to provide further details regarding product safety and efficacy of PreveLeak in subpopulations at risk of poor hemostasis undergoing cardiovascular surgical procedures. The results from this trial were presented at the European Society of Cardiothoracic Surgery meeting in October 2014 and confirm the safety and performance of PreveLeak for the proposed indications for use, and provided supporting evidence that PreveLeak continues to meet its design goals and user needs. These results have been submitted to the appropriate notified body in support of a European Union label expansion to include cardiovascular reconstructive surgical procedures.

## **Ready-to-Use 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 sold by GlaxoSmithKline and West-Ward Pharmaceuticals 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 Eagle's 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 this ready-to-use Argatroban in September 2011. In December 2011, Eagle conducted a voluntary recall of its 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 recommenced selling ready-to-use Argatroban to existing and new customers.

In 2014, our net sales of ready-to-use Argatroban totaled approximately \$15.1 million.

## **Recothrom**

### *Overview*

Recothrom is a topical human recombinant thrombin developed for use as an aid to hemostasis to help control oozing blood and mild bleeding during surgical procedures. 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. In February 2015, we acquired from BMS the remaining 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 2014, our net sales of Recothrom totaled approximately \$64.4 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. 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 by BMS. 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 in which 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, as well as integrated safety and immunogenicity results for all completed clinical trials, have been published.

### **Acute Care Generic 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 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 acute cardiovascular, surgery and perioperative care and serious infectious diseases, and we believe complement our marketed products and product candidates. We began selling three of our acute care generic products, midazolam, ondansetron and rocuronium, in the first quarter of 2013.

### **Registration Stage Products**

#### **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.

In the third quarter of 2013, our NDA for cangrelor for use in patients undergoing PCI or those that require bridging for oral antiplatelet therapy to surgery was accepted for filing by the FDA. In February 2014, the FDA Cardiovascular and Renal Drugs Advisory Committee advised against approval of our NDA. On April 30, 2014, the FDA issued a Complete Response Letter regarding our NDA for cangrelor. For the PCI indication, the FDA stated that the NDA cannot be approved at the time and suggested that we perform a series of clinical data analyses of our Phase 3 CHAMPION PHOENIX clinical trial, which is described below, review certain processes regarding data management, and provide bioequivalence information on the clopidogrel clinical supplies for our CHAMPION clinical program. For the BRIDGE indication, the FDA concluded that a prospective, adequate and well controlled study in which outcomes such as bleeding are studied would be required to provide the clinical data necessary to assess the benefit risk relationship in this indication. The FDA also provided additional comments for us to address, stating that the comments are not currently approvability issues, but could affect labeling. In December 2014, we submitted our response to the Complete Response Letter with respect to the PCI indication only and, in the response, withdrew our request for approval for the BRIDGE indication. The FDA accepted our resubmission and provided a PDUFA date in June 2015. The FDA action date, known as the PDUFA date, is the date by which the FDA is expected to make a decision on the NDA. The FDA has informed us that cangrelor will be reviewed at a Cardiovascular and Renal Drugs Advisory Committee Meeting that is scheduled for April 15, 2015.

In the fourth quarter of 2013, our MAA for cangrelor was accepted for review in the European Union. In September 2014, we received the Day 180 List of Outstanding Issues, or LOI, from the CHMP regarding our MAA for cangrelor in the European Union. The LOI contained one major objection regarding the benefit risk relationship of cangrelor. A Scientific Advisory Group (SAG) meeting was convened on December 1, 2014, and we submitted to the CHMP our response to the LOI in December 2014. In January 2015, the CHMP issued an opinion recommending marketing authorization for cangrelor in the European Union.

### *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<sup>®</sup> by Bristol-Myers Squibb Co./Sanofi Pharmaceuticals Partnership. Clopidogrel is also now available in various generic formulations. 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 clopidogrel 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 also have impaired bioavailability in patients in the acute and intensive care setting due to several issues, including nausea 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.

Based on input from 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.

*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 was longer. The loading dose of 300mg (labeled dose) or 600mg of clopidogrel is considered the usual care for patients undergoing PCI and is administered either prior to PCI or at the time of PCI, at the physician's discretion or as required by hospital protocol, when the anatomy is known and the decision has been made that the patient will undergo PCI. The primary endpoint of the trial is measured by the composite incidence of death, MI, ischemia-driven revascularization and stent thrombosis at 48 hours after randomization.

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 the prior CHAMPION trials.

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, which we commenced in March 2006 and October 2006, respectively, we compared cangrelor to eight 75 mg clopidogrel tablets (600 mg), given at the beginning of the procedure in the CHAMPION PCI trial and at end of the procedure in the CHAMPION-PLATFORM trial. The primary endpoints of each of the CHAMPION-PCI and the CHAMPION-PLATFORM trials measured a composite of death, MI, or urgent revascularization at 48 hours. 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 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.

In September 2013, we presented and published a pooled analysis of all three trials in our CHAMPION clinical trial program. In the approximately 25,000 patients undergoing PCI that participated in the trials cangrelor significantly reduced the odds of the primary composite endpoint of death, myocardial infarction, or MI, ischemia-driven revascularization and stent thrombosis at 48 hours after randomization as compared to active control (clopidogrel). We presented this pre-specified, pooled analysis of patient-level data at the European Society of Cardiology and published it in *The Lancet*.

*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 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.

*Other Studies.* In October 2013, we completed two pharmacodynamic trials evaluating the transition of intravenous cangrelor to chronic oral therapy with ticagrelor (BRILINTA<sup>®</sup>) or prasugrel (Effient<sup>®</sup>) in patients with coronary artery disease, or CAD. The pharmacodynamic studies were each conducted in 12 CAD patients to test the consistency of inhibition of platelet aggregation when oral ticagrelor or prasugrel were administered during or immediately after cangrelor infusion. Ticagrelor and prasugrel are the newest commercially available agents that inhibit platelets via the P2Y<sub>12</sub> receptor, the same receptor that is inhibited by cangrelor. These agents are typically administered with the goal of decreasing the risk of thrombotic events during and after PCI. In these studies, patients treated with intravenous cangrelor were directly transitioned to the oral drug without a significant decrease in the extent of inhibition of platelet aggregation. We believe that these studies support the clinical data from the CHAMPION PHOENIX trial in which the transition from cangrelor to oral clopidogrel 600mg administered immediately after cessation of the cangrelor infusion significantly reduced thrombotic events at 48 hours after randomization compared to clopidogrel alone.

## **IONSYS**

### *Overview*

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. We obtained rights to IONSYS in January 2013 in connection with our acquisition of Incline Therapeutics, Inc., or Incline.

In September 2014, the FDA accepted for filing a Supplemental New Drug Application, or sNDA, that we had submitted for IONSYS in the United States. The PDUFA date is April 30, 2015. In September 2014, the EMA accepted the MAA for IONSYS that we had submitted in the European Union. Subsequent to the FDA's acceptance for filing of the sNDA, we received in November 2014 a Discipline Review Letter from the FDA, which is a letter the FDA uses to convey early thoughts on possible deficiencies in a marketing approval application. In the letter, the FDA identified deficiencies in the results of human factors validation studies of IONSYS that we had included in the sNDA. Human factors validation studies focus on the interactions between people and devices to evaluate use-related risks and confirm that users can use the device safely and effectively. Based on discussions with the FDA, we implemented additional risk mitigations to reduce use errors associated with IONSYS and conducted additional human factors validation studies to support these mitigations. We submitted the results of the human factors validation studies to the FDA in January 2015, which we believe will be sufficient time to enable the FDA to review the results as part of our sNDA submission without causing a delay in the PDUFA date.

### *Medical Need*

Current post-operative pain management regimens include opioid analgesics administered by patient-controlled pain management systems, known as intravenous patient controlled analgesia or IV PCA, as well as by intermittent bolus administration (intravenously, intramuscular and oral). 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. IV PCA use has been associated with programming, medication, and pump errors, IV line complications, limited patient mobility, and consumption of significant amounts of hospital resources while the use of intermittent opioid analgesics are associated with analgesic gaps. We believe that IONSYS, if approved, will provide on-demand analgesia, avoiding the analgesic gaps, while eliminating the programming and other issues associated with IV PCA pump.

### *Clinical Development*

IONSYS was originally developed and evaluated in an extensive clinical program, including seven Phase 3 clinical trials that were conducted prior to our acquisition of the product. 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.

We completed both a pharmacokinetic study and usability study of IONSYS in the first quarter of 2013. The objective of the pharmacokinetic study was 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 was to assess ease of use with the enhanced IONSYS system in post-operative patients experienced by nurses, pharmacists and the patients themselves. Bioequivalence was successfully established between IONSYS and the previously approved IONSYS by statistical comparison of historical pharmacokinetics, or PK, data with in vivo-in vitro correlation re-established for IONSYS. The usability study successfully demonstrated ease of use for both patients and healthcare practitioners.

## **Raplixa**

### *Overview*

Raplixa is a fibrin sealant that is a dry powder topical formulation of fibrogen and thrombin that we are developing for use as an aid to stop mild to moderate bleeding during surgery. We acquired Raplixa as part of our acquisition of ProFibrix in August 2013. In November 2013, the EMA accepted for filing the MAA submitted by us in the European Union. In January 2015, the CHMP issued an opinion recommending marketing authorization for Raplixa in the European Union. In April 2014, the FDA accepted for filing the BLA submitted by us in the United States. In November 2014, the FDA informed us that it had extended the PDUFA date for the BLA for Raplixa by up to three months from the original date of January 31, 2015 based on a BLA amendment we submitted on manufacturing specifications.

### *Medical Need*

Fibrin sealants mimic the last stage of the human coagulation system to support local hemostasis as they generate semi-rigid, cross-linked fibrin clots that bind the surface of injured tissues to seal surfaces, support sutures, and improve the repair or healing of the injured tissues. The mechanism of action of Raplixa, like other fibrin sealants, causes blood to clot at the site of application because it contains thrombin and fibrinogen which are part of the normal blood coagulation process. Because Raplixa dissolves in blood on the surface of a bleeding site, blood cells, platelets, and circulating plasma proteins can be incorporated into the clot allowing it to resemble the fibrin clot that is formed during natural blood coagulation. As with other fibrin sealants, Raplixa is degraded and eliminated similarly to the process by which intrinsic degradation of natural clots occurs.

In current practice, typical fibrin sealants consist of human plasma-derived thrombin and fibrinogen that are filled and stored separately to avoid thrombin's enzymatic activity on fibrinogen before application to the intended site of action. In addition, most commercially-available products are stored frozen and must be thawed before they can be mixed and applied to a wound site. To improve the convenience and flexibility of use, we have designed Raplixa as a room-temperature stable, ready-to-use powder fibrin sealant that sticks on contact to bleeding sites and then quickly dissolves and activates to form a fibrin clot. The powder does not require reconstitution and may be used directly from the vial.

### *Clinical Development*

Prior to our acquisition of ProFibrix in 2013, two Phase 2 trials (FC-002 NL and FC-002 US) and a Phase 3 trial (FC-004) had been conducted to evaluate the safety and efficacy of Raplixa in different surgical indications in support of a general adjunct to hemostasis label claim. An additional small, first-in-human, Phase 2 trial was conducted in 29 patients undergoing liver resection at four hospitals in the Netherlands (FC-001) to demonstrate the safety of Raplixa prior to undergoing the larger Phase 2 trials.

The Phase 2 trials, FC-002 US and FC-002 NL, were conducted in spinal, vascular and liver surgical indications, which are characterized by diffuse and difficult to control mild to moderate bleeding and for which adjuncts to hemostasis are frequently required. FC-002 US included 70 patients that were undergoing spinal surgery, peripheral vascular surgery and general surgery. FC-002 NL enrolled 56 patients undergoing major hepatic resection. The goal of the completed Phase 2 trials was to generate an adequate safety database including 80 to 100 patients treated with Raplixa before proceeding to Phase 3. This goal was accomplished with a total of 86 patients treated with Raplixa in which both safety and efficacy of Raplixa was demonstrated. With regard to safety, adverse events were consistent with surgical procedures performed and patients' underlying diseases and generally similar between treatment arms.

The Phase 3 clinical trial of Raplixa, FINISH-3, which studied 719 surgical patients with mild to moderate surgical bleeding, met all primary and secondary hemostasis efficacy endpoints. The objective of the FINISH-3 trial was to demonstrate the superiority of Raplixa plus gelatin sponge over a gelatin sponge alone for use in stopping mild to moderate surgical bleeding in four distinct surgical indications: spinal surgery, hepatic resection, soft tissue dissection and vascular surgery. The FINISH-3 trial had a primary efficacy endpoint of time to hemostasis, or TTH, by surgical indication and secondary bleeding endpoints of restricted mean TTH (the difference in the area under the Kaplan-Meier TTH survival curves over a five minute evaluation time) by surgical indication and incidence of TTH at three and five minutes by surgical indication in the trial, and that the safety profile for Raplixa was consistent with the surgical population enrolled in the trial and the types of surgeries performed.

We are presently conducting a pediatric trial and a Phase 3b trial.

#### **RPX-602**

RPX-602 is a proprietary reformulation of Minocin IV utilizing magnesium sulfate that enables administration of minocycline in smaller volumes of fluids, and may improve the local tolerability of intravenous infusions. We acquired RPX-602 as part of our acquisition of Rempex. We submitted an sNDA in December 2014 and anticipate a PDUFA date in April 2015. If and when RPX-602 is approved by the FDA and commercially launched, we expect to cease marketing the current formulation of Minocin IV.

#### ***Research and Development Stage Products in Development***

#### **APB-700**

##### *Overview*

APB-700 is an intravenous anesthetic agent being developed for moderate or deep sedation and general anesthesia in patients undergoing diagnostic or therapeutic procedures. We acquired APB-700 in connection with our acquisition of Annovation BioPharma, Inc. in February 2015. APB-700 is a positive allosteric modulator of the  $\alpha$ -aminobutyric acid type A (GABAA) ligand-gated ion channel. The endogenous ligand for this channel is GABA, the major inhibitory neurotransmitter in the central nervous system. APB-700 has an ester bond that undergoes rapid cleavage via non-specific tissue esterases producing an inactive carboxylic acid metabolite. This chemical feature is intended to provide for both rapid onset of anesthesia as well as a more rapid and more consistent emergence than presently available intravenous agents.

##### *Medical Need*

Over the past decade, the number of surgical procedures performed has steadily increased and the proportion of those performed on an outpatient basis now exceeds 70% in most parts of the United States. At the same time, surgical care and procedural medicine have moved towards lighter anesthesia, minimal and focused procedural sedation, and teams that include many non-physician care providers. These dynamics are expanding most rapidly in the older population who are generally at higher risk due to a greater number of medical co-morbidities. In the European Union where the patient demographic is similar, there is pressure to provide high quality surgical care services with shorter stays to address the increasing costs and increasing demand for surgical care. In light of these trends, we believe that new agents need to be developed that are capable of producing highly specific depth of sedation or anesthesia yet also be highly reversible. We are developing APB-700 to meet the need for more effective drugs with a higher therapeutic index that exhibit a predictable pharmacokinetic/pharmacodynamics, or PK/PD, relationship and allow precisely tailored control of sedation and anesthesia.

##### *Clinical Development*

APB-700 has been characterized in a series of non-GLP and GLP in vitro and in vivo pharmacology (PK, PD) genotoxicity and safety pharmacology studies, as well as pilot and definitive acute toxicology studies. The Phase 1 clinical development program consists of a first-in-human, single bolus escalation study (ANVN-01) followed by a 30-minute infusion escalation Phase 1 trial (ANVN-02). Annovation conducted both Phase 1 clinical studies in The Netherlands. Annovation completed ANVN-01, and we expect to complete ANVN-02 in the first half of 2015. These studies are evaluating the drug's safety and tolerability, PK, PD, and will help determine a biologically active dose range.

Upon completion of ANVN-02, we anticipate that the next clinical trials we undertake will seek to optimize the bolus and infusion dosing regimens of APB-700 in order to finalize several dosing regimens for Phase 2 trials to be conducted in a variety of surgical and procedural settings. The final dosing regimens for APB-700 are anticipated to include either or both a bolus dose for induction of anesthesia followed by an infusion used for maintaining sedation and/or anesthesia.

#### **ALN-PCSSc**

##### *Overview*

ALN-PCSSc is a subcutaneously administered RNA interference, or RNAi, therapeutic considered to be a PCSK9 synthesis inhibitor which is being developed for the potential treatment of hypercholesterolemia. We obtained rights to this product candidate under a license and collaboration agreement that we entered into with Alnylam in February 2013 to develop, manufacture and commercialize RNAi therapeutics targeting the 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 low-density lipoprotein, or LDL, receptor levels on hepatocytes and the metabolism of LDL cholesterol, or LDL-C, which is commonly referred to as "bad" cholesterol. ALN-PCSSc is designed to inhibit the synthesis of PCSK9 and lead to reduced levels of LDL-C.

##### *Medical Need*

Despite the widespread use of statins, a large number of cardiovascular events still occur. Many of these events occur due to increased lipid related risk, predominantly driven by elevated LDL-C levels. Many patients, particularly those with familial dyslipidemias, do not achieve adequate LDL-C levels at the highest doses of statin even with the addition of therapies such as ezetimibe. Other patients are intolerant of statins or high doses of statins. We believe that, in these scenarios, new effective treatments to significantly lower LDL-C are needed. Clinical studies performed with monoclonal antibodies to PCSK9, with or without statin, and a preclinical study of ALN-PCSSc monotherapy conducted in non-human primates by Alnylam have shown that therapies that act on PCSK9 lower LDL-C by as much as 50%, and therefore have the potential to meet this unmet need for additional significant LDL-C reduction.

##### *Clinical Development*

Under our agreement with Alnylam, we and Alnylam initially collaborated on the development of ALN-PCSSc and ALN-PCS02, an intravenously administered RNAi therapeutic. 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. In October 2013, we and Alnylam selected a lead development candidate, ALN-PCSSc, for development for the potential treatment of hypercholesterolemia under the agreement. In making this decision, we and Alnylam considered data from non-human primate studies of ALN-PCSSc, which we presented at the Oligonucleotide Therapeutics Society meeting in which ALN-PCSSc caused an up to a 90% silencing of PCSK9 expression and an up to a 68% lowering of LDL-C in the absence of statins.

In December 2014, under the terms of the license and collaboration agreement with Alnylam, Alnylam initiated a Phase 1 clinical trial of ALN-PCSSc in the United Kingdom. The Phase 1 trial, for which Alnylam plans to enroll up to 76 healthy volunteer subjects, is being conducted as a randomized, single-blind, placebo-controlled, single ascending- and multi-dose, subcutaneous dose-escalation study. Pending the results of the Phase 1 clinical study of ALN-PCSSc, we expect to begin a Phase 2 study for ALN-PCSSc in the second half of 2015.

#### **Carbavance**

##### *Overview*

Carbavance is an antibiotic agent that we acquired in connection with our acquisition of Rempex and are developing for the treatment of hospitalized patients with serious gram-negative bacterial infections, including complicated urinary tract infections, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia, and bacteremia. Carbavance is a combination of RPX7009, a proprietary, novel beta-lactamase inhibitor, with meropenem, a well-known and marketed carbapenem antibiotic. Carbavance is focused on addressing one of the three urgent antimicrobial resistance threats identified by the U.S. Centers for Disease Control -- carbapenem-resistant Enterobacteriaceae, or CRE. The FDA designated Carbavance a QIDP under the GAIN provisions of the FDASIA. The QIDP designation provides Carbavance priority review by the FDA, eligibility for the FDA's "fast track" status, and an additional five years of exclusivity upon approval of the product. Carbavance is being developed under a cost-sharing arrangement with the Biomedical Advanced Research and Development Authority, or BARDA, of the U.S. Department of Health and Human Services, under which our subsidiary, Rempex Pharmaceuticals Inc., has the potential to receive up to \$89.8 million in funding to support the development of Carbavance.

##### *Medical Need*

Enterobacteriaceae are the largest group of gram-negative pathogens associated with healthcare-associated infections. Examples of bacterial pathogens that are members of the Enterobacteriaceae family are E. coli, Klebsiella pneumoniae, and Enterobacter cloacae. The CDC reports that approximately 140,000 Enterobacteriaceae infections occur annually. These infections are treated with a variety of antimicrobial agents, including cephalosporin and penicillin derivatives, and more recently the carbapenem class of antibiotics. Over time, Enterobacteriaceae develop resistance to antibiotics used to treat them. One important mechanism that results in resistance to beta-lactam antibiotics is bacterial acquisition of resistance genes that code for production of enzymes that

degrade this class of drugs, called beta lactamases. Over the last decade, clinical isolates of Enterobacteriaceae have acquired beta-lactamases that degrade all of the members of the beta-lactam class, including the carbapenem class of antibiotics. As a result, CRE infections are increasing among hospitalized patients and have become resistant to all or nearly all antibiotics available today. CRE was designated by the CDC as the most urgent antimicrobial resistance threat that causes systemic infections in hospitalized patients.

Beta lactamase inhibitors, or BLIs, have been developed to overcome, and are a proven approach to overcoming, beta lactamase-mediated resistance. With the rapid rise of beta lactamases resistant to carbapenems, or carbapenemases, a new generation of BLIs is needed because older agents have no important inhibitory activity against carbapenemases. We developed a novel BLI, RPX7009, which we combined with meropenem to create our fixed combination product, Carbavance. Meropenem is a carbapenem that is FDA-approved for the treatment of complicated intra-abdominal infections and complicated skin and skin structure infections in adults and pediatric patients, and for the treatment of bacterial meningitis, and has been marketed in the U.S. and worldwide for nearly two decades. Meropenem is considered one of the first line agents for the treatment of infections in the urinary and respiratory tracts, intraabdominal infections, skin and skin-structure infections, and bacteremia. RPX7009 has broad inhibitory activity against beta-lactamases, but was specifically designed to inhibit the serine carbapenemases such as Klebsiella pneumonia carbapenemase, or KPC, and to be combined with a carbapenem antimicrobial.

We are developing Carbavance to be a first line treatment for serious gram-negative infections in hospitalized patients, particularly in the setting of documented or suspected infections due to KPC-producing carbapenem-resistant Enterobacteriaceae.

#### *Clinical Development*

In December 2013, Rempex completed Phase 1 dose-escalation studies of Carbavance in healthy subjects. In these studies, safety was observed with our beta-lactamase inhibitor, RPX7009, alone and in combination with a carbapenem at expected therapeutic doses. In addition, the pharmacokinetics of our beta-lactamase inhibitor was similar to most carbapenem antibiotics, and there was no evidence of drug-drug interaction between our beta-lactamase inhibitor and meropenem. Additional studies of Carbavance demonstrated high penetration of meropenem and RPX7009 in lung tissues (to support studies in pulmonary infection), and good safety and pharmacokinetic properties in patients with renal impairment to support use in critically-ill patients.

In the fourth quarter of 2014, we enrolled the first patients in TANGO 1 and TANGO 2, our two Phase 3 clinical trials for Carbavance. The TANGO 1 Phase 3 clinical trial is a multi-center, randomized, double-blind, double-dummy study designed to evaluate the efficacy, safety, and tolerability of Carbavance compared to piperacillin/tazobactam in the treatment of complicated urinary tract infections, or cUTI, including acute pyelonephritis, in adults. We expect to enroll approximately 850 patients in the trial. Such patients will be randomized on a one-to-one basis to receive either Carbavance or piperacillin/tazobactam each given intravenously for up to 10 days. The TANGO 2 Phase 3 clinical trial is a multi-center, randomized, open-label study of Carbavance versus “best available therapy” in patients with selected serious infections due to carbapenem-resistant Enterobacteriaceae. Best available therapy will be selected from among antimicrobial agents that may have little to no activity against the CRE pathogen. We expect to enroll approximately 150 patients with cUTI, nosocomial pneumonia and/or bacteremia. Such patients will be randomized on a two-to-one basis into either Carbavance or “best available therapy” for up to 14 days.

#### **MDCO-216**

##### *Overview*

MDCO-216, a novel biologic, is a complex of a phospholipid and recombinantly manufactured ApoA-1 Milano, a naturally occurring variant of ApoA-1, a protein found in human high-density lipoprotein, or HDL. MDCO-216 has the potential to reverse atherosclerotic plaque development and reduce the risk of ischemic events in patients with ACS by stimulating the ABCA1 dependent cholesterol efflux pathway which is the first step in reverse cholesterol transport. We licensed exclusive worldwide rights to MDCO-216, from Pfizer in December 2009.

##### *Medical Need*

Cardiovascular disease is the major cause of mortality globally. In the first six to 12 months following an ACS, patients are at high risk of subsequent fatal and non-fatal cardiovascular events such as MI and stroke. Current therapies for atherosclerosis, the underlying disease that leads to these cardiovascular events, such as statins, predominantly target the reduction of LDL-C. These therapies primarily prevent cholesterol from accumulating in plaque, but do not leverage HDL or ApoA-1’s ability to rapidly remove cholesterol from plaque to treat atherosclerosis. This removal of cholesterol from plaque coupled with the anti-inflammatory properties of HDL and ApoA-1 represents a potential solution for stabilizing plaques and reducing the occurrence of these fatal and non-fatal cardiovascular events.

##### *Clinical Development*

In multiple non-clinical studies conducted prior to our acquisition of license rights in December 2009, the predecessor to MDCO-216, which was manufactured by a different process, was found to rapidly remove excess cholesterol from artery walls, thereby stabilizing and regressing atherosclerotic plaque burden. In a Phase 2 proof of concept study conducted from 2001 through

2003 in 57 patients, the predecessor to MDCO-216 demonstrated statistically significant reductions in total atheroma volume as measured by intravascular ultrasound, or IVUS, 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 initial Phase 2 trial with the predecessor of MDCO-216. Using these new methodologies, we manufactured MDCO-216 on a small scale for use in 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 promote cholesterol efflux, the first step in reverse cholesterol transport. Reverse cholesterol transport is the natural process by which the body removes cholesterol from atherosclerotic plaque in the arteries. In addition, in these studies, the treatment was well tolerated up to the highest dose tested (300 mg/kg).

In January 2014, we completed a Phase 1 single ascending dose study of MDCO-216 in 48 patients, which investigated the safety and tolerability of escalating single doses of MDCO-216 in healthy volunteers and in patients with stable coronary artery disease. This study was designed to characterize the single dose pharmacokinetics and pharmacodynamics of MDCO-216. This study also demonstrated that MDCO-216 significantly increases ABCA1 mediated cholesterol efflux in both healthy volunteers and patients with Coronary Artery Disease. Results were presented at the American Heart Association in November 2014. We expect to commence, in the second half of 2015, a Phase 2a proof of concept study to confirm whether five weekly infusions of MDCO-216 are able to reduce plaque burden based on coronary imaging parameters and various pharmacodynamics parameters including cholesterol efflux. Upon successful completion of this study, we would expect to conduct a Phase 2b study to establish a dose/exposure-effect relationship that will allow us to select a dose that can be tested for safety and efficacy in Phase 3 studies.

#### **Co-promotion Agreements**

Effective December 31, 2014, our co-promotion agreement with Boston Scientific Corporation, or BSX, and our global collaboration agreement with AstraZeneca LP were each terminated. As a result, as of December 31, 2014, we ceased to co-promote BSX’s Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System and AstraZeneca LP’s BRILINTA.

In 2014, we recognized \$16.0 million in co-promotion income under the collaboration agreement with AstraZeneca and \$5.0 million in co-promotion income under the co-promotion agreement with BSX, respectively.

#### **Sales and Distribution**

We market and sell Angiomax, Cleviprex, Minocin IV, Orbactiv, Recothrom, our ready-to-use Argatroban and three of our acute care generic products, midazolam, ondansetron and rocuronium, in the United States with a sales force experienced in selling to hospital customers. As of December 31, 2014, our sales force in the United States consisted of 267 representatives, whom we refer to as engagement partners and engagement managers. In support of our sales efforts, we focus or expect to focus:

- our Angiomax 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, including neurology, cardiology, surgical care and emergency medicine departments;
- our Minocin IV sales efforts on hospital systems and individual hospitals, including infectious disease, emergency medicine and critical care physicians, microbiologists and pharmacists;
- our Orbactiv sales efforts in the United States on hospital systems, individual hospitals, hospital and physician owned infusion centers and health care providers, including infectious disease and emergency room physicians, hospitalists, infectious disease pharmacists and microbiologists;
- our Recothrom sales efforts on the top identified accounts where surgical procedures, including orthopedic, burn, trauma, plastic, vascular, cardiothoracic, neurosurgical and general surgery, are performed in the United States; and
- our ready-to-use Argatroban sales efforts on group purchasing organizations, hospital systems, including hospital pharmacies and the acute care generic products sales efforts on hospital systems, including hospital pharmacies.

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, Minocin IV, Orbactiv, Recothrom, our ready-to-use Argatroban and the acute care generic products we market in the United States through a sole source distribution model with Integrated Commercialization Solutions, or ICS. Under this model, we currently sell Angiomax, Cleviprex, Minocin IV, Orbactiv, Recothrom, our ready-to-use Argatroban and our acute care generic products to our sole source distributor, ICS. ICS then sells these products to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals and infusion centers.

Our agreement with ICS, which we initially entered into in February 2007 and have subsequently amended from time to time, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex, Minocin IV, Orbactiv, Recothrom, our ready-to-use Argatroban and the acute care generic products we market in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of these products to maintain an appropriate level of inventory based on our wholesalers' 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 the products, subject to specified limitations in the agreement. The agreement terminates on February 28, 2019 and 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.

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, 2014, following our fourth quarter 2014 reorganization of our European operations, our sales force in Europe consisted of 12 active key account managers. This European sales force will target key hospitals with cardiac catheterization laboratories. As of December 31, 2014, we marketed and sold Angiomax in Australia and New Zealand with a sales force consisting of two engagement partners and three engagement managers. We also market and sell Angiomax outside the United States through distributors, including Sunovion Pharmaceuticals Inc., which distributes Angiomax in Canada, affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America, and through a joint venture with our partner, Windlas Healthcare Private Limited, in India. We also have agreements with other third parties for other countries outside of the United States, including Israel, Russia, Hong Kong and certain countries in the Middle East. As of December 31, 2014, we sold Cleviprex outside the United States in Australia and in certain European countries, and we sold PreveLeak outside of the United States in certain European countries, Turkey and South Africa. In December 2014, we entered into a strategic collaboration with SciClone Pharmaceuticals, or SciClone, under which we granted SciClone a license and the exclusive rights to promote, market and sell Angiomax and Cleviprex in China. Under the terms of the collaboration, SciClone will be responsible for all aspects of commercialization, including pre- and post-launch activities, for both products in the China market (excluding Hong Kong and Macau) and will assist us in the registration process for both products in China.

We are developing our global commercialization strategy for our products and products in development, if and when they are approved outside the United States. In the fourth quarter of 2014, we commenced a reorganization of our operations outside of the United States, which was intended to improve efficiency and better align our costs and employment structure with our strategic plans. We are exploring potential global collaboration opportunities for certain of our products and products in development. We believe that partnering with third parties has the potential to improve the performance of our marketed products and provide a viable platform to commercialize our products and products in development that are not yet approved, if and when they are approved and ready to be marketed.

## Manufacturing

We do not have a manufacturing infrastructure, other than for PreveLeak, and we 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. PreveLeak is currently manufactured in our Mountain View, California facility.

*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, 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 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 International A.G., or Patheon International, for the manufacture of Angiomax drug product. Pursuant to the agreement, Patheon International 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 International 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 the 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 International 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 International acting reasonably, is not a credit worthy substitute for us, is a competitor of Patheon International, or an entity with whom Patheon International has had prior unsatisfactory business relations.

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

*Cleviprex*

*Bulk Drug Substance.* In October 2002, we entered into a master research and manufacturing agreement with Johnson Matthey Pharma Services, or Johnson Matthey, for the manufacture of Cleviprex bulk drug substance for use for our clinical trials of Cleviprex

and for our commercial requirements. Johnson Matthey manufactures the bulk drug substance under project work orders agreed upon by the parties at the time of the order and governed by the master research and manufacturing agreement. Johnson Matthey has no obligation under the master agreement to accept project work orders from us.

*Drug Product.* In December 2003, we entered into a contract manufacturing agreement with Fresenius Kabi Clayton, L.P., which was subsequently assigned to Hospira, Inc., or Hospira. Pursuant to the agreement, Hospira is the exclusive supplier for all finished drug product of Cleviprex manufactured according to the original formulation for the intravenous treatment of primarily peri-operative hypertension using its proprietary formulation technology. Under the agreement, Hospira supplied us with the formulation of Cleviprex that was originally approved by the FDA.

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.

#### *Minocin IV and RPX-602*

*Bulk Drug Substance.* Prior to our acquisition of Rempex, in January 2013 Rempex entered into a master services agreement with IDT Australia Limited for the manufacture of minocycline hydrochloride parenteral active pharmaceutical ingredient, to be used for the supply of both Minocin IV and RPX-602. The agreement expires in January 2020 unless earlier terminated by us, for any reason, with 30 days' notice or by either party, due to a material breach of the agreement, after 30 days' notice if such breach is not cured within such 30-day period.

*Drug Product.* We purchase drug product for Minocin IV through Precision Dermatology, which acquires the drug from Patheon UK Limited, or Patheon UK, through work orders. Patheon UK has no obligation under the master agreement to accept project work orders from us. In December 2011, Rempex entered into a technology transfer services agreement with Patheon UK for the manufacture of engineering and scale-up batches of RPX-602. We expect to enter into a long-term commercial supply agreement for RPX-602 with Patheon UK.

#### *Orbactiv*

*Bulk Drug Substance.* Prior to our acquisition of Orbactiv, in December 2001, Targanta entered into a development and supply agreement with Abbott Laboratories, or Abbott, for the supply of Orbactiv bulk drug substance for clinical use in clinical trials. In January 2013, Abbott separated into two independent companies, Abbott and AbbVie Inc., or AbbVie. As a result of the separation, in August 2013 we entered into a new development and supply agreement regarding Orbactiv with AbbVie. Under the terms of the AbbVie agreement we are required to purchase Orbactiv bulk drug substance exclusively from AbbVie, unless AbbVie fails to deliver sufficient Orbactiv bulk drug substance to meet our needs. In such event, we may use another manufacturer to supply Orbactiv bulk drug substance for as long as AbbVie is unable to supply sufficient Orbactiv bulk drug substance. We are also required to purchase a minimum amount of Orbactiv bulk drug substance from AbbVie. The agreement expires six contract years from the date of the first sale of Orbactiv in the territory a product launch date, subject to automatic three-year renewal periods unless we give notice in writing to AbbVie 30 months prior to the end of any term of our intention not to renew the agreement. Additionally, AbbVie may terminate the agreement by notifying us in writing three years prior to the end of any term, of its intention to not renew the agreement. 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, AbbVie is required to return to us all unused raw materials associated with the bulk drug substance that has been paid for by us, cell banks, cell cultures, samples, viruses, genetic materials, data and any other property or other information furnished by us or acquired by AbbVie at our cost with respect to the commercial supply of bulk drug substance or Orbactiv under the agreement.

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 Orbactiv. We expect to use DSM as a supplier of Orbactiv bulk substance for commercial use.

*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. In October 2013, we entered into a master services agreement with Patheon UK for the manufacture of Orbactiv. Pursuant to the agreement, Patheon UK conducts the fill-finish of Orbactiv for our commercial sale supply in accordance with minimum quantity, binding yearly commitments provided by us. Our agreement with Patheon UK expires in December 2019, and is 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 the agreement at least 18 months prior to the end of the then current term.

#### *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.

#### *PreveLeak*

PreveLeak is a medical device that we manufacture in a facility that we lease in Mountain View, California. All manufacturing operations are performed by us except for final product sterilization, which is performed by Nutek Inc. Our lease on the Mountain View facility expires in May 2016. We believe the facility has sufficient capacity, and space to expand capacity, to produce the anticipated volumes of PreveLeak.

#### *Recothrom*

Prior to the closing of our exercise of the Recothrom option in February 2015, BMS supplied us with Recothrom. Upon our closing of the Recothrom option, we acquired certain inventory exclusively related to Recothrom and acquired BMS' rights, and assumed its obligations, under the supply agreements to which BMS was a party.

*Bulk Drug Substance.* Under a commercial supply agreement with AbbVie, Inc., or AbbVie, to which BMS was a party, AbbVie exclusively supplies us with recombinant thrombin bulk drug substance. Under this agreement, we are obligated to purchase minimum quantities of recombinant thrombin bulk drug substance annually at agreed upon specified prices. The supply agreement is terminable by us or AbbVie upon at least 18 months written notice to the other party. Each party may also terminate the supply agreement upon the filing of bankruptcy or insolvency of the other party or upon the material breach of any provision of the supply agreement that is not cured within 60 days of written notice.

*Drug Product.* Under a manufacturing services agreement with Patheon Italia S.p.A., or Patheon S.p.A., to which BMS was a party and a commercial supply agreement with Cook Pharmica LLC, or Cook Pharmica, to which BMS was a party, each of Patheon S.p.A and Cook Pharmica, supply us with finished vials of Recothrom drug product. Under the Cook Pharmica agreement, we are obligated to purchase minimum quantities at agreed upon specified prices. The manufacturing services agreement with Patheon S.p.A. expires on January 1, 2018 and automatically renews for 24 month terms until terminated by us or Patheon S.p.A with at least 12 months written notice prior to the end of the applicable renewal term. We and Patheon S.p.A. may terminate the manufacturing services agreement upon material breach of any representation, warranty or other obligation that is not cured within 60 days of written notice or upon insolvency, bankruptcy or the assignment of the manufacturing services agreement for the benefit of creditors. The commercial supply agreement with Cook Pharmica expires on March 10, 2017 and automatically renews for 12 month terms until terminated by us or Cook Pharmica with at least 18 months written notice prior to the end of the applicable renewal term. We and Cook Pharmica may terminate the commercial supply agreement for any reason with at least two years written notice. In addition, we and Cook Pharmica may terminate the commercial supply agreement upon the failure to comply with any of the other party's material obligations that is not cured within 30 days of written notice or immediately upon insolvency, bankruptcy, the appointment of a receiver or similar party, the assignment of the commercial supply agreement for the benefit of creditors or the inability of a party to pay all or substantially all of its debts as they become due.

#### *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 the 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 the 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. In May 2013, we entered into a master services agreement with Patheon UK for the manufacture of cangrelor. Pursuant to the agreement, Patheon UK conducts the fill-finish of cangrelor for injection drug product for our commercial sale supply in accordance with minimum quantity, binding yearly commitments provided by us. Our agreement with Patheon UK expires in December 2019, and is 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 the agreement at least 18 months prior to the end of the then current term.

### *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. At the appropriate time, 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. In September 2013, we entered 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-216*

*Bulk Drug Substance.* 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. In 2012 and 2013, we worked with Lonza to optimize the protein manufacturing process primarily to reduce the cost to manufacture the drug product to make it commercially viable. In February 2013 we entered into an agreement with Lonza to use this optimized process to manufacture MDCO-216 protein on a small scale for use in the upcoming Phase 2 trial of MDCO-216. In 2014, we entered into an agreement with Lonza to scale up the manufacturing process to supply a sufficient amount of MDCO-216 to support the planned Phase 3 clinical trials through potential commercial supply of MDCO-216.

*Drug Product.* MDCO-216 drug product for pre-clinical and early clinical studies was manufactured at OctoPlus. In 2014, we entered into an agreement with Cook Pharmica to scale up the drug product process and supply a sufficient amount of MDCO-216 to support the upcoming Phase 2 clinical trial.

### *Raplixia*

*Bulk Drug Substances.* Prior to our acquisition of ProFibrix, ProFibrix entered in an agreement with CSL Behring for the supply of human plasma derived fibrinogen and human plasma derived thrombin for development, clinical and, if Raplixia is approved for sale, commercial production of the product.

*Drug Product.* Prior to our acquisition of ProFibrix, ProFibrix entered into a development and commercial supply agreement with Novalaboratories Ltd. to spray dry, blend and fill finish the drug product under aseptic conditions. Novalaboratories Ltd. has

manufactured the materials for the Phase 3 trials of Raplixia and, if the product is approved for sale, will manufacture the commercial supply of Raplixia. In addition, Novalaboratories Ltd. releases the final packed drug product.

### *ABP-700*

*Bulk Drug Substance.* With our acquisition of Annovation in February 2015, we received sufficient bulk drug substance for our immediate development needs. We will evaluate commercial scale manufacturing partners as part of the development program for ABP-700, and we expect to enter into a commercial supply agreement with a suitably qualified supplier prior to conducting pivotal clinical trials.

*Drug Product.* During the development program, we will evaluate, select and enter into a supply agreement with a qualified commercial supplier of drug product.

### *ALN-PCSsc*

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.

### *Carbavance*

*Bulk Drug Substance.* Prior to our acquisition of Carbavance, Rempex entered into a master services agreement with Sigma-Aldrich, Inc. and a research and manufacturing services agreement with DSM Fine Chemicals Austria Nfg GmbH for the supply of bulk drug substance for RPX-7009, the proprietary, novel beta-lactamase inhibitor used in Carbavance.

*Drug Product.* Prior to our acquisition of Carbavance, in June 2012, Rempex entered into a development and clinical supply agreement with Hospira Worldwide, Inc. for clinical supplies of RPX-7009. In September 2012, Rempex entered into a master services agreement with ACS Dobfar S.p.A. for additional clinical supplies of RPX-7009. We expect to enter into a long-term commercial supply agreement for the manufacture of both the beta-lactamase inhibitor and the carbapenem used in Carbavance.

## **Business Development Strategy**

We continuously review opportunities to acquire products through licenses, product acquisitions and company acquisitions. We believe that we have proven capabilities in developing and commercializing in-licensed or acquired acute and intensive care drug candidates. 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 also acquire approved products that can be marketed in hospitals by our commercial organization.

We are exploring potential global collaboration opportunities for certain of our products and products in development. We believe that partnering with third parties has the potential to improve the performance of our marketed products and provide a viable platform to commercialize our products and products in development that are not yet approved, if and when they are approved and ready to be marketed.

## **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 treatment regimens combining heparin and GP IIb/IIIa inhibitors. Heparin is widely used in patients with ischemic heart disease, including PCI procedures. 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 include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin (eptifibatide) from Merck & Co., Inc., and Aggrastat (tirofiban) from Iroko Pharmaceuticals, LLC and MediCure Inc. Although their use may have decreased in recent years, GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy in high risk patients as compared to Angiomax.

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 heparin or a combination of heparin and 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. However, we remain in patent infringement litigation with other abbreviated new drug application, or ANDA, filers. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015. 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.

Eagle has announced that it is developing bivalirudin as a ready to use liquid formulation. Eagle has announced that it expects to submit a 505(b)(2) NDA for the product in the second quarter of 2015 and is seeking to begin commercial sales of the product in the United States in 2016. If approved, this formulation would compete with Angiomax.

#### *Recothrom, Raplixa and PreveLeak*

Recothrom was developed, and Raplixa is being developed, as a surgical hemostat to be applied topically to stop bleeding. Recothrom typically is used to treat mild bleeding and oozing and Raplixa is being developed for mild to moderate bleeding. PreveLeak was developed as a surgical sealant, applied topically, to prevent bleeding through suture holes. All of these products are used as adjuncts to normal surgical techniques including cautery, sutures, and staples.

There are a number of different classes of topical hemostats and surgical sealants used to prevent or stop bleeding. These include:

- 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 a granular bovine or porcine gelatin component that is mixed with saline or reconstituted thrombin to form a semi-solid, flowable putty;

- fibrin sealants, which consist of thrombin and fibrinogen that can be sprayed or applied via patch directly to the bleeding surface; and
- surgical sealants, which can be composed of glutaraldehyde and bovine serum albumin, polyethylene glycol polymers, and cyanoacrolates.

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

Recothrom competes primarily with other active hemostats (bovine thrombin and human plasma-derived thrombin). Recothrom is the only topical thrombin that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or with gelatin in sponge or granular form. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, THROMBIN-JMI<sup>®</sup>, a bovine derived thrombin marketed by Pfizer, and EVITHROM<sup>®</sup>, 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'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 mechanical hemostats such as gelatin and collagen pads, flowable hemostats and fibrin sealants. Many of these competitive hemostatic agents are relatively inexpensive and have been widely used for many years.

We believe that Raplixa, if approved, will compete with other active hemostats that include thrombin and fibrinogen (fibrin sealants) and products that are a combination of thrombin and a gelatin matrix (flowable hemostats). However Raplixa's competitive positioning will depend on the approved label and the competitive market in specific countries. Currently, there are two liquid fibrin sealants commercially available in the United States. Tisseel, marketed by Baxter, and Evicel, marketed by Ethicon, are both derived from pooled human plasma-derived thrombin and human pooled fibrinogen. Both of these products are also available in the European Union along with Beriplast P which is marketed by CSL Behring. Fibrin sealant patches include Tachosil, marketed by Baxter in the United States and Takeda in the European Union, and Evarrest, marketed by Ethicon in both the United States and European Union are also considered potential competitors in the fibrin sealant category. Within the flowable category, both FloSeal<sup>®</sup>, marketed by Baxter, and Surgiflo, marketed by Ethicon, are commercially available in the United States and European Union. Both FloSeal and Surgiflo have the potential to compete with Raplixa and Recothrom.

PreveLeak competes primarily with other surgical sealants, and secondarily with the fibrin sealants, including those described above. BioGlue, which is marketed by CryoLife, Coseal, which is marketed by Baxter, and Omnex, which is marketed by Ethicon, are expected to compete with PreveLeak based on their composition and use. Each of these products, along with PreveLeak, is a synthetic sealant that is ready to use right from the delivery system and is quick to seal because it functions independent of the coagulation cascade to achieve hemostasis. Coseal is a polyethyleneglycol (PEG) based sealant that is reconstituted in the syringe before application and is approved for use as a vascular sealant. BioGlue is a surgical sealant composed of bovine serum albumin (BSA) and glutaraldehyde that has been approved for cardiac as well as vascular surgeries. Omnex is a cyanoacrylate-based sealant that is approved for use at the anastomotic vascular reconstructions. All of these products are used as adjuncts to sutures and staples.

#### *Cleviprex*

Cleviprex competes with a variety of antihypertensive agents in the acute care setting, many of which are generic and inexpensive. The determination of which therapeutic agent to use depends on a variety of factors, including patient diagnosis, how quickly blood pressure control needs to be achieved, relevant surgeries or procedures that may be planned in the near future, co-morbidities and end organ damage. Treatment options vary widely, have different mechanisms of action, including variable PK/PD effects and metabolic pathways. Cleviprex's principal competitors include labetalol, nicardipine, sodium nitroprusside and nitroglycerine.

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

Our ready-to-use formulation of Argatroban that we license from Eagle competes with marketed versions of Argatroban sold by GlaxoSmithKline, West-Ward Pharmaceuticals 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.

#### *Minocin IV and RPX-602*



Minocin IV competes with, and if approved the new RPX-602 formulation of Minocin IV will compete with, other antibiotics that are used for the treatment of infections due to Acinetobacter. The predominant antibiotic agents used to treat Acinetobacter are tigecycline and colistin, which are used “off-label” for this pathogen, but are more established in the marketplace and are less expensive.

#### *Orbactiv*

Orbactiv competes 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. Competition in the market for therapeutic products that address serious gram-positive bacterial infections is intense. Some of these products are branded and subject to patent protection, and others are available on a generic basis. The more established products include vancomycin, ceftaroline (Teflaro), clindamycin (Cleocin), daptomycin (Cubicin) and linezolid (Zyvox), and recently approved products that may be competitive include Sivextro from Cubist Pharmaceuticals, Inc (now a subsidiary of Merck & Co., Inc.), Dalvance from Durata Therapeutics, Inc. (now a subsidiary of Actavis plc) and Vibativ from Theravance Biopharma, Inc. Several companies have products in development that, if approved, may compete with Orbactiv.

#### *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 assist us 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 and fast onset of platelet inhibition to prevent thrombotic events during and immediately after PCI while providing fast offset of effect to prevent bleeding risk during and after surgery.

#### *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. A potential patient-controlled competitor for IONSYS is an oral sufentanil dispensing system, Zalviso using NanoTab, which is in Phase 3 development by AcelRx, 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.

### **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 was set to expire in March 2010, but the term was extended to December 15, 2014 by the U.S. Patent and Trademark Office, or 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 and are also entitled to a six-month period of pediatric exclusivity following expiration of the patents. 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, and possibly as early as June 15, 2015, the date of expiration of the patent term of the '404 patent and the six month pediatric exclusivity.

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 on Form 10-K.

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

*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 certain patents and patent applications licensed from AstraZeneca which relate 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 also have an issued patent, U.S. Patent No. 8,658,676, which covers the Cleviprex formulation and which is set to expire in October 2031. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we have 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 was set to expire in November 2014, but the term has been extended to November 2019 in most European countries where Cleviprex has been approved via a supplementary protection certificate. The European patent office has also issued to us a patent covering compositions of matter of Cleviprex having certain stability profiles, which will expire in July 2029. 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.

*Orbactiv.* As a result of our acquisition of Targanta, we obtained an exclusive license from Eli Lilly to patents and patent applications covering Orbactiv, its uses, formulations and analogs. Under this license, we are responsible for prosecuting and maintaining these patents and patent applications. The principal patent for Orbactiv in both the United States and Europe is set to expire in November 2015. We have filed for a patent term extension for this patent in the United States. We have issued patents directed to the process of making Orbactiv in the United States. These patents are set to expire in 2017 if no patent term extension is obtained. We also have a U.S. patent covering the use of Orbactiv in treating certain skin infections that expires in August 2029. We have also filed and are prosecuting a number of patent applications relating to Orbactiv and its uses.

*PreveLeak.* As a result of our acquisition of Tenaxis, we acquired a portfolio of patents and patent applications covering PreveLeak, its uses and the process of making PreveLeak. The expiration dates of these U.S. patents range from September 2022 to December 2028. In Europe, we have an issued patent covering PreveLeak which expires in December 2028. We are also currently prosecuting patent applications relating to PreveLeak in the United States and in certain 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. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. On March 29, 2012, Eagle, which directed and controlled the enforcement of its intellectual property rights with respect to ready-to-use Argatroban, filed suit against Sandoz in the U.S. District Court for the District of New Jersey for infringement of its ready-to-use Argatroban patents. In November 2012, Eagle advised us

that it entered into a settlement agreement with Sandoz, and as part of the settlement, Eagle agreed to give Sandoz the right to introduce an authorized generic version of ready-to-use Argatroban. Sandoz currently markets two ready-to-use generic formulations of Argatroban.

*Recothrom.* In February 2015, we acquired from BMS its portfolio of patents and patent applications pertaining to Recothrom's pharmaceutical formulations and methods of manufacturing. The expiration dates of these patents range from July 2015 to February 2029 in the United States. Prior to the acquisition of BMS' portfolio of patents and patent applications pertaining to Recothrom, BMS also filed and we are currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. We believe that, as a biologic, Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020. Although the FDA has issued draft guidance documents, to date it has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA or biosimilar provisions enacted in 2010 under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, including the exclusivity provisions for reference products. As a result, it is possible that the FDA will decide to interpret the provisions in such a way that Recothrom is not considered to be a reference product for the purposes of the statute or to be entitled to any period of regulatory exclusivity. Moreover, even if Recothrom is considered to be a reference product eligible for such exclusivity, that exclusivity will not prevent other companies from filing full BLAs for competing versions of Recothrom, including competing recombinant thrombin products. As a result, if such companies can complete and the FDA permits the submission of and approves such full BLAs, competing products may get onto the market before the regulatory exclusivity period for Recothrom expires in January 2020.

*Cangrelor.* We have exclusively licensed from AstraZeneca rights to patent and patent applications covering formulations, process of making, and uses of cangrelor. Under the license, AstraZeneca is responsible for prosecuting and maintaining the patents and patent applications licensed from AstraZeneca which relate to cangrelor. 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.

*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 June 2015 to June 2032 in the United States. In Europe, the expiration date of patents covering the IONSYS device range from May 2016 to September 2021. We are also currently prosecuting patent applications relating to IONSYS in the United States and in certain foreign countries.

*Raplixa.* As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited, or Quadrant. One U.S. patent licensed from Quadrant covers the composition of matter of Raplixa, and is set to expire in May 2017 if no patent term extension is obtained. We have a U.S. patent, U.S. Patent No. 8,846,105, which covers Raplixa suitable for certain applications that expires in January 2031. We have also filed and are prosecuting a number of patent applications related to the use and production of Raplixa. As a biologic, we believe Raplixa 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 Raplixa, if approved.

*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 and its uses. 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 no patent term extension is obtained. We are also prosecuting a number of patent applications related to the use of MDCO-216 in 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.

*ABP-700.* In connection with our acquisition of Annovation, we obtained an exclusive license from The General Hospital Corporation certain patents and patent applications covering ABP-700 and its analogs. These patent applications, some of which are jointly owned by Annovation and The General Hospital Corporation, are being prosecuted both in the United States and in certain foreign countries.

*ALN-PCS.* We have exclusively licensed from Alnylam patents covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases for purposes of developing and commercializing such RNAi therapeutics. Some of these patents are directed to general RNAi technology and expire between 2016 and 2028 in the United States. Other patents are directed to specific compositions of the PCSK9 product being developed under our license from Alnylam and to methods of treatment using such PCSK9 product and expire in May 2027 in the United States. In addition, Alnylam has filed and is prosecuting a number of patent applications in the United States and in certain foreign countries.

*Carbavance.* As a result of our acquisition of Rempex, we acquired a portfolio of patent applications covering the composition of matter of Carbavance and its formulation and use. The principal U.S. patent for Carbavance is set to expire in August 2031 if no patent term extension is obtained. A corresponding patent application is pending in Europe and other foreign countries. In addition, we are currently prosecuting other patent applications relating to Carbavance's composition of matter and its use in the United States and in certain foreign countries.

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<sup>®</sup> name and logo, Angiomax<sup>®</sup>, Angiox<sup>®</sup>, Cleviprex<sup>®</sup>, Carbavance<sup>™</sup>, IONSYS<sup>®</sup>, Kengrexal<sup>™</sup>, Orbactiv<sup>®</sup>, PreveLeak<sup>™</sup>, Raplixa<sup>™</sup> and Recothrom<sup>®</sup> 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.

*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 2014, we incurred approximately \$128.4 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 increased by one percentage point. As of December 15, 2014, we no longer owe royalties to Biogen or HRI relating to sales of Angiomax in the United States.

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 2014, we incurred approximately \$2.9 million in royalties related to Angiomax under the agreement with HRI.

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

The licenses and rights under the agreement remain in force on a country-by-country basis until we cease selling Cleviprex in such country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress our concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days' written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice if the breach is not cured within such 60 days. During 2014, we incurred \$0.8 million in royalties related to Cleviprex under our agreement with AstraZeneca.

*Orbactiv.* 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 Orbactiv 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 Orbactiv 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 Orbactiv in the United States and to commercialize Orbactiv in the United States. If we breach that obligation, Eli Lilly may terminate our license in the United States, license rights to Orbactiv could revert to Eli Lilly and we would lose our rights to develop and commercialize Orbactiv. 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.

*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, as amended in January 2010 and September 2012, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties on sales or ready-to-use Argatroban, but such milestones and royalties have been replaced under the license agreement by a profit sharing arrangement in which we share equally with Eagle the gross profits, as defined in the license agreement, of our sales of ready-to-use Argatroban. 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 payment of \$32.0 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 the 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 the agreement is terminated with respect to a product, the parties shall agree upon a substitute product.

*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.

*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

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 \$83.0 million in sales milestone payments, of which we paid \$2.5 million in September 2014 upon MAA submission in EU. 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.

*Raplixa.* As a result of our acquisition of ProFibrix, we are a party to a license agreement, as amended, with Quadrant Drug Delivery Limited, or Quadrant, through our ProFibrix subsidiary. Under the terms of the agreement, Quadrant granted ProFibrix worldwide licenses under specified patent rights and know-how to develop, use, manufacture and commercialize Raplixa. The licenses granted by Quadrant under the agreement are exclusive with respect to the patents and know-how within specified fields and nonexclusive with respect to the patents and know-how within other specified fields.

Under the agreement, Quadrant is entitled to annual minimum royalty payments of £100,000 plus adjustments for the U.K. retail prices index, which are creditable against specified royalties based on the following: net sales of Raplixa; Raplixa products covered by specified nonexclusively licensed patents; and Raplixa products embodying specified licensed know-how. Cumulative royalties on any given product cannot exceed 4% of net sales. In addition, royalties based on licensed patents and licensed know-how are subject to a 50% reduction of such royalties if specified competing products achieve more than a 30% market share in the applicable country. Under the agreement, royalties based on licensed patents expire upon the expiration of the applicable licensed patent, and royalties based on licensed know-how expire ten years after the commencement of marketing in the applicable country.

Either Quadrant 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. Quadrant may also terminate the agreement due to ProFibrix's winding up, bankruptcy, entering into any voluntary arrangements with its creditors outside of bankruptcy, ceasing to do business or becoming unable to pay its debts when due. Neither party has any discretionary right to terminate the agreement. If not terminated earlier pursuant to its terms, the agreement terminates upon the expiration of the last patent or patent application to expire under the agreement.

*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 \$10.0 million upon entering into the agreement and agreed to pay up to an aggregate of \$410.0 million upon the achievement of specified clinical, regulatory and sales milestones. We are obligated to make royalty payments, which are payable on a product-by-product and country-by-country basis, until the latest of the expiration of the last patent or patent application covering MDCO-216, the expiration of any market exclusivity and a specified period of time after the first commercial sale of MDCO-216. In addition, we agreed to pay Pfizer a portion of the consideration received by us or our affiliates in connection with sublicenses. Under the agreement, we may sublicense the intellectual property to third parties, provided that we have complied with Pfizer's right of first negotiation and, in the case of sublicenses to unaffiliated third parties in certain countries, provided that we first obtain Pfizer's consent. We, either directly or through our affiliates or sublicensees, have also agreed to use commercially reasonable 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 the 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 the 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.

*Alnylam License Agreement.* 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 \$25.0 million in an initial license payment and agreed to pay up to \$180.0 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.

*ABP-700.* As a result of our acquisition of Annovation, we, through our subsidiary Annovation, are a party to a license agreement with The General Hospital Corporation. Under the terms of the agreement, Annovation licensed from the General Hospital Corporation exclusive worldwide rights to certain patents, patent applications and other intellectual property related to ABP-700. We will be obligated to pay General Hospital Corporation up to an aggregate of \$6.5 million upon achievement of specified development, regulatory and sales milestones. In addition, we will be obligated to pay General Hospital Corporation low single-digit percentage royalties on a product-by-product and country-by-country basis based on net sales of ABP-700 products until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell ABP-700 products in a country and the date ten years from our first commercial sale of ABP-700 products in such country. We are required to use commercially reasonable efforts to develop the ABP-700 product and achieve specified stages of clinical development within specified time periods.

## Customers

We currently sell Angiomax, Cleviprex, Minocin IV, Orbactiv, Recothrom, the acute care generic products that we market and ready-to-use Argatroban in the United States to our sole source distributor, ICS. ICS accounted for 95%, 89% and 90% of our net revenue for 2014, 2013 and 2012, respectively. At December 31, 2014 and 2013, amounts due from ICS represented approximately \$193.4 million and \$120.9 million, or 95% and 92%, of gross accounts receivable, respectively.

## 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 and biologics, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act respectively and their implementing regulations. We cannot market or commercially distribute a drug until we have submitted an application for marketing authorization to the FDA, and the FDA has approved it. Both before and after approval is obtained, violations of regulatory requirements may result in various adverse consequences, including, among other things, 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.

Sponsors of drugs may apply for a Special Protocol Assessment, or 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, 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 and are 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 granting final approval to 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 product, such as a new dosage form, route of administration, combination,

or indication. Under the Best Pharmaceuticals for Children Act, federal law also provides that periods of patent and non-patent marketing exclusivity listed in the Orange Book for a drug may be extended by six months if the NDA sponsor conducts pediatric studies identified by the FDA in a written request. For written requests issued by the FDA after September 27, 2007, the date of enactment of the Food and Drug Administrative Amendment Act (FDAAA), the FDA must grant pediatric exclusivity no later than nine months prior to the date of expiration of patent or non-patent exclusivity in order for the six-month pediatric extension to apply to that exclusivity period.

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application. 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication(s) sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the 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 and 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. Although the FDA has issued draft guidance documents, to date it has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA or biosimilar provisions enacted in 2010 under the BPCIA, 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. A number of states have recently considered and in some cases, adopted legislation governing the substitution of interchangeable biosimilars for the reference product.

#### *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 on Form 10-K, 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.

#### *“Generating Antibiotic Incentives Now,” Provisions of Food and Drug Administration Safety and Innovation Act*

On July 9, 2012, President Obama signed the FDASIA. Under the GAIN provisions of FDASIA, the FDA may designate a product as a 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 developed Orbactiv for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of Orbactiv for other indications, including ABSSSIs in children, uncomplicated bacteremia, endocarditis, prosthetic joint infections, and other gram-positive bacterial infections. We are also developing Carbavance for the treatment of hospitalized patients with serious gram-negative bacterial infections. In November 2013, the FDA designated Orbactiv a QIDP. In August 2014, following approval of Orbactiv, the FDA informed us that Orbactiv met the criteria for an additional five years of non-patent exclusivity to be added to the five year exclusivity period already provided by the Food, Drug and Cosmetic Act. As a result, Orbactiv's non-patent regulatory exclusivity is scheduled to expire in August 2024. In addition, in December 2013, the FDA designated Carbavance a QIDP. We expect that, if we submit an NDA for Carbavance and the NDA is approved, Carbavance would receive an additional five-years of non-patent exclusivity.

#### *Pharmaceutical Coverage, Pricing and Reimbursement*

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payers, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product once coverage is approved. Third-party payers 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 health economic studies in order to demonstrate the economics 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 economically viable. Even if a drug product is covered, a payer'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 payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and economic benefit of medical products and services, in addition to their safety and efficacy. If these third-party payers do not consider our products to be economically beneficial 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 payers 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. For example, in a recent final rule regarding the Medicare Hospital Outpatient Prospective Payment System, CMS finalized a new “bundling” policy that will affect reimbursement for a number of medicines prescribed in connection with certain Medicare hospital outpatient services, including PCI, beginning on January 1, 2015. The medicines affected by this policy include, among others, Angiomax. This particular policy is one example of a broader trend in health care in which the government and other payors are seeking to move from individualized “fee for service” payments toward a system focused on “bundled” payments for more comprehensive packages of services and episodes of care. 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 payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA and a related reconciliation bill, which we collectively refer to as the Affordable Care Act, or ACA, contain provisions that may reduce the profitability of drug products, including, for example, increased rebates for covered outpatient drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

#### *Foreign Regulations*

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

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

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

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

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

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

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

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

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

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

- *Decentralised procedure.* Using the decentralised procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European 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 \$159.2 million in 2014, \$146.9 million in 2013 and \$126.4 million in 2012.

## Employees

As of February 24, 2015, we employed 727 persons worldwide. We believe that our success depends greatly on our ability to identify, attract and retain capable employees. We have assembled a management team with significant experience in drug development and commercialization. In October 2014, we commenced implementation of a reorganization of our European operations intended to improve efficiency and better align our costs and employment structure with our strategic plans. As a result of this reorganization, we reduced our personnel in Europe by 46 employees. Impacted employees were eligible to receive severance payments in specified amounts, and general benefits and outplacement services for specified periods in accordance with our policies and local requirements. 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 Part II, Item 8. *Financial Statements and Supplementary Data* of this Annual Report on Form 10-K, and Part II, Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this Annual Report on Form 10-K.

## Our Corporate Information

We were incorporated in Delaware on July 31, 1996. Our principal executive offices are located at 8 Sylvan Way, Parsippany, New Jersey 07054, and our telephone number is (973) 290-6000.

## 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.

### 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 on Form 10-K. 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. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Annual Report on Form 10-K as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.*

### Risks Related to Our Financial Results

***Our business is very dependent on the commercial success of Angiomax. If Angiomax does not continue to generate significant revenues, 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 continue to account for the significant majority of our revenue in 2015. 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. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015;
- 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 payers 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, particularly in light of the expiration of our principal patents covering Angiomax in Europe in 2015.

We continue to develop Angiomax for use in additional patient populations, including patients with structural heart disease, patients undergoing PEI. 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, 2014, our inventory of Angiomax was \$68.3 million, and we had inventory-related purchase commitments totaling \$20.1 million for 2015 and no commitments for 2016 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, increase our accrual for product returns or increase our deferred tax valuation allowance, or we could incur other costs related to operating our business, each of which could negatively impact our results of operations and our financial condition.

***Depending upon our success in obtaining regulatory approvals, we may commercially launch and commence sales of up to five of our products and products in development in the United States by the end of 2015. If we are not successful with the commercial launches of these products and products in development or experience significant delays in doing so, our business likely would be materially harmed.***

We commercially launched Orbactiv in the United States in October 2014 and plan to launch PreveLeak in the United States in 2015. Subject to receiving approval of regulatory submissions that we have made for cangrelor, IONSYS, Raplixa and RPX-602, we plan to commercially launch these registration stage product candidates in the United States by the end of 2015. We may also commercially launch or relaunch by ourselves or through arrangements with third parties up to five of our products and products in development in Europe by the end of 2015, subject to receiving regulatory approval. The commercial launches of this number of products in such a short period of time will require significant efforts from us and the devotion of substantial resources as we will need to finalize regulatory submissions, work with regulatory authorities in their evaluation of our submissions, have



manufactured sufficient quantities of product to commence commercial sales and establish the commercial infrastructure necessary to commercially launch these products and products in development.

Our ability to successfully commercially launch these products and products in development will depend on our ability to:

- make regulatory submissions and obtain regulatory approvals in the timeframes anticipated;
- train our existing sales force to market and sell the products that are to be sold by it;
- train, deploy and support a qualified sales force to market and sell Orbactiv, Minocin IV and other infectious disease products;
- secure formulary approvals at our hospital customers;
- have third parties manufacture the products in sufficient quantities;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations;
- receive adequate levels of coverage and reimbursement for these products from governments and third-party payers;
- develop and execute marketing and sales strategies and programs for the products.

We expect that the revenues from these products and products in development will represent a significant portion of our revenues in the future, particularly if and when Angiomax becomes subject to generic competition. As a result, if we are unable to successfully commercialize these products and products in development, our business, results of operations and financial condition likely would be materially harmed.

***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 outstanding 1.375% Convertible Senior Notes due 2017, which we refer to as the 2017 notes, and the \$400.0 million aggregate principal amount of our outstanding 2.50% Convertible Senior Notes due 2022, which we refer to as the 2022 notes, and to make principal payments on the 2017 notes and the 2022 notes at maturity or upon conversion. In addition, as part of our business development strategy, we generally structure our license agreements and acquisition agreements so that a significant portion of the total license or acquisition cost is contingent upon the successful achievement of specified development, regulatory or commercial milestones. As a result, we will require cash to make payments upon achievement of these milestones under the license agreements and acquisition agreements to which we are a party. Upon the closing of the Recothrom transaction in February 2015, we paid BMS approximately \$127.7 million, including approximately \$39.3 million for inventory. In addition, we have agreed to pay BMS up to an additional \$4.9 million upon the delivery of certain additional inventory following the closing, subject to specified terms and conditions. In addition, upon the closing of the Annovation transaction in February 2015, we paid approximately \$28.4 million in cash to Annovation's equityholders. We may be required to pay Annovation's equityholders up to an additional \$26.3 million upon achievement of certain development and regulatory milestones, and we may be required to pay other third parties up to \$6.5 million upon achievement of certain development, regulatory and commercial milestones. We may also have to make contingent cash payments upon the achievement of specified development, regulatory or commercial milestones of up to:

- \$49.4 million due to the former equityholders of Targanta and up to \$25.0 million in additional payments to other third parties for the Targanta transaction;
- \$189.3 million due to the former equityholders of Incline and up to \$113.0 million in additional payments to other third parties for the Incline transaction;
- \$140.0 million for the ProFibrix transaction;

- \$315.7 million for the Rempex transaction;
- \$112.0 million for the Tenaxis transaction;
- \$170.0 million for the license and collaboration agreement with Alnylam;
- \$422.0 million due to our licensing of MDCO-216 from Pfizer; and
- \$54.5 million due to our licensing of cangrelor from AstraZeneca.

Our total potential milestone payment obligations related to development, regulatory and commercial milestones for our products and products in development under our license agreements and acquisition agreements, assuming all milestones are achieved in accordance with the terms of these agreements, would be approximately \$1,624.0 million. Of this amount, approximately \$180.0 million relates to development milestones, \$482.0 million relates to regulatory approval milestones and \$962.0 million relates to commercial milestones.

In addition, of the total potential milestone payment obligations, based on our earliest anticipated timeline for the achievement of development, regulatory and commercial milestones, we expect that we would make total milestone payments under our license agreements and acquisition agreements of up to \$294.0 million during the remainder of 2015. The majority of these anticipated payments for 2015 relate to the achievement of regulatory approval milestones for cangrelor, IONSYS, Raplixa, RPX-602, and PreveLeak, and the remainder of these payments relate to the achievement of development and commercial milestones for our other products in development.

Our future capital requirements will depend on 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. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015;
- the extent to which our submissions and planned submissions for regulatory approval of products in development are approved on a timely basis, if at all;
- the extent to which our products other than Angiomax and our products in development are commercially successful in the United States;
- the extent to which we are successful in our efforts to commercialize our products and products in development if and when approved outside the United States;
- the consideration paid by us and to be 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, Orbactiv and our products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of our approved products in additional countries and for additional indications, and of our products in development globally;
- whether we develop and commercialize our products in development on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- the continuation or termination of third-party manufacturing, distribution and sales and marketing arrangements;

- the size, cost and effectiveness of our sales and marketing programs globally;
- the amounts of our payment obligations to third parties as to our products and products in development; and
- our ability to defend and enforce our intellectual property rights.

If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to lower than anticipated sales of our marketed products, particularly if Angiomax becomes subject to generic competition in the United States earlier than May 1, 2019, or due to higher than anticipated costs associated with product launches, investments in research and development or otherwise, we likely will need to sell additional equity or debt securities or seek additional financing through other arrangements to increase our cash resources. Any sale of additional equity or debt securities may result in dilution to our stockholders. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the 2017 notes and the 2022 notes, market conditions or otherwise. 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 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 additional capital by selling equity or debt securities or through other arrangements in the future, 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 capital would be in our interest and in the interest of our stockholders, we may seek to sell equity or debt securities or seek financings through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders and increased liquidity requirements. 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, 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 all of the products we sell in the United States through a sole source distribution model. Under this model, we currently sell these products to our sole source distributor, ICS. ICS then sells these products to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell most of our future products in the United States through the same sole source distribution model. Our revenue from sales of these products in the United States is exclusively from sales to ICS pursuant to our agreement with them. 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 Annovation, Incline, ProFibrix, Rempex, Tenaxis and the Recothrom product and related assets from BMS, and we 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 and other human diseases. We may not realize the anticipated benefits of an acquisition, license, or collaboration, 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;
- inadequate or unfavorable clinical trial results from acquired or contracted for products in development;
- 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. In addition, even if we are able to achieve the long-term benefits associated with our strategic transactions, our expenses and short-term costs may increase materially and adversely affect our liquidity and short-term profitability. Further, 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 intangible assets, 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, 2014, we had an accumulated deficit of approximately \$77.1 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.

#### **Risks Related to Our Notes**

***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. Servicing this debt, including the 2017 notes and the 2022 notes, will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay the 2017 notes, the 2022 notes or our other debt.***

We have incurred a significant amount of indebtedness. Our maintenance of this level of indebtedness could have adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to general adverse economic, industry and market conditions;
- limiting our ability to obtain additional financing in the future;
- 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 less debt, better debt servicing options or better access to capital resources.

In addition, our ability to make scheduled payments of the principal of, to pay interest on or to refinance the 2017 notes or the 2022 notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the notes. 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 to refinance such indebtedness. 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 2017 notes or the 2022 notes or to repurchase the 2017 notes or the 2022 notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the 2017 notes or 2022 notes.***

Holders of the 2017 notes and the 2022 notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change, as defined in the applicable indenture, at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any, as described in the applicable indenture. In addition, upon conversion of the 2017 notes and the 2022 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 applicable indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase notes, to pay the notes at maturity 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 existing indebtedness (including, in the case of the 2017 notes, the 2022 notes) and future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the applicable indenture or to pay any cash payable on future conversions of the notes as required by the applicable indenture would constitute a default under the applicable indenture. A default under the applicable indenture governing the 2017 notes or the 2022 notes, respectively, or the fundamental change itself could also lead to a default under agreements governing our existing indebtedness (including, in the case of the 2017 notes, the 2022 notes) and 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 2017 notes or the 2022 notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the 2017 notes or the 2022 notes is triggered, holders of such notes will be entitled to convert the notes at any time during specified periods at their option, which are set forth in the applicable indenture. If one or more holders elect to convert their notes, we would be required, with respect to each \$1,000 principal amount of notes, to make cash payments equal to the lesser of \$1,000 and the sum of the daily conversion values, 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 2017 notes and the 2022 notes, could have a material effect on our reported financial results.***

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments that may be settled entirely or partially in cash upon conversion (such as the 2017 notes and the 2022 notes) in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the 2017 notes and the 2022 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 would be treated as original issue discount for purposes of accounting for the debt component of the 2017 notes and the 2022 notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the 2017 notes and the 2022 notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the 2017 notes and 2022 notes.

In addition, under certain circumstances, convertible debt instruments that may be settled entirely or partly in cash (such as the 2017 notes and 2022 notes) 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 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 2017 notes or the 2022 notes, then our diluted earnings per share would be adversely affected.

***We may incur substantially more debt or take other actions which would intensify the risks discussed above.***

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. We and our subsidiaries are not restricted under the terms of the applicable indenture governing the 2017 notes or the 2022 notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the applicable indenture governing the 2017 notes or the 2022 notes that could have the effect of diminishing our ability to make payments on the notes when due.

#### **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, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors are substantially larger than we are and 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 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 in many cases generic products, that are approved and marketed for the indications for which our 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. Set forth in the risk factors that follow this risk factor is additional information regarding competition for our three marketed products that generate or are expected to generate a significant portion of our revenue, Angiomax, Recothrom and Orbactiv. A description of the competition for our other products and products in development is included under the caption "Part I, Item 1. *Business-Competition*" of this Annual Report on Form 10-K.

We compete, in the case of our approved and 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. 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.

***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 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 include ReoPro from Eli Lilly and Company and Johnson & Johnson/Centocor, Inc., Integrilin from Merck & Co., Inc., and Aggrastat from Cardiome Pharma Corp. and MediCure Inc. Although their use may have decreased in recent years, GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy to Angiomax. Physicians and medical decision-makers may choose to use heparin combined with GP IIb/IIIa inhibitors due to their years of experience with this combination therapy, reluctance to change existing hospital protocols and pathways and results of clinical trials or nonclinical studies by us or third parties relating to Angiomax. For instance, we believe that the data presented in March 2014 from the HEAT-PPCI, an open-label, single-center randomized controlled trial that compared unfractionated heparin versus bivalirudin in primary PCI and reported findings of increased complications following primary PCI with bivalirudin versus heparin, has caused some physicians and medical decision-makers, principally in Europe, to choose to use heparin instead of Angiomax, which has adversely affected our sales of Angiomax. In addition, we believe that pricing pressure from third-party payers has caused some physicians and medical decision-makers to choose to use heparin due to its cost. Physicians' and medical decision-makers' resistance to the use of Angiomax 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. However, we remain in patent infringement litigation with other abbreviated new drug application, or ANDA, filers. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in

any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015. 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. We believe that, in anticipation of a possible adverse court decision for our company in our Angiomax patent litigation, some buyers of Angiomax may reduce, delay or forego purchases of Angiomax.

Eagle has announced that it is developing bivalirudin as a ready to use liquid formulation. Eagle has announced that it expects to submit a 505(b)(2) NDA for the product in the second quarter of 2015 and is seeking to begin commercial sales of the product in the United States in 2016.

***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 and surgical sealants used to prevent or stop bleeding, including:

- 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 a granular bovine or porcine gelatin component that is mixed with saline or reconstituted thrombin to form a semi-solid, flowable putty;
- fibrin sealants, which consist of thrombin and fibrinogen that can be sprayed or applied via patch directly to the bleeding surface; and
- surgical sealants, which can be composed of glutaraldehyde and bovine serum albumin, polyethylene glycol polymers, and cyanoacrolates.

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

Recothrom competes primarily with other active hemostats (bovine thrombin and human plasma-derived thrombin). Recothrom is the only topical thrombin that is not derived from bovine or human pooled plasma and can be used as a stand-alone product or with gelatin in sponge or granular form. Currently, there are two other stand-alone topical thrombin products commercially available in the United States, THROMBIN-JMI<sup>®</sup>, a bovine derived thrombin marketed by Pfizer, and EVITHROM<sup>®</sup>, 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 mechanical hemostats such as gelatin and collagen pads, flowable hemostats and fibrin sealants. Many of these competitive hemostatic agents are relatively inexpensive and have been widely used for many years.

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 from Recothrom could be adversely affected.

***Orbactiv faces significant competition from branded and generic drugs treating ABSSSI, which may limit the use of Orbactiv and adversely affect our anticipated revenues.***

Orbactiv is an intravenous antibiotic approved by the FDA for the treatment of ABSSSI, caused or suspected to be caused by susceptible gram-positive bacteria, including MRSA.

Competition in the market for therapeutic products that address serious gram-positive bacterial infections is intense. In particular, there are a variety of available therapies marketed for the treatment of ABSSSI. Some of these products are branded and subject to patent protection, and others are available on a generic basis. Many of these approved products, including vancomycin, ceftaroline (Teflaro), clindamycin (Cleocin), daptomycin (Cubicin) and linezolid (Zyvox) are well established therapies and are

widely accepted by physicians, patients and hospital decision-makers. Additionally, insurers and other third-party payers may encourage the use of generic products. Vancomycin, for instance, which is sold in a relatively inexpensive generic form, has been widely used for over 50 years, is the most frequently used IV antibiotic, and we believe, based on our market research, is prescribed to approximately two-thirds of all hospitalized ABSSSI patients. If physicians and hospital decision-makers do not accept the potential advantages of Orbactiv, or are otherwise hesitant or slow to adopt Orbactiv, our anticipated revenues could be adversely affected.

There are also a number of products recently approved or in clinical development by third parties to treat ABSSSI. Recently approved products include Sivextro from Cubist Pharmaceuticals, Inc (now a subsidiary of Merck & Co, Inc.), Dalvance from Durata Therapeutics, Inc. (now a subsidiary of Actavis plc) and Vibativ from Theravance Biopharma, Inc. Additionally, several companies have products in development that, if approved, may compete with Orbactiv, including Cempra, Inc., Debiopharm Group (through acquisition of Affinium Pharmaceuticals), Melinta Therapeutics, Inc. (formerly Rib-X Pharmaceuticals, Inc.), Paratek Pharmaceuticals, Inc., Nabriva Therapeutics AG and Furiex Pharmaceuticals, Inc. (a subsidiary of Actavis plc). If any of these product candidates or any other products developed by our competitors are more effective, safer, more convenient or less costly than Orbactiv, or would otherwise render Orbactiv obsolete or non-competitive, our anticipated revenues from Orbactiv 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. Because we have only the limited internal scientific research capabilities that we acquired in some of our acquisitions 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 to us development stage compounds, clinical stage product candidates or approved products. Since 2008, for instance, we have acquired Targanta, Incline, ProFibrix, Rempex, Tenaxis, Annovation, and the Recothrom product and related assets from BMS, licensed marketing rights to the ready-to-use formulation of Argatroban, licensed development and commercialization rights to MDCO-216, MDCO-157 and ALN-PCSsc, and licensed the non-exclusive rights to sell and distribute ten acute care generic products. The success of this business strategy depends upon our ability to identify, select and acquire or license pharmaceutical products that meet the criteria we have established. 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, available cash flows and institutional experience. In addition, we may compete with emerging companies taking similar or different approaches to product acquisition. Therefore, we may not be able to acquire or license the rights to additional product candidates or approved products on terms that we find acceptable, or at all.

Because of the intense competition for these types of product candidates and approved products, the cost of acquiring, 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 GmbH in August 2008, in response to serious unexpected patient safety issues encountered during a clinical trial. Similarly, following our review of data from the pharmacokinetic and pharmacodynamic study of several doses of MDCO-157 and oral clopidogrel in healthy volunteers, we elected not to proceed with the further development of MDCO-157, which we had licensed from CyDex Pharmaceuticals, Inc.

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 products in development 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 intravenous antihypertensive drugs in each drug class, and revenues from Cleviprex were adversely affected. If we fail to secure and maintain formulary inclusion for our products on favorable terms or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our products and our business, results of operations and financial condition could be materially adversely affected.

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

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

***If 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 develop our business infrastructure and 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.***

Our ability to support the sales and marketing of our products in the United States and globally will depend on our ability to properly scale our internal organization and infrastructure to accommodate the development and, upon approval, commercialization of our products and products in development. To manage our existing and planned future growth and the increasing breadth and complexity of our activities, we need to properly invest in personnel, infrastructure, information management systems and other operational resources. If we are unable to scale global operations successfully and in a timely manner, the growth of our business may be limited. Developing our business infrastructure and operations may be more difficult, more expensive or take longer than we anticipate. We may also need to revise our strategy for developing the proper infrastructure and operations periodically. In the fourth quarter of 2014, we implemented a reorganization of our European operations, including a workforce reduction and the consolidation of European sites, for which we recorded, in the aggregate, a one-time charge of approximately \$9.0 million in the fourth quarter of 2014. 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 development of our business infrastructure and operations could strain our operational, human and financial resources. In order to manage the development of our business infrastructure and global operations, 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 business, then our 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, 2014, we had \$36.6 million in sales outside of the United States and we have historically encountered difficulty in selling Angiomax outside of the United States. Our foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States. These risks and uncertainties include:

- political and economic determinations that adversely impact pricing or reimbursement policies;
- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- compliance with complex and changing foreign legal, tax, accounting and regulatory requirements;
- 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 payers or other third-party payers is not available or limited for our products, pricing is delayed or set at unfavorable levels or access to our products is reduced or terminated by governmental and other third-party payers, our ability to generate revenue would be adversely affected.***

Acceptable levels of coverage and reimbursement of drug treatments by government payers, 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 payers, 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 Orbactiv, could substantially affect the likelihood of reimbursement and the level of reimbursement for Orbactiv. 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 payers, 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. If these third-party payers do not consider our products to be economically beneficial 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 payers 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. For example, in a recent final rule regarding the Medicare Hospital Outpatient Prospective Payment System, CMS finalized a new “bundling” policy that will affect reimbursement for a number of medicines prescribed in connection with certain Medicare hospital outpatient services, including PCI, beginning on January 1, 2015. The medicines affected by this policy include, among others, Angiomax. This particular policy is one example of a broader trend in health care in which the government and other payors are seeking to move from individualized “fee for service” payments toward a system focused on “bundled” payments for more comprehensive packages of services and episodes of care. 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 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 pricing and, as a result, the number of procedures that are performed. Since the PPACA was enacted, other legislative changes have been proposed and adopted. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding. In addition to federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures could adversely impact our business and future results. If governmental organizations and third-party payers 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 \$10.0 million per occurrence and \$10.0 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.

***Our reliance on government funding for Carbavance adds uncertainty to our research and commercialization efforts with respect to Carbavance.***

We expect that a significant portion of the funding for the development of Carbavance will come from a contract with BARDA. BARDA is entitled to terminate our BARDA contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond amounts currently obligated under the existing contract, and there can be no assurance that our BARDA contract will not be terminated. Changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of antibacterial products such as Carbavance. If our BARDA contract is terminated or suspended, or if there is any reduction or delay in funding under our BARDA contract, we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to Carbavance.

***Our reliance on government funding for Carbavance may impose requirements that increase the costs of commercialization and production of Carbavance developed under that government-funded program.***

Our BARDA contract includes provisions that reflect the U.S. government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- unilaterally reduce or modify the government's obligations under such contracts, including by imposing equitable price adjustments, without the consent of the other party;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to renew the contract;
- claim rights to data, including intellectual property rights, developed under such contracts;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations in the event of wrongdoing by us;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts;
- suspend or debar the contractor from doing future business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies funded by the government and developed by us related to Carbavance, and we may not be able to prohibit third party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain non-proprietary contract information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance under our BARDA contract, as well as our accounting and general business practices related to our BARDA contract. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs.

***Laws and regulations affecting government contracts, including our BARDA contract, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.***

We must comply with numerous laws and regulations relating to the administration and performance of our BARDA contract. Among the most significant government contracting regulations are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, U.S. government agencies such as the Department of Health and Human Services, or DHHS, and the Defense Contract Audit Agency, or DCAA, routinely audit and investigate government contractors for compliance with applicable laws and standards. These agencies review a contractor's performance under its contracts, including contracts with BARDA, cost structure and compliance with applicable laws, regulations and standards.

These agencies also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be paid, while such costs already paid must be refunded. If we are audited and such audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of any government contracts, including our BARDA contract;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

***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. For example, in the fourth quarter of 2014, Brent Furse, Executive Vice President, Chief Customer Officer, and Cees Heiman, Executive Vice President,

Chief Innovation Officer, departed from our company. 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.

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

*We do not have manufacturing or supply capabilities and are completely dependent on third parties for the manufacture and supply of our products, other than for PreveLeak. 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, other than for PreveLeak. 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 or products in development, other than PreveLeak, 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 and products in development, other than PreveLeak. We expect to continue this manufacturing strategy for all of our other 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 our products and products in development, which could affect our ability to complete clinical trials of our products and products in development 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.

*Our reliance on third-party manufacturers and suppliers to supply our products and products in development may increase the risk that we will not have appropriate supplies of our products or our products in development, 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 non-renewal 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 products in development 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 current good manufacturing practices, or 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 products in development, delays, suspension or withdrawal of approvals, suspension of clinical trials, license revocation, seizures or recalls of products in development 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.



***We may depend on collaborations with third parties for the development and commercialization of certain of our products in development. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products in development.***

We may seek to develop and commercialize certain of our products in development through a variety of types of collaboration arrangements. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Other than our collaboration arrangement with Alnylam, we are not currently a party to any such arrangement and we may not be able to enter into any similar arrangements on a timely basis, on favorable terms or at all. Our ability to enter into such arrangements with respect to products in development that are subject to licenses may be limited by the terms of those licenses. If we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products in development. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our products in development could pose a number of risks to us, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our products in development or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products in development if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or otherwise expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or products in development or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products and products in development.

Collaboration agreements may not lead to development or commercialization of products in development in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages or subject to fines and penalties.***

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.

#### **Risks Related to Regulatory Matters**

***If we do not obtain regulatory approvals for our products in development in any jurisdiction or for our products in any additional jurisdictions, we will not be able to market our products and products in development 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 products in development in the United States and from foreign regulatory authorities in order to sell our products in development 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.

We have a pipeline of acute and intensive care hospital products in development, including our four registration stage product candidates, cangrelor, IONSYS, Raplixa, and RPX-602, for which we have submitted applications for regulatory approval in the United States. We cannot be assured that we will make our planned submissions when we anticipate, that the submissions will be accepted for filing, or that the applicable regulatory authorities will approve our applications on a timely basis or at all.

Developing and obtaining regulatory approval for product candidates is a lengthy process, often taking a number of years, is uncertain and is expensive. All of the product candidates that we are developing, or may develop in the future, require research and development, preclinical studies, nonclinical testing and clinical trials prior to seeking regulatory approval and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our product candidates. As a result, the development of product candidates may take longer than anticipated or not be successful at all.

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.

Certain of our products in development have experienced regulatory and/or clinical setbacks in the past, including cangrelor and IONSYS. For example, in February 2014, the FDA Cardiovascular and Renal Drugs Advisory Committee advised against approval of cangrelor for use in patients undergoing PCI or those that require bridging from oral antiplatelet therapy to surgery. On April 30, 2014, the FDA issued a Complete Response Letter regarding our NDA for cangrelor. For the PCI indication, the FDA stated that the NDA cannot be approved at the present time. The FDA suggested that we perform a series of clinical data analyses of the CHAMPION PHOENIX study, review certain processes regarding data management, and provide bioequivalence information on the clopidogrel clinical supplies for the CHAMPION trials. For the BRIDGE indication, the FDA concluded that

a prospective, adequate and well-controlled study in which outcomes such as bleeding are studied would be required to provide the clinical data necessary to assess the benefit-risk relationship in this indication. The FDA also provided additional comments for us to address, stating that the comments are not currently approvability issues, but could affect labeling. In December 2014, we submitted our response to the Complete Response Letter with respect to the PCI indication only and, in the response, we withdrew our request for approval for the BRIDGE indication. The FDA accepted our resubmission and provided a PDUFA date in June 2015. No assurances can be made that our response to the Complete Response Letter will be adequate. In addition, no assurances can be made with respect to our ability to obtain regulatory approval and to commercially develop cangrelor, and we may only be able to do so after conducting further trials responsive to the FDA's concerns, which could be costly and which we may choose not to conduct. In September 2014, we received the Day 180 List of Outstanding Issues from the CHMP regarding our MAA for cangrelor in the European Union. The LOI contained one major objection regarding the benefit-risk relationship of cangrelor. A Scientific Advisory Group (SAG) meeting was convened on December 1, 2014, and we submitted to the CHMP our response to the LOI in December 2014.

In addition, subsequent to the FDA's acceptance for filing of the sNDA for IONSYS, we received in November 2014 a Discipline Review Letter from the FDA with respect to our sNDA for IONSYS. A Discipline Review Letter is a letter the FDA uses to convey early thoughts on possible deficiencies in a marketing approval application. In the letter, the FDA identified deficiencies in the results of human factors validation studies of IONSYS that we had included in the sNDA. Human factors validation studies focus on the interactions between people and devices to evaluate use-related risks and confirm that users can use the device safely and effectively. Based on discussions with the FDA, we implemented additional risk mitigations to reduce use errors associated with IONSYS and conducted additional human factors validation studies to support these mitigations. We submitted the results of the human factors validation studies to the FDA in January 2015, which we believe will be sufficient time to enable the FDA to review the results as part of our sNDA submission without causing a delay in the PDUFA date. However, there can be no assurance that the results of the studies will be satisfactory to the FDA or that there will be no delay in the PDUFA date.

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

***We cannot expand the indications for which we are marketing 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 this indication or other indications for Angiomax, 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 in development, 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 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 products in development fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products and products in development 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 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.

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 FCPA 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.

***The production of fentanyl hydrochloride, used in IONSYS is highly regulated through an annual allocation quota made by the Drug Enforcement Administration, or DEA, in the United States and our specific allocation by the DEA could significantly limit the development, production or sale of IONSYS.***

Fentanyl hydrochloride is subject to the DEA's production and procurement quota scheme where the DEA establishes annually an aggregate quota for how much fentanyl may be produced in total in the United States based on an estimate of the quantity needed to meet legitimate scientific and medicinal needs that is then allocated among individual companies based on applications submitted annually by these individual companies to request an individual production and procurement quotas. These applications generally require substantial evidence and documentation of expected legitimate medical and scientific needs before the DEA makes its decision in allocating annual quotas to those manufacturers. The aggregate production quotas and individual production and procurement quotas may be adjusted from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. The DEA may choose to set the aggregate fentanyl hydrochloride quota lower than the total amount requested by the companies.

While it is possible to petition the DEA for an increase in the annual aggregate quota allocated to us after it is fixed, there is no guarantee that the DEA would act favorably upon such a petition. Our production and procurement quota of fentanyl hydrochloride may not be sufficient to meet commercial demand or clinical development needs. Any delay or refusal by the DEA in establishing the production and/or procurement quota or a reduction in our quota for fentanyl or a failure to increase it over time as we anticipate could delay or stop the development, production or sale of IONSYS or cause us to fail to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

#### **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.***

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 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.

In September 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.

In January 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, as described in Part I, Item 3. *Legal Proceedings*, of this Annual Report on Form 10-K. On July 12, 2013, the U.S. District Court for the District of Delaware in our patent infringement litigation with Hospira issued its Markman decision as to the claim construction of the '727 patent and the '343 patent. The district court's decision varied from the other Markman decisions that we have received in our other patent infringement litigations. On July 22, 2013, we filed a motion for reconsideration of the district court's claim construction ruling on the grounds that the district court (i) impermissibly imported process limitations disclosed in a preferred embodiment into the claims, (ii) improperly transformed product claims into product-by-process claims, (iii) improperly rendered claim language superfluous and violated the doctrine of claim differentiation, and (iv) improperly construed limitations based on validity arguments that have not yet been presented. On August 22, 2013, the district court denied the motion for reconsideration. A three day bench trial was held in September 2013 and a post-trial briefing was completed in December 2013. On March 31, 2014, the district court issued its trial opinion. With respect to patent validity, the district court held that the '727 and '343 patents were valid on all grounds. Specifically, the district court found that Hospira had failed to prove that the patents were either anticipated and/or obvious. The district court further held that the patents satisfied the written description requirement, were enabled and were not indefinite. With respect to infringement, based on its July 2013 Markman decision, the district court found that Hospira's ANDAs did not meet the "efficient mixing" claim limitation and thus did not infringe the asserted claims of the '727 and '343 patents. The district court found that the other claim limitations in dispute were present in Hospira's ANDA products. The district court entered a final judgment on April 15, 2014. On May 9, 2014, we filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. On May 23, 2014, Hospira filed a notice of cross-appeal. We filed our opening appeal brief on August 13, 2014. Hospira filed its opening appeal brief on September 26, 2014 asserting that the claim constructions and non-infringement findings were correct. Hospira also seeks to overturn the finding of patent validity. Briefing was completed in December 2014. An oral argument before the United States Court of Appeals for the Federal Circuit has been scheduled for March 5, 2015. If our appeal is not successful or Hospira's cross-appeal is successful, then Angiomax could be subject to generic competition earlier than anticipated, possibly as early as June 15, 2015, the date of the expiration of the patent term of the '404 patent and the six month pediatric exclusivity, including from Hospira's generic bivalirudin, as well as potentially Teva's and APP's generic bivalirudin products.

In our patent infringement litigation with Mylan, we completed a six day trial directed to the validity and infringement of the '727 patent in June 2014. On October 27, 2014, the U.S. District Court for the Northern District of Illinois issued an opinion and order finding that Mylan's ANDA product infringes all of the asserted claims of the '727 patent. The district court further found that Mylan failed to prove that the same asserted claims of the '727 patent are invalid or unenforceable. Specifically, the district court found that Mylan failed to prove its allegations of anticipation, obviousness, non-enablement and unenforceability due to inequitable conduct. On October 28, 2014 and November 13, 2014, Mylan filed Notices of Appeal to the U.S. Court of Appeals for the Federal Circuit. On November 25, 2014, we filed a Notice of Cross-Appeal of the district court's summary judgment of noninfringement of the asserted claims of the '343 patent that it had issued on December 16, 2013 and the district court's Markman Order on August 6, 2012. We expect that appellate briefing will be completed by the end of May 2015 and that the district court will schedule oral arguments after briefing has been completed. If we receive an adverse decision on Mylan's appeals, then Angiomax could be subject to generic competition earlier than anticipated, including from Mylan's generic bivalirudin, as well as potentially Teva's and APP's generic bivalirudin products. For additional details regarding our ongoing patent infringement litigation with Mylan, see Part I, Item 3. *Legal Proceedings* of this Annual Report on Form 10-K.

There can be no assurance as to the outcome of our infringement litigation. 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 and as early as June 15, 2015, the date of

expiration of the patent term of the '404 patent and the six month pediatric exclusivity. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax would 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 FTC and 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 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:

- 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 in contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings and may be 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. 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 products in development 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 covers the composition of matter of Angiomax. 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 and are also entitled to a six-month period of pediatric exclusivity following expiration of the patents. In response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we have filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent. 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 other ANDA filers. In our litigation with Hospira, we have appealed the decision of the district court that Hospira's ANDA did not infringe the asserted claims of the '727 and '343 patents. In our litigation with Mylan, Mylan has appealed the district court's finding that Mylan's ANDA product infringes the asserted claims of the '727 patent, and we have appealed the district court's summary judgment of noninfringement of the asserted claims of the '343 patent. If we are unable to maintain our market exclusivity for Angiomax in the United States through enforcement of our U.S. patents covering Angiomax, as a result of an adverse decision in our patent litigation or otherwise, including if we lose our appeal in our litigation with Hospira or if Mylan prevails in its appeal, Angiomax could be subject to generic competition earlier than May 1, 2019, and possibly as early as June 15, 2015, the date of expiration of the patent term of the '404 patent and the six month pediatric exclusivity.

Our patent infringement litigation involving the '727 patent and '343 patent is described in more detail in Part I, Item 3. *Legal Proceedings*, of this Annual Report on Form 10-K.

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

*Recothrom.* In February 2015, we acquired from BMS its portfolio of patents and patent applications pertaining to Recothrom's pharmaceutical formulations and methods of manufacturing. The expiration dates of these patents range from July 2015 to February 2029 in the United States. Prior to the acquisition of BMS's portfolio of patents and patent applications pertaining to Recothrom, BMS also filed and we are currently prosecuting a number of patent applications relating to Recothrom in the United States and in foreign countries. We believe that, as a biologic, Recothrom is entitled to regulatory exclusivity as a "reference product" in the United States expiring in January 2020. Although the FDA has issued draft guidance documents, to date it has not issued any regulations or final guidance explaining how it will implement the abbreviated BLA or biosimilar provisions enacted in 2010 under the Biologics Price Competition and Innovation Act of 2009, including the exclusivity provisions for reference products. As a result, it is possible that the FDA will decide to interpret the provisions in such a way that Recothrom is not considered to be a reference product for the purposes of the statute or to be entitled to any period of regulatory exclusivity. Moreover, even if Recothrom

is considered to be a reference product eligible for such exclusivity, that exclusivity will not prevent other companies from filing full BLAs for competing versions of Recothrom, including competing recombinant thrombin products. As a result, if such companies can complete and the FDA permits the submission of and approves such full BLAs, competing products may get onto the market before the regulatory exclusivity period for Recothrom expires in January 2020.

*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 also have an issued patent, U.S. Patent No. 8,658,676, or the '676 patent, which covers the Cleviprex formulation and is set to expire in October 2031. We have filed for patent term extensions, also known as supplementary protection certificates, in European countries where we have 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 was set to expire in November 2014, but the term has been extended to November 2019 in most European countries where Cleviprex has been approved via a supplementary protection certificate. The European patent office has also issued to us a patent covering compositions of matter of Cleviprex having certain stability profiles, which will expire in July 2029. 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. In February 2012, we were notified that Sandoz had submitted an ANDA seeking permission to market its second generic version of ready-to-use Argatroban prior to the expiration of these patents. On March 29, 2012, Eagle, which directed and controlled the enforcement of its intellectual property rights with respect to ready-to-use Argatroban, filed suit against Sandoz in the U.S. District Court for the District of New Jersey for infringement of its ready-to-use Argatroban patents. In November 2012, Eagle advised us that it entered into a settlement agreement with Sandoz, and as part of the settlement, Eagle agreed to give Sandoz the right to introduce an authorized generic version of ready-to-use Argatroban. Sandoz currently markets two ready-to-use generic formulations of Argatroban.

*Cangrelor.* 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.

*Orbactiv.* The principal patent for Orbactiv in both the United States and Europe is set to expire in November 2015. We have filed for a patent term extension for this patent in the United States. We also have issued patents directed to the process of making Orbactiv. These patents are set to expire in 2017 if no patent term extension is obtained. We also have a U.S. patent covering the use of Orbactiv in treating certain skin infections that expires in August 2029. We have also filed and are prosecuting a number of patent applications relating to Orbactiv and its uses.

*Raplixa.* As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited, or Quadrant. One U.S. patent licensed from Quadrant covers the composition of matter of Raplixa and is set to expire in May 2017 if no patent term extension is obtained. We also have an issued U.S. patent, U.S. Patent No. No. 8,846,105, which covers Raplixa suitable for certain applications that expires in January 2031. We have also filed and are prosecuting a number of patent applications related to the use and production of Raplixa. As a biologic, we believe Raplixa 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 Raplixa, if approved.

*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 June 2015 to June 2032 in the United States. In Europe, the expiration date of patents covering the IONSYS device range from May 2016 to September 2021. We are also currently prosecuting patent applications relating to IONSYS 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 no patent term extension is obtained. We are also prosecuting a number of patent applications related to the use of MDCO-216 in 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.

*ABP-700.* In connection with our acquisition of Annovation, we obtained an exclusive license from The General Hospital Corporation pertaining to certain patents and patent applications covering ABP-700 and its analogs. These patent applications,

some of which are jointly owned by Annovation and The General Hospital Corporation, are currently being prosecuted by The General Hospital Corporation in the United States and in certain foreign countries.

*ALN-PCS.* We have exclusively licensed from Alnylam patents covering RNAi therapeutics targeting PCSK9 for the treatment of hypercholesterolemia and other human diseases for purposes of developing and commercializing such RNAi therapeutics. Some of these patents are directed to general RNAi technology and expire between 2016 and 2028 in the United States. Other patents are directed to specific compositions of the PCSK9 product being developed under our license from Alnylam and to methods of treatment using such PCSK9 product and expire in May 2027 in the United States. In addition, Alnylam has filed and is prosecuting a number of patent applications in the United States and in certain foreign countries.

*Carbavance.* As a result of our acquisition of Rempex, we acquired a portfolio of patent applications covering the composition of matter of Carbavance and its formulation and use. The principal U.S. patent for Carbavance is set to expire in August 2031 if no patent term extension is obtained. A corresponding patent application is pending in Europe and other foreign countries. In addition, we are currently prosecuting other patent applications relating to Carbavance's composition of matter and its use in the United States and in certain foreign countries.

*PreveLeak.* As a result of our acquisition of Tenaxis, we acquired a portfolio of patents and patent applications covering PreveLeak, its uses and the process of making PreveLeak. The expiration dates of these U.S. patents range from September 2022 to December 2028. In Europe, we have an issued patent covering PreveLeak which expires in December 2028. We are also currently prosecuting patent applications relating to PreveLeak in the United States and in certain foreign countries.

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.

In addition to seeking to enforce our patent rights, we have in the past and may in the future seek to enforce our other intellectual property rights, including, for example, our trademark rights in order to prevent third parties from using the same or confusingly similar trademarks. We may not be successful in enforcing such rights and preventing such use. Further, certain of our trademark rights are licensed to us by third parties and, in certain circumstances, on a non-exclusive basis, which does not afford us the right to prevent third parties from using such trademarks. Failure to adequately pursue and enforce our intellectual property rights could damage our brands, enable others to compete with our products and impair our competitive position.

***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 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 that we entered into in connection with the convertible note hedge and warrant transactions may affect the price of our common stock.***

In connection with the sale of the 2017 notes, we entered into convertible note hedge and warrant transactions with several of the initial purchasers of the 2017 notes, their affiliates and other financial institutions, whom we refer to as 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 2017 notes (and are likely to do so during any observation period related to a conversion of the 2017 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, 2013 to February 27, 2015, the last reported sale price of our common stock ranged from a high of \$40.39 per share to a low of \$20.36 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:

- approval or rejection of submissions for marketing approval for our products and products in development;
- regulatory actions by the FDA or a foreign jurisdiction limiting or revoking the use of our products or products in development;
- 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;
- announcements of results of clinical trials or nonclinical studies by us or third parties relating to our products, products in development or those of our competitors or of 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. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015;
- developments in our ongoing litigation and 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 Select 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.

***We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management's attention and have a material adverse effect on our business, financial condition and results of operations.***

In February 2014, a class action lawsuit was filed against us and certain of our current and former officers alleging, among other things, that we and certain of our current and former officers violated federal securities laws because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding the results of clinical trials which tested the efficacy and safety of cangrelor. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. The class action lawsuit is described in more detail in Part I, Item 3. *Legal Proceedings*, of this Annual Report on Form 10-K.

While we believe we have meritorious defenses, we cannot predict the outcome of this lawsuit. There may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from this lawsuit, as it is currently at an early stage, and we cannot be certain how long it may take to resolve or the possible amount of any damages, if any, that we may be required to pay. We have not established any reserves for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgment or enter into settlement of claims for monetary damages. A decision adverse to our interests on this lawsuit could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. In addition, the uncertainty of the currently pending lawsuit could lead to more volatility in our stock price.

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

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

- Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;
- our board of directors has the authority to issue, without a vote or action of stockholders, up to 5,000,000 shares of a new series of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of our common stock;
- our directors are elected to staggered terms, which prevents our entire board of directors from being replaced in any single year;
- our directors may be removed only for cause and then only by the affirmative vote of the holders of at least 75% of the votes which all stockholders would be entitled to cast in any annual election of directors;
- the size of our board of directors is determined by resolution of the board of directors;
- any vacancy on our board of directors, however occurring, including a vacancy resulting from an enlargement of our board, may only be filled by vote of a majority of our directors then in office, even if less than a quorum;
- only our board of directors, the chairman of the board or our president may call special meetings of stockholders;
- our by-laws may be amended, altered or repealed by (i) the affirmative vote of a majority of our directors, subject to any limitations set forth in the by-laws, or (ii) the affirmative vote of the holders of at least 75% of the votes which all the 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, U.S., which we refer to as Global Center-1. The lease for Global Center-1 covers 173,146 square feet and expires January 2024. In December 2013, we opened our Global Center-2 office in Zurich, Switzerland. The lease for Global Center-2 covers 1,651 square meters and expires November 30, 2022.

We also lease small offices and other facilities in Waltham and Cambridge, Massachusetts, U.S.; Redwood City and San Diego, California, U.S.; Seattle, Washington, U.S.; Montreal, Canada; Milton Park, Abingdon, United Kingdom; Hong Kong; Paris, France; Rome, Italy; Munich, Germany; Vienna, Austria; Brussels, Belgium; Amsterdam, Netherlands; Leiden, Netherlands; Madrid, Spain; Helsinki, Finland; Copenhagen, Denmark; Stockholm, Sweden; Warsaw, Poland; Sydney, Australia; Auckland, New Zealand; Sao Paulo, Brazil; and New Delhi, India.

We believe that all of our facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

**Item 3. *Legal Proceedings.***

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

***'727 Patent and '343 Patent Litigations***

*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. On July 12, 2013, the Court issued its Markman decision as to the claim construction of the '727 patent and the '343 patent. The Court's decision varied from the other Markman decisions that we have received in our other patent infringement litigations. On July 22, 2013, we filed a motion for reconsideration of the Court's claim construction ruling on the grounds that the Court (i) impermissibly imported process limitations disclosed in a preferred embodiment into the claims, (ii) improperly transformed product claims into product-by-process claims, (iii) improperly rendered claim language superfluous and violated the doctrine of claim differentiation, and (iv) improperly construed limitations based on validity arguments that have not yet been presented. On August 22, 2013, the district court denied the motion for reconsideration. A three day bench trial was held in September 2013 and a post-trial briefing was completed in December 2013. On March 31, 2014, the Court issued its trial opinion. With respect to patent validity, the Court held that the '727 and '343 patents were valid on all grounds. Specifically, the Court found that Hospira had failed to prove that the patents were either anticipated and/or obvious. The Court further held that the patents satisfied the written description requirement, were enabled and were not indefinite. With respect to infringement, based on its July 2013 Markman decision, the Court found that Hospira's ANDAs did not meet the "efficient mixing" claim limitation and thus did not infringe the asserted claims of the '727 and '343 patents. The Court found that the other claim limitations in dispute were present in Hospira's ANDA products. The Court entered a final judgment on April 15, 2014. On May 9, 2014, we filed a notice of appeal to the United States Court of Appeals for the Federal Circuit. On May 23, 2014, Hospira filed a notice of cross-appeal. We filed our opening appeal brief on August 13, 2014. Hospira filed its opening appeal brief on September 26, 2014 asserting that the claim constructions and non-infringement findings were correct. Hospira also seeks to overturn the finding of patent validity. Briefing was completed in December 2014. An oral argument before the United States Court of Appeals for the Federal Circuit has been scheduled for March 5, 2015. If the appeal is not successful or Hospira's cross-appeal is successful, then Angiomax could be subject to generic competition earlier than anticipated, possibly as early as June 15, 2015, the date of expiration of the patent term of the '404 patent and the six month pediatric exclusivity, including from Hospira's generic bivalirudin, as well as potentially Teva's and APP's generic bivalirudin products.

*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 have completed fact and expert discovery. On June 21, 2013, Mylan filed a summary judgment motion of non-infringement of the '727 and '343 patents and alternatively that the '727 patent was invalid. The Court's decision granted non-infringement of the '343 patent and denied the motion with respect to non-infringement and invalidity of the '727 patent. A six day trial directed to the '727 patent was completed on June 18, 2014. Post-trial briefs were filed on July 1, 2014 and July 11, 2014. On October 27, 2014, the Court issued an opinion and order finding that Mylan's ANDA product infringes all of the asserted claims of the '727 patent. The Court further found that Mylan failed to prove that the same asserted claims of the '727 patent are invalid or unenforceable. Specifically, the Court found that Mylan failed to prove its allegations of anticipation, obviousness, non-enablement and unenforceability due to inequitable conduct. On October 28, 2014 and November 13, 2014, Mylan filed Notices of Appeal to the U.S. Court of Appeals for the Federal Circuit. On November 25, 2014, we filed a Notice of Cross-Appeal of the district court's summary judgment of noninfringement of the asserted claims of the '343 patent that it had issued on December 16, 2013 and the district court's Markman Order on August 6, 2012. Appellate briefing should be completed by approximately May 2015. An oral argument will be scheduled



after that. If we receive an adverse decision on appeal, then Angiomax could be subject to generic competition earlier than anticipated, including from Mylan's generic bivalirudin, as well as potentially Teva's and APP's generic bivalirudin products.

*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. 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. At the direction of the Court, on May 13, 2013, the motion was withdrawn by Dr. Reddy's. We have pending motions seeking further fact discovery of Dr. Reddy's. The parties have yet to enter the expert phase of the case. No schedule or trial date has been set.

*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 Dr. Reddy's action. Sun's answer denied infringement of the '727 patent and '343 patent. On June 7, 2012, the Court held an initial case scheduling conference. The parties proceeded with fact discovery. Following a December 20, 2013 status conference, the parties began discussing a stay in the case. Following further conferences with the Court a stipulation to stay the case was submitted and subsequently entered by the Court on April 1, 2014.

*Apotex Inc.*

In March 2013, we were notified that Apotex 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 May 1, 2013, we filed suit against Apotex Inc. and Apotex Corp., which we refer to collectively as Apotex, in the U.S. District Court for the District of New Jersey for infringement of the '727 and '343 patents. The case has been assigned to the same judge and magistrate judge as the Dr. Reddy's and Sun actions. Apotex filed its answer on July 19, 2013 and raised counterclaims of non-infringement and invalidity. A scheduling conference before the magistrate judge was held on December 16, 2013. Following a subsequent conference on April 15, 2014 and further directions from the Court to resubmit a discovery schedule, the Court entered a revised discovery schedule on July 17, 2014. A Markman hearing commenced on January 22, 2015 and we expect this hearing to be completed on March 3, 2015. Fact and expert discovery are still to be completed. The schedule does not indicate a trial date but the judge has indicated a potential August 2015 trial date.

*Exela Pharma Sciences, LLC*

In March 2014, we were notified that Exela Pharma Sciences, LLC, 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 25, 2014, we filed suit against Exela Pharma Sciences, LLC, Exela PharmSci, Inc. and Exela Holdings, Inc., which we collectively refer to as Exela, in the U.S. District Court for the Western District of North Carolina for infringement of the '727 and '343 patents. Exela filed its answer on June 3, 2014 and raised counterclaims of non-infringement, invalidity and unenforceability due to inequitable conduct. We filed a reply on July 11, 2014. The parties have conducted a Rule 26 conference. The Court has set a pretrial schedule through a June 2015 Markman hearing. On November 4, 2014, Exela filed a motion for judgment on the pleadings based on noninfringement. The motion was fully briefed on December 23, 2014. Claim construction discovery is under way. No dates have been set for the completion of fact and expert discovery. No trial date has been set.

*Accord Healthcare Inc., USA*

In June 2014, we were notified that Accord Healthcare Inc., or Accord, had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 and '343 patents. On July 24, 2014, we filed suit against Accord and its parent, Intas Pharmaceuticals Ltd., or Intas, in the U.S. District Court for the Middle District of North Carolina for infringement

of the '727 patent and '343 patent. On September 26, 2014, Accord and Intas filed an answer denying infringement and asserting that the '727 and '343 patents are invalid. The parties have conducted a Rule 26 conference. The Court has set February 17, 2016 for the close of all discovery and has not set a trial date.

*Aurobindo Pharma Limited*

In March 2014, we were notified that Aurobindo Pharma Limited 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 11, 2014, we filed suit against Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., which we refer to collectively as Aurobindo, in the U.S. District Court for the District of New Jersey for infringement of the '727 and '343 patents. The case has been assigned to the same judge and magistrate judge as the Dr. Reddy's, Sun and Apotex actions. Aurobindo filed its answer on July 3, 2014 and raised counterclaims of non-infringement and invalidity. A scheduling conference before the magistrate judge was held on November 20, 2014. No dates have been set for the completion of fact and expert discovery. No trial date has been set.

***Class Action Litigation***

On February 21, 2014, a class action lawsuit was filed against us and certain of our current and former officers in the United States District Court for the District of New Jersey by David Serr on behalf of stockholders who purchased or otherwise acquired our common stock between February 20, 2013 through February 12, 2014, which we refer to as the class period. On July 22, 2014, the Court entered an order appointing one of our stockholders, Warren H. Schuler, the lead plaintiff and Pomerantz LLP the lead counsel. Plaintiffs filed an amended complaint on September 17, 2014, which asserts claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, including allegations that our stock was artificially inflated during the class period because we and certain current and former officers allegedly made misrepresentations or did not make proper disclosures regarding the results of clinical trials, which tested the efficacy and safety of cangrelor. Specifically, the amended complaint alleges that statements made throughout the class period about the trials were misleading because they failed to disclose that cangrelor did not show superiority to the drug clopidogrel, that the clinical trials were unethically and inappropriately administered, that clopidogrel was not administered optimally, and that cangrelor patients exhibited higher bleeding rates. The amended complaint seeks, among other relief, class certification of the lawsuit, unspecified damages, interest, attorneys' fees, expert fees and other costs. On November 17, 2014 we and certain of our current and former officers moved to dismiss the amended complaint. Plaintiffs filed an opposition to the motion to dismiss on December 19, 2014 and we filed a reply brief in further support of the motion on January 16, 2015. Briefing is now complete and the motion is under consideration by the Court. We believe we have valid defenses to the claims in the lawsuit, will deny liability and intend to defend ourselves vigorously. There can be no assurance, however, that we will be successful. An adverse resolution of the lawsuit could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of the lawsuit or to reasonably estimate a range of potential losses, if any, related to the lawsuit.

**Item 4. *Mine Safety Disclosures.***

Not applicable.

**PART II**

**Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities 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
<b>Year Ended December 31, 2013</b>		
First Quarter	\$ 35.19	\$ 24.01
Second Quarter	\$ 37.40	\$ 28.63
Third Quarter	\$ 34.81	\$ 28.70
Fourth Quarter	\$ 39.40	\$ 30.60
<b>Year Ended December 31, 2014</b>		
First Quarter	\$ 41.28	\$ 27.14
Second Quarter	\$ 29.75	\$ 23.53
Third Quarter	\$ 29.82	\$ 22.31
Fourth Quarter	\$ 28.03	\$ 19.92

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on February 24, 2015, we had 166 holders of record of our common stock.

#### Dividends

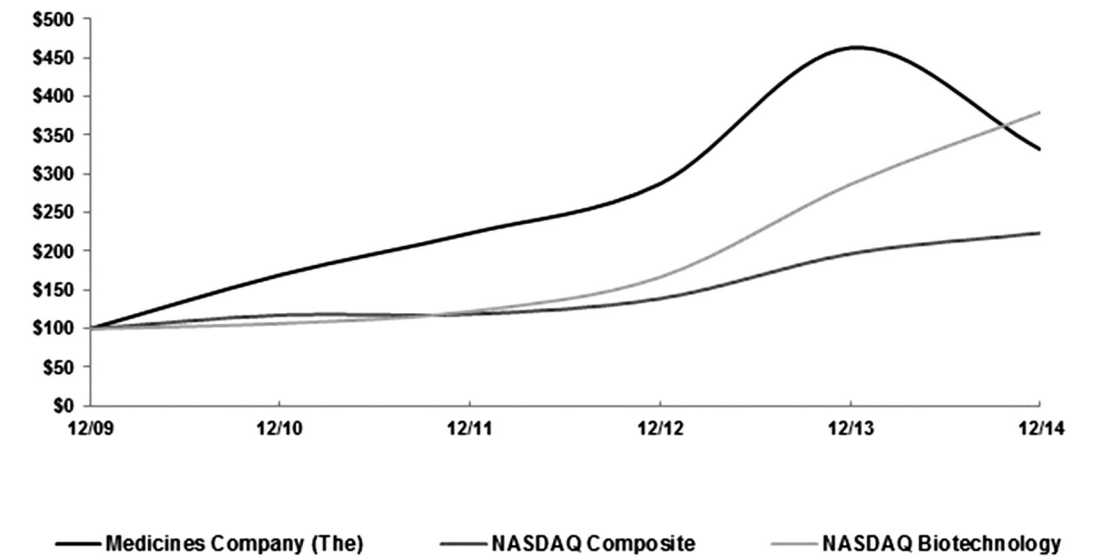
We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will 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, 2009 to December 31, 2014. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

#### COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Medicines Company (The), the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



\*\$100 invested on 12/31/09 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/09*	12/10*	12/11*	12/12*	12/13*	12/14*
<b>The Medicines Company</b>	<b>100.00</b>	<b>169.42</b>	<b>223.50</b>	<b>287.41</b>	<b>463.07</b>	<b>331.77</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>117.61</b>	<b>118.70</b>	<b>139.00</b>	<b>196.83</b>	<b>223.74</b>
<b>NASDAQ Biotechnology</b>	<b>100.00</b>	<b>106.73</b>	<b>122.40</b>	<b>166.72</b>	<b>286.55</b>	<b>379.71</b>

\* Fiscal year ended December 31.

This performance graph shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, 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 for the periods presented. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2014, 2013, 2012, 2011, and 2010.

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and related notes included in this Annual Report on Form 10-K and “Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands, except per share data)				
<b>Statements of Operations Data</b>					
Net revenue	\$ 724,408	\$ 687,864	\$ 558,588	\$ 484,732	\$ 437,645
Operating expenses:					
Cost of revenue	287,630	262,785	177,339	156,866	129,299
Research and development	159,181	146,930	126,423	110,180	85,241
Selling, general and administrative	342,164	264,958	171,753	159,617	158,690
Total operating expenses	788,975	674,673	475,515	426,663	373,230
Income (loss) from operations	(64,567)	13,191	83,073	58,069	64,415
Settlement	25,736	—	—	17,984	—
Co-promotion and profit share income	24,236	17,383	10,000	—	—
Loss in equity investment	(1,711)	—	—	—	—
Interest expense	(15,701)	(15,531)	(8,005)	—	—
Investment impairment	(7,500)	—	—	—	—
Other income (expense)	322	1,577	1,140	1,790	(267)
Income (loss) before income taxes	(39,185)	16,620	86,208	77,843	64,148
(Provision for) benefit from income taxes	6,837	(1,360)	(35,038)	50,034	40,487
Net income (loss)	(32,348)	15,260	51,170	127,877	104,635
Net loss attributable to non-controlling interest	138	252	84	—	—
Net income (loss) attributable to The Medicines Company	\$ (32,210)	\$ 15,512	\$ 51,254	\$ 127,877	\$ 104,635
Basic earnings per common share attributable to The Medicines Company	\$ (0.50)	\$ 0.27	\$ 0.96	\$ 2.39	\$ 1.98
Diluted earnings per common share attributable to The Medicines Company	\$ (0.50)	\$ 0.25	\$ 0.93	\$ 2.35	\$ 1.97
Shares used in computing basic earnings (loss) per common share	64,473	58,096	53,545	53,496	52,842
Shares used in computing diluted earnings (loss) per common share	64,473	62,652	55,346	54,407	53,184

	As of December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
<b>Balance Sheet Data</b>					
Cash and cash equivalents, available for sale securities and accrued interest receivable	\$ 370,741	376,727	570,669	\$ 340,886	\$ 247,923
Working capital	253,151	417,188	621,169	327,088	239,251
Total assets	1,885,705	1,741,282	972,182	692,647	474,124
Long-term liabilities	561,791	674,868	250,754	26,370	31,156
Accumulated deficit	(77,109)	(44,899)	(60,411)	(111,665)	(239,542)
Total stockholders’ equity	920,091	892,161	586,222	511,642	357,598

**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 on Form 10-K. In addition to the historical information, the discussion in this Annual Report on Form 10-K 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 on Form 10-K.*

**Overview**

***Our Business***

We are a global biopharmaceutical company focused on saving lives, alleviating suffering and contributing to the economics of healthcare by focusing on leading acute/intensive care hospitals worldwide. We market Angiomax<sup>®</sup> (bivalirudin), Cleviprex<sup>®</sup> (clevidipine) injectable emulsion, Minocin (minocycline) for injection, Orbactiv<sup>®</sup> (oritavancin), PreveLeak<sup>™</sup> and Recothrom<sup>®</sup> Thrombin topical (Recombinant). We also have a pipeline of acute and intensive care hospital products in development, including four registration stage product candidates for which we have submitted applications for regulatory approval in the United States, cangrelor, IONSYS<sup>®</sup> (fentanyl iontophoretic transdermal system), Raplixa<sup>™</sup>, formerly referred to as Fibrocaps<sup>™</sup>, and RPX-602, and four research and development product candidates, ABP-700, ALN-PCSSc, Carbavance<sup>™</sup> and MDCO-216. We refer to our registration stage product candidates and our research and development product candidates as our products in development. We have the right to develop, manufacture and commercialize ALN-PCSSc under our collaboration agreement with Alnylam Pharmaceuticals, Inc., or Alnylam. We believe that these 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 products in development, we sell a ready-to-use formulation of Argatroban and 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 are currently selling three of our acute care generic products, midazolam, ondansetron and rocuronium.

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 are described in more detail in Part I, Item 1. *Business* 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. *Business* of this Annual Report on Form 10-K.

Our revenues to date have been generated primarily from sales of Angiomax in the United States. In 2014, we had net revenue from sales of Angiomax of approximately \$635.7 million, net revenue from sales of Recothrom of approximately \$64.4 million and aggregate net revenue from sales of Cleviprex, Minocin IV, PreveLeak and ready-to-use Argatroban of approximately \$24.3 million.

Cost of revenue represents expenses in connection with contract manufacture of our products sold and logistics, product costs, royalty expenses and amortization of the costs of license agreements, amortization of product rights and other identifiable intangible assets, from product and business acquisitions. 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 share-based compensation expense, which we allocate based on the responsibilities of the recipients of the share-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 U.S. Patent and Trademark Office, or 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.

In September 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.

In January 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 new drug application, or 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.

On July 12, 2013, the U.S. District Court for the District of Delaware in our patent infringement litigation with Hospira issued its Markman decision as to the claim construction of the '727 patent and the '343 patent. The district court’s decision varied from the other Markman decisions that we have received in our other patent infringement litigations. On July 22, 2013, we filed a motion for reconsideration of the district court’s claim construction ruling on the grounds that the district court (i) impermissibly imported process limitations disclosed in a preferred embodiment into the claims, (ii) improperly transformed product claims into product-by-process claims, (iii) improperly rendered claim language superfluous and violated the doctrine of claim differentiation, and (iv) improperly construed limitations based on validity arguments that have not yet been presented. On August 22, 2013, the district court denied the motion for reconsideration. A three day bench trial was held in September 2013 and a post-trial briefing was completed in December 2013. On March 31, 2014, the district court issued its trial opinion. With respect to patent validity, the district court held that the '727 and '343 patents were valid on all grounds. Specifically, the district court found that Hospira had failed to prove that the patents were either anticipated and/or obvious. The district court further held that the patents satisfied the written description requirement, were enabled and were not indefinite. With respect to infringement, based on its July 2013 Markman decision, the district court found that Hospira’s ANDAs did not meet the “efficient mixing” claim limitation and thus did not infringe the asserted claims of the '727 and '343 patents. The district court found that the other claim limitations in dispute were present in Hospira’s ANDA products. The district court entered a final judgment on April 15, 2014. On May 9, 2014, we filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit. On May 23, 2014, Hospira filed a notice of cross-appeal. We filed our opening appeal brief on August 13, 2014. Hospira filed its opening appeal brief on September 26, 2014 asserting that the claim constructions and non- infringement findings were correct. Hospira also seeks to overturn the finding of patent validity. Briefing was completed in December 2014. An oral argument before the United States Court of Appeals for the Federal Circuit has been scheduled for March 5, 2015. If our appeal is not successful or Hospira’s cross-appeal is successful, then Angiomax could be subject to generic competition earlier than anticipated, possibly as early as June 15, 2015, the date of the expiration of the patent term of the '404 patent and the six month pediatric exclusivity, including from Hospira’s generic bivalirudin, as well as potentially Teva’s and APP’s generic bivalirudin products.

In our patent infringement litigation with Mylan, we completed a six day trial directed to the validity and infringement of the '727 patent in June 2014. On October 27, 2014, the U.S. District Court for the Northern District of Illinois issued an opinion and order finding that Mylan’s ANDA product infringes all of the asserted claims of the '727 patent. The district court further found that Mylan failed to prove that the same asserted claims of the '727 patent are invalid or unenforceable. Specifically, the district court found that Mylan failed to prove its allegations of anticipation, obviousness, non-enablement and unenforceability due to inequitable conduct. On October 28, 2014 and November 13, 2014, Mylan filed Notices of Appeal to the U.S. Court of Appeals for the Federal Circuit. On November 25, 2014, we filed a Notice of Cross-Appeal of the district court’s summary judgment of noninfringement of the asserted claims of the '343 patent that it had issued on December 16, 2013 and the district court’s Markman Order on August 6, 2012. We expect that appellate briefing will be completed by the end of May 2015 and that the district court will schedule oral arguments after briefing has been completed. If we receive an adverse decision on Mylan’s appeals, then Angiomax could be subject to generic competition earlier than anticipated, including from Mylan’s generic bivalirudin, as well as potentially Teva’s and APP’s generic bivalirudin products.

We remain in infringement litigation involving the '727 patent and '343 patent with the other ANDA filers, as described in Part I, Item 3. *Legal Proceedings*, of this Annual Report on Form 10-K. There can be no assurance as to the outcome of our infringement litigation. 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 and as early as June 15, 2015, the date of expiration of the patent term of the '404 patent and the six month pediatric exclusivity.

We expect to incur substantial legal expenses related to these matters.

### ***Business Development Activity***

*Annovation BioPharma, Inc.* In February 2015, we completed the acquisition of Annovation BioPharma, Inc., or Annovation, and Annovation became our wholly owned subsidiary. As a result of the acquisition of Annovation, we acquired ABP-700, a novel intravenous anesthetic. Under the terms of the terms of the acquisition agreement, we paid to the holders of Annovation's capital stock and the holders of options to purchase shares of Annovation's capital stock, which we refer to collectively as the Annovation equityholders, an aggregate of approximately \$28.4 million in cash. In addition, we may be required to pay Annovation equityholders up to an additional \$26.3 million in milestone payments subsequent to the closing if we achieve certain development and regulatory approval milestones at the times and on the conditions set forth in the acquisition agreement. We have also agreed to pay Annovation equityholders a low single digit percentage of worldwide net sales, if any, of certain Annovation products, including ABP-700, during a specified earnout period. In addition, as a result of our acquisition of Annovation, we, through our subsidiary Annovation, are a party to a license agreement with The General Hospital Corporation. Under the agreement, we will be obligated to pay General Hospital Corporation up to an aggregate of \$6.5 million upon achievement of specified development, regulatory and sales milestones. We will also be obligated to pay General Hospital Corporation low single-digit percentage royalties on a product-by-product and country-by-country basis based on net sales of ABP-700 products until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell ABP-700 products in a country and the date ten years from our first commercial sale of ABP-700 products in such country.

*Tenaxis Medical, Inc.* In May 2014, we completed our acquisition of Tenaxis Medical, Inc., or Tenaxis, and Tenaxis became our wholly owned subsidiary. As a result of the acquisition of Tenaxis, we acquired Tenaxis's sole product, PreveLeak, a vascular and surgical sealant that mechanically seals both human tissue and artificial grafts. In the United States, PreveLeak received a premarket approval from the FDA in March 2013 for use as a vascular sealant, but it has not yet been commercialized in the United States. We expect to begin selling PreveLeak in the United States in 2015. In the European Union, PreveLeak is approved with a European CE Mark for sale as a surgical sealant indicated for vascular, cardiac and soft tissue reconstructions to achieve hemostasis by mechanically sealing areas of leakage. Pursuant to this approval, PreveLeak has been sold in the European Union since September 2008.

Under the merger agreement, we paid to the holders of Tenaxis's capital stock, the holders of options to purchase shares of Tenaxis's capital stock (whether or not such capital stock or options were vested or unvested as of immediately prior to the closing) and the holders of certain warrants and side letters, which we refer to collectively as the Tenaxis equityholders, an aggregate purchase price of approximately \$58.9 million in cash, subject to customary adjustments at and after the closing. At the closing, we deposited approximately \$5.4 million of the purchase price into an escrow fund for the purposes of securing the indemnification obligations of the Tenaxis equityholders to us for any and all losses for which we are entitled to indemnification pursuant to the merger agreement and to provide the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process. During the third quarter of 2014, we finalized the purchase price adjustment process, which resulted in an insignificant adjustment to the purchase price. To the extent that any amounts remain in the escrow fund after October 1, 2015 and are not subject to claims by us, such amounts will be released to the Tenaxis equityholders, subject to certain conditions set forth in the merger agreement.

In addition, we have agreed to pay to the Tenaxis equityholders milestone payments subsequent to the closing, if we achieve certain regulatory approval milestones and commercial net sales milestones with respect to PreveLeak, at the times and on the conditions set forth in the merger agreement. In the event that all of the milestones set forth in the merger agreement are achieved in accordance with the terms of the merger agreement, we will pay the Tenaxis equityholders up to an additional \$112.0 million in cash in the aggregate.

*Promus PREMIER Stent System Co-Promotion.* In December 2013, we entered into a co-promotion agreement with Boston Scientific Corporation, or BSX, for the Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System, or Promus PREMIER Stent System, to provide promotional support for the Promus PREMIER Stent System in U.S. hospitals. For the year ended December 31, 2014, we recognized \$5.0 million in co-promotion income from BSX. Effective December 31, 2014, our co-promotion agreement with BSX was terminated and we ceased to co-promote the Promus PREMIER Stent System.

*Rempex Pharmaceuticals, Inc.* In December 2013, we acquired Rempex Pharmaceuticals, Inc., or Rempex, a company focused on the discovery and development of new antibacterial drugs to meet the growing clinical need created by multi-drug resistant bacterial pathogens. As a result of the transaction, we acquired Rempex's marketed product, Minocin IV, a broad-spectrum

tetracycline antibiotic, and Rempex's portfolio of product candidates, including Rempex's RPX-602, a proprietary reformulation of Minocin IV utilizing magnesium sulfate, Rempex's Carbavance product candidate, an investigational agent that is a combination of RPX-7009, a proprietary, novel beta-lactamase inhibitor, with a carbapenem, and Rempex's other product candidates. Upon the completion of the acquisition, Rempex became our wholly owned subsidiary.

Under the merger agreement for the acquisition, we paid to the holders of Rempex's capital stock, the holders of options to purchase shares of Rempex's capital stock and the holders of certain phantom stock units, which we collectively refer to as the Rempex equityholders, an aggregate of approximately \$140.0 million in cash, plus approximately \$0.3 million in purchase price adjustments.

In addition, we agreed to pay to the Rempex equityholders milestone payments subsequent to the closing, if we achieve certain development and regulatory approval milestones and commercial sales milestones with respect to Minocin IV, RPX-602, Carbavance and Rempex's other product candidates, at the times and on the conditions set forth in the merger agreement. In the event that all of the milestones set forth in the merger agreement are achieved in accordance with the terms of the merger agreement, we will pay the Rempex equityholders an additional \$214.0 million in cash in the aggregate for achieving development and regulatory milestones and an additional \$120.0 million in cash in the aggregate for achieving commercial milestones, in each case, less certain transaction expenses and employer taxes owing because of the milestone payments.

Pursuant to the terms of the merger agreement, as a result of certain milestone payments becoming due within eighteen months following the closing, in October 2014, we entered into an escrow agreement and deposited an aggregate of \$14.0 million into an escrow fund during the fourth quarter of 2014. To the extent that any amounts remain in the escrow fund after June 3, 2015 and not subject to claims by us, such amounts will be released to the Rempex equityholders, subject to certain conditions set forth in the merger agreement.

*ProFibrix B.V.* On August 5, 2013, we completed our acquisition of all of the outstanding equity of ProFibrix, pursuant to a share purchase agreement entered into with ProFibrix and its equityholders on June 4, 2013. Under the share purchase agreement, the closing of the transaction was subject to our satisfactory review of the then pending Phase 3 clinical trial results of ProFibrix's lead biologic, Raplixa (formerly known as Fibrocaps). In connection with entering into the agreement, we paid ProFibrix a \$10.0 million option payment. Upon the completion of the acquisition, ProFibrix became our wholly owned subsidiary.

ProFibrix does not have any marketed products and has been engaged since its inception in developing fibrinogen based products for the hemostasis and regenerative medicine markets. Raplixa is a dry powder topical formulation of fibrinogen and thrombin being developed to help stop bleeding during surgery. On August 5, 2013, in connection with the closing, we announced that the Phase 3 clinical trial of Raplixa, FINISH-3, which studied 719 surgical patients with mild to moderate surgical bleeding, met all primary and secondary hemostasis efficacy endpoints in four distinct surgical indications of spinal surgery, hepatic resection, soft tissue dissection and vascular surgery.

Following our review of the Phase 3 trial results, on August 2, 2013, we notified ProFibrix that we wished to proceed with the consummation of the transaction. At the closing, we paid an aggregate purchase price of \$90.9 million in cash. We deposited \$9.0 million of the purchase price into an escrow fund for the purpose of (i) securing the indemnification obligations of the ProFibrix equityholders and optionholders to us for any and all losses for which we are entitled to indemnification under the share purchase agreement, and (ii) providing the source of recovery for any amounts payable to us as a result of the post-closing purchase price adjustment process. To the extent that any amounts remain in the escrow fund after December 4, 2015 and not subject to claims by us, such amounts will be released to the ProFibrix equityholders, subject to certain conditions set forth in the merger agreement.

Under the terms of the share purchase agreement, we are also obligated to pay up to an aggregate of \$140.0 million in cash to the ProFibrix equityholders and optionholders upon the achievement of certain U.S. and European regulatory approvals prior to January 1, 2016 and certain U.S. and European sales milestones during the 24-month period that follows the initial commercial sale of Raplixa. As a result of our acquisition of ProFibrix, we acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited, or Quadrant, which included the U.S. patent directed to the composition of matter of Raplixa. Under the terms of a license agreement between ProFibrix and Quadrant, we are required to pay low single digit percentage royalties based on annual worldwide net sales of licensed products, including Raplixa, by us or our affiliates and sublicensees. The royalties are subject to reduction in specified circumstances.

*Alnylam License Agreement.* 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 \$25.0 million in an initial license payment and agreed to pay up to \$180.0 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. Pursuant to the agreement, we exercised our option and on February 6, 2015 we completed our acquisition of the remaining assets held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, in February 2013 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. Upon closing the exercise of the option, in February 2015 we paid BMS approximately \$127.7 million in the aggregate, including approximately \$39.3 million for inventory. In addition, we have agreed to pay BMS up to an additional \$4.9 million upon the delivery of certain additional inventory following the closing, subject to specified terms and conditions.

We did 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 any significant tangible assets related to the Recothrom business, other than inventory. Under the master transaction agreement, we paid BMS quarterly tiered royalty payments during the two-year collaboration term equal to a percentage of worldwide net sales of Recothrom.

*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 merger agreement with Incline, we paid to Incline's equityholders and optionholders an aggregate of approximately \$155.2 million in cash. In addition, we paid approximately \$13.0 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 an additional \$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 merger agreement, to the extent that any amounts remained in the escrow fund after July 4, 2014 and not subject to claims by us, such amounts were to be released to Incline's equityholders and optionholders, subject to certain conditions set forth in the merger agreement. In December 2014, we entered into a settlement and amendment to the merger agreement, which resulted in revisions to certain milestone triggers, a reduction in total potential milestone payments and the immediate release of the escrow fund to us.

Under the terms of our agreement with Incline, as amended, we agreed to pay up to \$189.3 million in cash in the aggregate, less certain related expenses, to Incline's former equityholders and optionholders and up to \$115.5 million in additional payments to other third parties, if we enter into a license agreement in Japan or achieve certain regulatory approval or sales milestones with respect to IONSYS.

*Collaboration with AstraZeneca LP.* On April 25, 2012, we entered into a global collaboration agreement with AstraZeneca LP, pursuant to which we and AstraZeneca agreed to collaborate globally to develop and commercialize certain acute ischemic heart disease compounds. For the year ended December 31, 2014, AstraZeneca LP paid us \$16.0 million under the agreement. Effective December 31, 2014, our global collaboration agreement with AstraZeneca LP was terminated and we ceased to co-promote AstraZeneca LP's BRILINTA.

*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 \$49.4 million as certain milestones have not been achieved by specified dates. We

will owe \$49.4 million if aggregate net sales of Orbactiv in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, and up to an additional \$40 million in additional payments to other third parties.

*Curacyte Discovery GmbH.* In August 2008, we acquired Curacyte Discovery GmbH, or Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, was primarily engaged in the discovery and development of small molecule serine protease inhibitors. In connection with the acquisition, we paid Curacyte AG an initial payment of €14.5 million in August 2008 (approximately \$22.9 million at the time of payment) and €3.5 million in December 2009 (approximately \$5.2 million at the time of payment), €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.

#### **BARDA Agreement**

In February 2014, our subsidiary Rempex entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, of the U.S. Department of Health and Human Services, under which Rempex has the potential to receive up to \$89.8 million in funding to support the development of Carbavance. The BARDA agreement is a cost-sharing arrangement that consists of an initial base period and seven option periods that BARDA may exercise in its sole discretion pursuant to the BARDA agreement. The BARDA agreement provides for an initial commitment by BARDA of an aggregate of \$19.8 million for the initial base period and the first option period, and up to an additional \$70.0 million if the remaining six option periods are exercised by BARDA. In October 2014, BARDA exercised the second option, increasing BARDA's total commitment to \$37.8 million. Under the cost-sharing arrangement, Rempex will be responsible for a designated portion of the costs associated with each period of work. If all option periods are exercised by BARDA, the estimated period of performance would be extended until approximately July 31, 2019. BARDA is entitled to terminate the agreement, including the projects under the BARDA agreement for convenience, in whole or in part, at any time and is not obligated to provide continued funding beyond current year amounts from Congressionally approved annual appropriations. We expect to use the total award under the BARDA agreement to support non-clinical development activities, clinical studies, manufacturing and associated regulatory activities designed to obtain marketing approval of Carbavance in the United States for treatment of serious gram-negative infections. The BARDA agreement also covers initial non-clinical studies to assess the potential usefulness of Carbavance for treatment of certain gram-negative bioterrorism agents. Under the terms of our agreement with Rempex, we agreed to pay Rempex equityholders on a quarterly basis, as part of our development milestones, a specified percentage of amounts actually received by us from BARDA. We recorded approximately \$9.5 million of reimbursements by the government as a reduction of research and development expenses for the year ended December 31, 2014.

#### **Convertible Senior Note Offerings**

##### *2017 Notes*

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 2017 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2017 notes. The net proceeds from the offering were \$266.2 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2017 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 2017 notes will mature on June 1, 2017. The 2017 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 2017 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 2017 notes and equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated. The 2017 notes are effectively junior in right of payment to any of our secured indebtedness 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 2017 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 2017 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the 2017 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 2017 notes being converted, subject to a daily share cap, as described in the Indenture. Holders of 2017 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 2017 notes.

The conversion rate for the 2017 notes was initially, and remains, 35.8038 shares of our common stock per \$1,000 principal amount of 2017 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 governing the 2017 notes.

We may not redeem the 2017 notes prior to maturity and are not required to redeem or retire the 2017 notes periodically. However, upon the occurrence of a "fundamental change", as defined in the indenture governing the 2017 notes, subject to certain conditions, in lieu of converting their 2017 notes, holders may require us to repurchase for cash all or part of their 2017 notes at a repurchase price equal to 100% of the principal amount of the 2017 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 2017 notes in connection with such change of control in certain circumstances.

The indenture governing the 2017 notes contains customary events of default with respect to the 2017 notes, including that upon certain events of default, including our failure to make any payment of principal or interest on the 2017 notes when due and payable, occurring and continuing, the trustee for the 2017 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2017 notes by notice to us and the trustee for the 2017 notes, may, and the trustee at the request of such holders, subject to the provisions of the indenture governing the 2017 notes, shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 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 2017 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*

In connection with the offering of the 2017 notes, on June 5, 2012, we entered into convertible note hedge transactions and warrant transactions with several of the initial purchasers of the 2017 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 2017 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 2017 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 2017 notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the 2017 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.

#### *2022 Notes*

On January 13, 2015, we completed our private offering of \$400.0 million aggregate principal amount of our 2.50% convertible senior notes due 2022, or the 2022 notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 2022 notes. The aggregate principal amount of 2022 notes sold reflects the exercise in full by the initial purchasers of the 2022 notes of their option to purchase up to an additional \$50.0 million in aggregate principal amount of the 2022 notes. The net proceeds from the offering were \$387.1 million, after deducting the initial purchasers' discounts and commissions and our offering expenses.

The 2022 notes will bear cash interest at a rate of 2.50% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 notes will mature on January 15, 2022.

Holders may convert their 2022 notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances: (1) during any calendar quarter commencing on or after March 31, 2015 (and only during such calendar quarter), if the last reported sale price of our 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 on each applicable trading day; (2) during the five business day period after any five consecutive trading day period, or measurement period, in which the trading price, as defined in the indenture governing the 2022 notes, per \$1,000 principal amount of 2022 notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) during any period after we have issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or (4) upon the occurrence of specified corporate events. On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay cash up to the aggregate principal amount of the 2022 notes to be converted and deliver shares of our common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 notes being converted, subject to a daily share cap.

The conversion rate for the 2022 notes was initially, and remains, 29.8806 shares of our common stock per \$1,000 principal amount of the 2022 notes, which is equivalent to an initial conversion price of approximately \$33.47 per share of our common stock.

We may not redeem the 2022 notes prior to January 15, 2019. We may redeem for cash all or any portion of the 2022 notes, at our option, on or after January 15, 2019 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 notes, which means that we are not required to redeem or retire the 2022 notes periodically.

If we undergo a fundamental change, as defined in the indenture governing the 2022 notes, subject to certain conditions, holders of the 2022 notes may require us to repurchase for cash all or part of their 2022 notes at a repurchase price equal to 100% of the principal amount of the 2022 notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2022 notes are our senior unsecured obligations and will rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2022 notes; equal in right of payment to our existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The indenture governing the 2022 notes contains customary events of default with respect to the 2022 notes, including that upon certain events of default (including our failure to make any payment of principal or interest on the 2022 notes when due and payable) occurring and continuing, the trustee for the 2022 notes by notice to us, or the holders of at least 25% in principal amount of the outstanding 2022 notes by notice to us and the trustee for the 2022 notes, may, and the trustee at the request of such holders (subject to the provisions of the indenture governing the 2022 notes) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the 2022 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

#### **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 under which Biogen licensed Angiomax to us. 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. As of December 15, 2014, we no longer owe royalties to Biogen or HRI relating to sales of Angiomax in the United States. Consistent with past practice, Biogen has informed us of their intention to audit our books and records to verify the accuracy of the amounts paid to Biogen under the License Agreement.

#### **European Reorganization**

On October 22, 2014, we commenced implementation of a reorganization of our European operations intended to improve efficiency and better align our costs and employment structure with our strategic plans. The reorganization included a workforce reduction and the consolidation of certain European sites into a single location in Zurich, Switzerland. We substantially completed this reorganization by the end of the fourth quarter of 2014.

In the year ended December 31, 2014, we recorded, in the aggregate, a one-time charge of approximately \$9.0 million associated with this reorganization of our European operations. Of the approximately \$9.0 million of charges related to the 2014 European reorganization, \$8.5 million were cash charges and \$0.5 million were non-cash charges. We expect to make all of the cash payments related to the European reorganization during 2015. We expect to realize estimated annualized cost savings from the reorganization in the range of \$20.0 million to \$25.0 million starting in the first quarter of 2015.

#### 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 on Form 10-K, 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 on Form 10-K. 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 developed Orbactiv for the treatment of ABSSSI, including infections caused by MRSA, and are exploring the development of Orbactiv for other indications, including ABSSSI in children, uncomplicated bacteremia, endocarditis, prosthetic joint infections, and other gram-positive bacterial infections. We are also developing Carbavance for the treatment of hospitalized patients with serious gram-negative bacterial infections. In November 2013, the FDA designated Orbactiv a QIDP. In August 2014, following approval of Orbactiv, the FDA informed us that Orbactiv met the criteria for an additional five years of non-patent exclusivity to be added to the five year exclusivity period already provided by the Food, Drug and Cosmetic Act. As a result, Orbactiv's non-patent regulatory exclusivity is scheduled to expire in August 2024. In December 2013, the FDA designated Carbavance a QIDP. We expect that, if we submit an NDA for Carbavance and the NDA is approved, Carbavance would receive an additional five-years of non-patent exclusivity.

## Results of Operations

### Years Ended December 31, 2014 and 2013

#### Net Revenue:

Net revenue increased 5.3% to \$724.4 million for the year ended December 31, 2014 as compared to \$687.9 million for the year ended December 31, 2013.

The following table reflects the components of net revenue for the years ended December 31, 2014 and 2013:

	Year Ended December 31,		Change	Change
	2014	2013	\$	%
	(In thousands)			
Angiomax	\$ 635,703	\$ 608,572	\$ 27,131	4.5%
Recothrom	64,448	63,256	1,192	1.9%
Other products	24,257	16,036	8,221	51.3%
<b>Total net revenue</b>	<b>\$ 724,408</b>	<b>\$ 687,864</b>	<b>\$ 36,544</b>	<b>5.3%</b>

Net revenue increased by \$36.5 million, or 5.3%, to \$724.4 million in 2014 compared to \$687.9 million in 2013, reflecting an increase of \$58.4 million or 9.3% in the United States partially offset by a decrease of \$21.8 million, or 37.4%, in international markets. Total net revenue increase was comprised of price increases of \$28.2 million, principally due to price increases for Angiomax in the United States, net volume increases of \$7.2 million due to increased unit shipments to our customers and the favorable impact from foreign exchange rates of \$0.1 million. Net revenue from worldwide sales of Angiomax increased by \$27.1 million in 2014 primarily due to increased sales in the United States. Angiomax sales in United States increased by \$49.3 million reflecting an increase of \$29.5 million associated with price increases and an increase of \$19.8 million due to increased shipments to our customers. International sales of Angiomax decreased by \$22.2 million primarily as a result of decreased unit shipments to our customers.

Net revenue in 2014 from Recothrom increased by \$1.2 million, as 2014 reflects the first full year of sales for Recothrom following our commencement of sales in February 2013. Other product revenue increases were primarily due to increases in revenue from ready-to-use Argatroban of \$3.8 million and from Cleviprex of \$2.1 million, primarily due to volume increases associated with increased shipments to our customers and the one-time increases of \$1.6 million in net revenue from of ready-to-use Argatroban and \$0.7 million in net revenue from Cleviprex, as a result of a change in our revenue recognition policy to recognize product sales previously deferred as of December 31, 2013. Other product revenue also included an increase of \$2.3 million due to the launches of Orbactiv and PreveLeak in 2014 and the impact of a full year of revenue for Minocin IV, acquired from Rempex in December 2013.

*Angiomax.* Net revenue increased by \$27.1 million, or 4.5%, to \$635.7 million in 2014 compared to \$608.6 million in 2013, primarily due to price increases in the United States and increased unit shipments to customers. Net revenue in the United States in both 2014 and 2013 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Under the 340B Drug Pricing 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 \$16.7 million to \$73.6 million in 2014 compared to \$56.9 million in 2013, primarily due to higher amounts ordered by eligible hospital customers. Rebates related to the PPACA increased by \$0.8 million to \$2.3 million in 2014 compared to \$1.5 million in 2013.

Net revenue outside of the United States decreased by \$22.2 million to \$36.2 million in 2014 compared to \$58.4 million in 2013, primarily due in part to a decline in sales in Europe where some hospitals chose to use heparin instead of Angiomax for primary PCI following the publication of data from the HEAT-PPCI trial in March 2014, as well as a diversion of primary PCI patients into a large scale, cross-Europe clinical trial and the ongoing cost-of-care pressures in Europe causing some physicians and medical decision-makers to choose to use heparin due to its cost.



*Recothrom.* Net revenue from Recothrom increased by \$1.2 million, or 1.9%, to \$64.4 million in 2014 compared to \$63.3 million in 2013 due to a full quarter of sales during the first quarter of 2014. We commenced sales of Recothrom on February 8, 2013 pursuant to the master transaction agreement with BMS.

*Other products.* Net revenue from sales of Cleviprex, Orbactiv, Minocin IV, PreveLeak and ready-to-use Argatroban increased by \$8.2 million or 51.3%, to \$24.3 million in 2014 compared to \$16.0 million in 2013, primarily due to increases in revenue of \$2.1 million for Cleviprex and of \$3.8 million for ready-to-use Argatroban. The increase in revenue for these products reflects increased unit shipments to customers as well as the impact of a change in our revenue recognition method for Cleviprex and ready-to-use Argatroban in the first quarter of 2014. Under our revised revenue recognition policy, beginning in the first quarter of 2014, we recognize revenue for Cleviprex and ready-to-use Argatroban as product is sold to Integrated Commercialization Solutions, or ICS. For periods prior to 2014, we recognized revenue for Cleviprex and ready-to-use Argatroban using the deferred revenue model. During 2014, we recognized \$0.7 million in net sales of Cleviprex and \$1.6 million in net sales of ready-to-use Argatroban, that had been previously deferred as of December 31, 2013, net of chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges. Net revenue from sales of Cleviprex was \$6.8 million in 2014, compared to \$4.7 million in 2013. Net revenue from sales of ready-to-use Argatroban was \$15.1 million in 2014, compared to \$11.2 million in 2013. Net revenue from sales of Orbactiv, Minocin IV and PreveLeak was \$2.4 million in 2014.

*Cost of Revenue:*

Cost of revenue in 2014 was \$287.6 million, or 39.7% of net revenue, compared to \$262.8 million, or 38.2% of net revenue, in 2013.

Cost of revenue during these periods consisted of:

- expenses in connection with the manufacture of our products sold;
- royalty expenses under our agreements with Biogen and HRI related to Angiomax, our agreement with AstraZeneca related to Cleviprex, our agreement with Lilly related to Orbactiv and our agreement with Eagle related to ready-to-use Argatroban;
- amortization of the costs of license agreements, product rights, developed product rights and other identifiable intangible assets, which result from product and business acquisitions and impairment charges related to product rights;
- logistic costs related to Angiomax, Cleviprex, Orbactiv, Minocin IV, PreveLeak and ready-to-use Argatroban, including distribution, storage, and handling costs; and
- expenses under our license agreement with BMS for Recothrom and expenses under our supply agreement for Recothrom with BMS including product cost and logistics as well as royalty expense and amortization of product license.

**Cost of Revenue**

	Year Ended December 31,			
	2014	% of Total Cost	2013	% of Total Cost
	(In thousands)		(In thousands)	
Manufacturing/Logistics	\$ 98,199	34%	\$ 84,725	32%
Royalty	142,585	50%	154,099	59%
Amortization of acquired product rights and intangible assets	46,846	16%	23,961	9%
<b>Total cost of revenue</b>	<b>\$ 287,630</b>	<b>100%</b>	<b>\$ 262,785</b>	<b>100%</b>

Cost of revenue increased by \$24.8 million in 2014 compared to 2013, primarily due to increases in manufacturing and logistics costs associated with sales of Recothrom, amortization of acquired product rights and intangible assets and an impairment charge on product licenses of \$21.5 million to cost of revenue as a result of a reduction in estimated future cash flows expected to be generated by our acute care generic products. These increases were partially offset by a decrease in royalty expenses associated

with Angiomax reflecting the termination of the royalty obligation to Biogen and HRI on the U.S. sales of Angiomax in connection with the '404 patent in the United States on December 15, 2014.

*Research and Development Expenses:*

**Research and Development**

	Year Ended December 31,			
	2014	% of Total R&D	2013	% of Total R&D
Marketed products	\$ 35,109	22.1%	\$ 56,639	38.5%
Research and development candidates	45,638	28.7%	44,361	30.2%
Research and development product candidates	78,345	49.2%	45,930	31.3%
<b>Total research and development expenses</b>	<b>\$ 159,092</b>	<b>100.0%</b>	<b>\$ 146,930</b>	<b>100.0%</b>

For these periods, our marketed products consist of Angiomax, Cleviprex, Minocin IV, Orbactiv, PreveLeak, ready-to-use Argatroban, Recothrom and certain of our acute care generic drugs. Registration stage product candidates include cangrelor, IONSYS, Raplixa and RPX-602. Research and development stage product candidates include ALN-PCSSc, Carbavance, MDCO-216 and other early stage compounds.

Research and development expenses increased by \$12.2 million in 2014 compared to 2013, primarily due to expenses associated with Carbavance, RPX-602, Raplixa and MDCO-216. Research and development expenses associated with Carbavance and RPX-602 increased by \$25.6 million and \$2.3 million, respectively, reflecting full year clinical trial and manufacturing development expenses following our December 2013 acquisition of Rempex. Research and development expenses associated with Raplixa increased by \$9.8 million reflecting full year manufacturing and regulatory filing related costs following our August 2013 acquisition of ProFibrix. Research and development expenses associated with MDCO-216 increased by \$18.5 million to support manufacturing development scale up efforts. These increases were offset by decreased expenses associated with Orbactiv and cangrelor of \$18.9 million and \$10.2 million, respectively, due to higher clinical, manufacturing, regulatory and statistical activities in 2013 related to the preparation of the NDAs for Orbactiv and cangrelor which we submitted in the second half of 2013 and a decrease of \$10.4 million in payments to Alnylam reflecting an initial license payment of \$25.0 million to Alnylam under our license and collaboration agreement in the first quarter of 2013.

We expect research and development expenses in 2015 to include costs for global regulatory activities related to IONSYS and Orbactiv in the United States and European Union, and costs for regulatory activities related to Cleviprex, cangrelor and Raplixa outside of the United States; manufacturing development activities for Carbavance, IONSYS, Orbactiv, MDCO-216 and ALN-PCSSc; and clinical trials of MDCO-216 and ALN-PCSSc; continuation of our ongoing Phase 3 clinical trial of Carbavance; and additional clinical trials of Angiomax, cangrelor, Cleviprex and Orbactiv for use in additional patient populations and lifecycle management activities.

*Selling, General and Administrative Expenses:*

	Year Ended December 31,		Change	
	2014	2013	\$	%
	(In thousands)			
Selling, general and administrative expenses	\$ 342,164	\$ 264,958	\$ 77,206	29.1%

Selling, general and administrative expenses increased by \$77.2 million in 2014 as compared to 2013, primarily due to a \$25.8 million increase in selling, marketing and promotional expenses and a \$52.0 million increase in general corporate and administrative expenses.

Selling, marketing and promotional expenses increased by \$25.8 million primarily to support our product launches of Orbactiv and Minocin IV.

General corporate and administrative expenses increased by \$52.0 million, primarily due to increases of \$27.8 million in corporate infrastructure costs to support our growing product portfolio resulting from our acquisitions during 2013 and 2014; increases of \$19.5 million in accretion costs associated with the fair value adjustments of the contingent consideration due to the former equityholders of Targanta, Incline, ProFibrix, Rempex and Tenaxis; increases of \$9.5 million in share-based compensation; and increases of \$4.4 million in employee severance and other costs associated with the reorganization of our European operations as compared to charges incurred in the first quarter 2013 related to our 2013 reduction in force. These increases were partially offset by decreases of \$9.2 million in deal-related costs in connection with our 2013 acquisitions and of \$5.0 million reflecting the 2013 arbitration award to Eagle.

We expect our selling, general and administrative expenses will increase in 2015 due to increased costs related to potential commercial launches of our product candidates.

*Settlement:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Settlement	\$ 25,736	—	\$ 25,736	*

\*Represents an increase in excess of 100%

In December 2014, we entered into a settlement and amendment to the merger agreement with Incline Therapeutics, Inc., which resulted in revisions to certain milestone triggers, a reduction in total milestone payments and the immediate release of the escrow fund to us. As a result, in December 2014, we recorded \$25.7 million in one-time income in connection with the settlement with the former equityholders of Incline related to the representations and warranties included in the merger agreement.

*Co-promotion and Profit Share Income:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Co-promotion and profit share income	\$ 24,236	\$ 17,383	\$ 6,853	39.4%

Co-promotion and profit share income increased by \$6.9 million in 2014 to \$24.2 million from \$17.4 million in 2013 primarily due to higher co-promotion income from our agreement with BSX to promote the Promus PREMIER Stent System and an increase in the profit share income under our license agreement with Eagle related to ready-to-use Argatroban during 2014. We recognized \$5.0 million in revenue as a result of our co-promotion agreement with BSX. Our co-promotion income related to our agreement with AstraZeneca LP to promote BRILINTA stayed generally consistent from 2013 to 2014. AstraZeneca LP and BSX terminated their agreement with us to co-promote, BRILINTA and Promus PREMIER Stent System, respectively at the end of 2014. As a result, we will not receive any further income under our agreements with the AstraZeneca LP and the BSX.

*Loss in equity investment:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Loss in equity investment	(1,711)	—	\$ (1,711)	*

\*Represents an increase in excess of 100

In September 2014, we acquired additional shares of preferred stock of Annovation resulting in us having significant influence over Annovation. In 2014, we recorded a loss of \$1.7 million for our proportionate share of Annovation's losses under the equity method of accounting.

*Interest Expense:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Interest expense	\$ (15,701)	\$ (15,531)	\$ (170)	(1.1)%

During 2014, we recorded approximately \$15.7 million in interest expense related to the 2017 notes as compared to \$15.5 million in 2013. We issued the 2017 notes on June 11, 2012 and have recorded interest from that date. We expect interest expense to increase in 2015 as a result of the interest expense due under the 2022 notes.

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Investment impairment	\$ (7,500)	—	\$ (7,500)	*

\*Represents an increase in excess of 100

During 2014, we recorded an investment impairment charge of \$7.5 million representing an other-than temporary decline in the value of our investment in the common stock of GeNO, LLC.

*Other Income:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Other income	\$ 322	\$ 1,577	\$ (1,255)	(79.6)%

Other income, which is comprised of interest income, gains and losses on foreign currency transactions, decreased by \$1.3 million to \$0.3 million for 2014, from \$1.6 million in 2013. This decrease was primarily due to lower gains on foreign currency transactions in 2014 than in 2013.

*Benefit (Provision) for Income Tax:*

	Year Ended December 31,		Change \$	Change %
	2014	2013		
	(In thousands)			
Benefit (provision) for income tax	\$ 6,837	\$ (1,360)	\$ 8,197	*

\*Represents an increase in excess of 100%

Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and numerous foreign jurisdictions. We recorded a \$6.8 million benefit and a \$1.4 million provision for income taxes for 2014 and 2013, respectively, based on a loss and income before taxes for such periods of \$39.2 million and \$16.6 million, respectively. Our effective income tax rates for 2014 and 2013 were approximately (17.5)% and 8.1%, respectively. The 2014 effective tax rate includes the non-cash tax impact arising from changes in contingent consideration related to the Targanta, Incline, ProFibrix, Rempex and Tenaxis acquisitions. The 2013 effective income tax rate includes a non-cash benefit of \$13.6 million related to a change in the estimate for California state taxes as a result of our business combinations and the effect of a one-time income tax benefit arising from the retroactive reinstatement of the research and development tax credit.

At December 31, 2014, we maintained a \$43.9 million valuation allowance against \$149.4 million of deferred tax assets compared to a \$4.2 million valuation allowance against \$124.6 million of deferred tax assets at December 31, 2013.

Deferred income taxes arise from temporary differences between the tax and financial statement recognition of revenue and expense. In evaluating our ability to realize our deferred tax assets within the jurisdiction from which they arise, we consider all available positive and negative evidence on a periodic basis in light of changing facts and circumstances. These include, without limitation, the status of litigation with respect to the Angiomax patents and the potential impact to projections of future taxable income, scheduled reversal of deferred tax liabilities, tax planning strategies, 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. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we are using to manage the underlying businesses.

Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes that would have a material effect on our results of operations, cash flows, or financial position.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations.

Our annual effective tax rate for 2015 will be higher than 2014 due to higher nondeductible charges for contingent consideration related to our acquisitions.

#### Years Ended December 31, 2013 and 2012

##### Net Revenue:

Net revenue increased 23.1% to \$687.9 million for the year ended December 31, 2013 as compared to \$558.6 million for the year ended December 31, 2012.

The following table reflects the components of net revenue for the years ended December 31, 2013 and 2012:

#### Net Revenue

	Year Ended December 31,		Change	Change
	2013	2012	\$	%
	(In thousands)			
Angiomax	\$ 608,572	\$ 548,229	\$ 60,343	11.0%
Recothrom	63,256	—	63,256	100.0%
Other products	16,036	10,359	5,677	54.8%
<b>Total net revenue</b>	<b>\$ 687,864</b>	<b>\$ 558,588</b>	<b>\$ 129,276</b>	<b>23.1%</b>

Net revenue increased by \$129.3 million, or 23.1%, to \$687.9 million in 2013 compared to \$558.6 million in 2012, reflecting increases of \$117.4 million or 22.9% in the United States, and \$11.9 million or 25.5% in international markets. The net revenue increase was comprised of net volume increases of \$27.0 million due to increased unit shipments to customers of Angiomax and price increases of \$32.2 million, principally due to a price increase for Angiomax effective as of January 1, 2013 in the United States, and favorable impact from foreign exchange of \$0.5 million. In addition, the net revenue increase included \$63.3 million in net revenue from Recothrom, which we first began selling in the United States in February 2013.

*Angiomax.* Net revenue increased by \$60.3 million, or 11.0%, to \$608.6 million in 2013 compared to \$548.2 million in 2012, primarily due to the January 1, 2013 price increase in the United States and increased unit sales globally. Net revenue in the United States in both 2013 and 2012 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Chargebacks related to the 340B Drug Pricing Program increased by \$9.3 million to \$56.9 million in 2013 compared to \$47.6 million in 2012, primarily due to higher amounts paid to eligible hospital customers. Rebates related to the PPACA increased by \$0.2 million to \$1.5 million in 2013 compared to \$1.3 million in 2012. Net revenue from sales of Angiomax outside the United States increased in 2013 compared to 2012 due to greater demand by existing hospital customers and the addition of new hospital customers in Switzerland, France, Italy, Germany and the United Kingdom, offset by reduction of net revenue from sales in Russia.

*Recothrom.* Net revenue from Recothrom was \$63.3 million in 2013. We commenced sales of Recothrom in the United States in February 2013 pursuant to the master transaction agreement with BMS.

*Other Products.* Net revenue from sales of Cleviprex and ready-to-use Argatroban increased by \$5.7 million, or 54.8%, to \$16.0 million in 2013 from \$10.4 million in 2012. Net revenue from sales of Cleviprex was \$4.7 million in 2013, compared to \$3.0 million in 2012, primarily due to net volume increases. Net revenue from sales of ready-to-use Argatroban was \$11.2 million in 2013, compared to \$7.3 million in 2012. Net revenue from Minocin IV was \$0.1 million in 2013. We commenced sales of Minocin IV on December 3, 2013 after the acquisition of Rempex.

In December 2011, Eagle conducted a voluntary recall of ready-to-use Argatroban due to the presence of particulate matter in some vials. Our net revenue from sales of ready-to-use Argatroban in the 2012 period was adversely impacted by the recall, as we did not sell ready-to-use Argatroban from December 2011 to April 2012.

##### Cost of Revenue:

Cost of revenue in 2013 was \$262.8 million, or 38% of net revenue, compared to \$177.3 million, or 32% of net revenue, in 2012.

Cost of revenue during 2013 and 2012 consisted of:

- expenses in connection with the manufacture of our products sold and logistics costs related to Angiomax, Cleviprex and ready-to-use Argatroban, including distribution, storage, and handling costs;
- 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
- amortization of the costs of license agreements, product rights and other identifiable intangible assets, which result from product and business acquisitions.

Cost of revenue during 2013 also included expenses related to our license agreement with BMS for Recothrom and expenses related to our supply agreement for Recothrom with BMS including product cost and logistics including royalties and amortization related to Recothrom.

#### Cost of Revenue

	Year Ended December 31,			
	2013	% of Total Cost	2012	% of Total Cost
	(In thousands)			
Manufacturing/Logistics	\$ 84,725	32%	\$ 50,506	28%
Royalty	154,099	59%	125,930	71%
Amortization of product rights and intangible assets	23,961	9%	903	1%
<b>Total cost of revenue</b>	<b>\$ 262,785</b>	<b>100%</b>	<b>\$ 177,339</b>	<b>100%</b>

Cost of revenue increased by \$85.4 million during 2013 compared to 2012. These increases were primarily due to an increase in royalty expense to Biogen due to higher royalty-bearing sales under our agreement with Biogen, an increased royalty rate which commenced on January 1, 2013 under the letter agreement that we entered into with Biogen on August 7, 2012. Cost of revenue also increased due to our expenses related to Recothrom under the master transaction agreement and supply agreement with BMS which we entered into in February 2013, including royalties to BMS in connection with our sales of Recothrom which commenced

in February 2013, manufacturing and logistics costs associated with our sales of Recothrom and the amortization of product rights and intangible assets associated with Recothrom.

### Research and Development Expenses

	Year Ended December 31,			
	2013	% of Total R&D	2012	% of Total R&D
Marketed products	24,394	16.6%	\$ 13,170	10.4%
Research and development candidates	76,606	52.1%	84,542	66.9%
Research and development product candidates	45,930	31.3%	28,711	22.7%
<b>Total research and development expenses</b>	<b>\$ 146,930</b>	<b>100.0%</b>	<b>\$ 126,423</b>	<b>100.0%</b>

For these periods, our marketed products consisted of Angiomax, Cleviprex, Minocin IV, ready-to-use Argatroban, Recothrom and certain of our acute care generic drugs, our registration stage product candidates, include cangrelor, oritavancin, IONSYS, Raplixa and RPX-602 and our research and development stage product candidates include ALN-PCSSc, Carbavance, MDCO-216 and other early stage compounds.

Research and development expense increased by \$20.5 million, to \$146.9 million in 2013, from \$126.4 million in 2012. During 2013 research and development expenses increased for ALN-PCSSc, IONSYS, Fibrocaps, Angiomax and MDCO 216 by \$25.0 million, \$16.7 million, \$8.6 million, \$10.8 million and \$5.4 million, respectively. Increases in research and development expenses for Alnylam as a result of a license and collaboration agreement we entered into in February 2013, for which we paid an upfront payment of \$25.0 million. IONYS and Fibrocaps were acquired in January 2013 and August 2013, respectively and as a result research and development expenses increased. The increase in Angiomax research and development is the result of commencement in patient enrollments in our ENDOMAX and GLOBAL LEADERS trials, initiated start-up activities related to our HORIZONS AMI II trial and continued enrollment in our BRAVO-2 trial. MDCO-216 research and development expense increased in 2013 as a result of Phase-1 trial in healthy volunteers that was commenced in February of 2013.

The increased research and development expense is offset by decreases in research and development costs for cangrelor, infrastructure costs, oritavancin, MDCO-2010 and MDCO-157 in the amounts of \$28.5 million, \$6.8 million, \$4.8 million, \$4.2 million and \$2.1 million, respectively. Decrease in research and development expense for cangrelor is the result of decrease in clinical trial costs due to completion in patient enrollments of CHAMPION PHOENIX in October 2012. Infrastructure costs consist of costs in support of product development efforts such as data management, statistical analysis, and analysis of pre-clinical data. These costs decreased year over year primarily due to restructuring costs associated with Leipzig, Germany site closure in 2011. Research and development costs related to Oritavancin decreased in 2013 as a result of decrease in clinical trial costs due to completion of patient enrollment in SOLO I in October 2012 and SOLO II in April 2013. MDCO-2010 and MDCO-157 research and development costs decreased in 2013 as a result of discontinued development in October 2012 and termination of our license agreement with CyDex Pharmaceuticals, Inc in July 2013.

### Selling, General and Administrative Expenses:

	Year Ended December 31,		Change	
	2013	2012	\$	%
(In thousands)				
Selling, general and administrative expenses	\$ 264,958	\$ 171,753	\$ 93,205	54.3%

Selling, general and administrative expenses increased by \$93.2 million in 2013 as compared to 2012, primarily due to a \$34.7 million increase in selling, marketing and promotional expenses and a \$58.5 million increase in general corporate and administrative expenses.

Selling, marketing and promotional expenses increased by \$34.7 million primarily due to our commencement of promotion of Recothrom, increased promotional efforts for Angiomax and Cleviprex globally and ready-to-use Argatroban in the United States, and spending in preparation for the commercial sale of our registration stage product candidates, if and when approved.

General corporate and administrative expenses increased by \$58.5 million primarily due to our 2013 acquisitions of Incline, ProFibrix and Rempex and due to our licensing of Recothrom which contributed an aggregate of \$43.0 million in general and administrative expenses, a \$6.6 million increase in legal costs associated with our ongoing patent infringement litigation and the now completed Eagle arbitration, a \$5.0 million arbitration award to Eagle, a \$4.3 million increase in employee severance and other employee related termination costs associated with our first quarter 2013 reduction in force, a \$6.3 million increase in share-based compensation, offset by a \$11.9 million gain associated with a reduction in the fair value of the contingent consideration due to the former shareholders of Targanta. The \$43.0 million increase in general corporate and administrative expenses associated with the acquisitions of Incline, ProFibrix, Rempex and the licensing of Recothrom includes \$30.3 million associated with the fair value adjustments of the contingent consideration due to the former shareholders of Incline, ProFibrix and Rempex, \$9.7 million in legal and other transaction costs related to our acquisitions of Incline, ProFibrix and Rempex and the licensing of Recothrom, and \$3.0 million in additional corporate infrastructure costs required to support Incline, ProFibrix, Rempex and Recothrom. The \$11.9 million gain associated with reduction in the fair value of the contingent consideration due to the former shareholders of Targanta is the result of our second quarter 2013 determination that it was not probable that we would obtain regulatory approval of oritavancin in the United States by December 31, 2013.

### Co-promotion and Profit Share Income:

	Year Ended December 31,		Change	
	2013	2012	\$	%
(In thousands)				
Co-promotion and profit share income	\$ 17,383	\$ 10,000	\$ 7,383	73.8%

During 2013, we recorded co-promotion and profit share income of approximately \$17.4 million primarily in connection with our collaboration agreement with AstraZeneca LP 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 also had limited profit share income from our license agreement with Eagle related to ready-to-use Argatroban.

### Interest Expense:

	Year Ended December 31,		Change	
	2013	2012	\$	%
(In thousands)				
Interest expense	\$ (15,531)	\$ (8,005)	\$ (7,526)	(94.0)%

During 2013, we recorded approximately \$15.5 million in interest expense related to the 2017 notes as compared to \$8.0 million in 2012. We issued the 2017 notes on June 11, 2012 and have recorded interest from that date.

### Other Income:

	Year Ended December 31,		Change	
	2013	2012	\$	%
(In thousands)				
Other income	\$ 1,577	\$ 1,140	\$ 437	38.3%

Other income, which is comprised of interest income, gains and losses on foreign currency transactions, increased by \$0.4 million to \$1.6 million of income for 2013, from \$1.1 million for 2012. This increase was primarily due to higher gains on foreign currency transactions in 2013, but was partially offset by decreased interest associated with investment of lower levels of cash.

### (Provision) for Income Tax:

	Year Ended December 31,		Change	Change
	2013	2012	\$	%
	(In thousands)			
(Provision) for income tax	\$ (1,360)	\$ (35,038)	\$ 33,678	96.1%

Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and numerous foreign jurisdictions. We recorded a \$1.4 million and a \$35.0 million provision for income taxes for 2013 and 2012, respectively, based on income before taxes for such periods of \$16.9 million and \$86.3 million. Our effective income tax rates for 2013 and 2012 were approximately 8.1% and 40.6%, respectively. During 2013, we recorded a non-cash benefit of \$13.6 million related to a change in the estimate for California state taxes as a result of our business combinations. The 2013 effective tax rate also included the non-cash tax impact arising from changes in contingent consideration related to the Targanta, Incline, ProFibrix and Rempex acquisitions. The 2013 effective income tax rate also reflects the effect of a one-time income tax benefit arising from the retroactive reinstatement of the research and development tax credit included in The American Tax Relief Act of 2012, which was signed into law on January 2, 2013. The 2012 effective tax rate includes the non-cash tax impact arising from changes in contingent consideration related to the Targanta acquisition.

At December 31, 2013, we maintained a \$4.2 million valuation allowance against \$124.7 million of deferred tax assets compared to a \$2.4 million valuation allowance against \$82.2 million of deferred tax assets at December 31, 2012.

Deferred income taxes arise from temporary differences between the tax and financial statement recognition of revenue and expense. In evaluating our ability to realize our deferred tax assets within the jurisdiction from which they arise, we consider all available positive and negative evidence on a periodic basis in light of changing facts and circumstances. These include, without limitation, scheduled reversal of deferred tax liabilities, projections of future taxable income, tax planning strategies, 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. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates we are using to manage the underlying businesses.

Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes that would have a material effect on our results of operations, cash flows, or financial position.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception, we have financed our operations principally through revenues from sales of Angiomax, Recothrom and our other products and the sale of common stock, convertible promissory notes and warrants. We had \$370.7 million in cash and cash equivalents as of December 31, 2014.

### Cash Flows

As of December 31, 2014, we had \$370.7 million in cash and cash equivalents, as compared to \$376.7 million as of December 31, 2013. The decrease in cash and cash equivalents was primarily due to \$84.8 million in net cash used in investing activities, partially offset by \$67.3 million of net cash provided by operating activities and \$8.8 million in net cash provided by financing activities.

Net cash provided by operating activities was \$67.3 million in 2014, compared to net cash provided by operating activities of \$91.4 million in 2013. The decrease was primarily due to our net loss, the effect of non-cash items and changes in working capital items. The cash provided by operating activities in 2014 primarily relates to non-cash items of \$126.5 million offset by a net loss of \$32.3 million and \$26.8 million decrease from changes in working capital adjustments. Non-cash items consist of depreciation and amortization, asset impairment charges, share-based compensation expense and adjustments in contingent consideration. The changes in working capital items reflect an increase in accounts receivable of \$54.7 million, primarily due to an increase in our net revenue for Angiomax in the United States following our announcement in December 15, 2014 of a price increase for Angiomax effective on January 1, 2015.

Net cash provided by operating activities was \$91.4 million in 2013, compared to net cash provided by operating activities of \$46.3 million in 2012. The increase was primarily due to the effect of non-cash items and changes in working capital items. The cash provided by operating activities in 2013 included net income of \$15.3 million and non-cash items of \$65.9 million consisting primarily of depreciation and amortization, share-based compensation expense and change in contingent consideration and a \$10.3 million increase resulting from changes in working capital adjustments.

During 2014, \$84.8 million in net cash was used in investing activities, which reflected \$58.9 million incurred in connection with our Tenaxis transaction and milestone payments related the regulatory approval of Orbactiv. Fixed asset purchases during 2014 was approximately \$7.3 million.

During 2013, \$504.4 million in net cash was used in investing activities, which reflected \$542.6 million incurred in connection with our Incline, ProFibrix, Rempex and Recothrom transactions and \$13.6 million used for fixed asset purchases. These amounts were partially offset by \$50.7 million in proceeds from the maturity and sale of available for sale securities.

Net cash provided by financing activities was \$8.8 million in 2014, which primarily consists of \$17.3 million in proceeds from option exercises and purchases of stock under our employee stock purchase plan and \$1.4 million in excess tax benefits. These increases were offset partially by milestone payments of \$10.0 million made to Rempex equityholders upon the achievement of certain milestones.

Net cash provided by financing activities was \$271.5 million in 2013, which primarily reflected \$189.6 million in net proceeds from the sale of common stock in our June 2013 offering and \$74.2 million of proceeds from option exercises, excess tax benefits and purchases of stock under our employee stock purchase plan.

### Funding Requirements

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 the 2017 notes and the \$400.0 million aggregate principal amount of the 2022 notes, and to make principal payments on the 2017 notes and the 2022 notes at maturity or upon conversion. In addition, as part of our business development strategy, we generally structure our license agreements and acquisition agreements so that a significant portion of the total license or acquisition cost is contingent upon the successful achievement of specified development, regulatory or commercial milestones. As a result, we will require cash to make payments upon achievement of these milestones under the license agreements and acquisition agreements to which we are a party. Upon the closing of the Recothrom transaction in February 2015, we paid BMS approximately \$127.7 million, including approximately \$39.3 million for inventory. In addition, we have agreed to pay BMS up to an additional \$4.9 million upon the delivery of certain additional inventory following the closing, subject to specified terms and conditions. In addition, upon the closing of the Annovation transaction in February 2015, we paid approximately \$28.4 million in cash to Annovation's equityholders. We may be required to pay Annovation's equityholders up to an additional \$26.3 million upon achievement of certain development and regulatory milestones and we may be required to pay other third parties up to \$6.5 million upon achievement of certain development, regulatory and commercial milestones. We may also have to make contingent cash payments upon the achievement of specified development, regulatory or commercial milestones of up to:

- \$49.4 million due to the former equityholders of Targanta and up to \$25.0 million in additional payments to other third parties for the Targanta transaction;
- \$189.3 million due to the former equityholders of Incline and up to \$113.0 million in additional payments to other third parties for the Incline transaction;
- \$140.0 million for the ProFibrix transaction;
- \$315.7 million for the Rempex transaction;
- \$112.0 million for the Tenaxis transaction;
- \$170.0 million for the license and collaboration agreement with Alnylam;
- \$422.0 million due to our licensing of MDCO-216 from Pfizer; and
- \$54.5 million due to our licensing of cangrelor from AstraZeneca.

Our total potential milestone payment obligations related to development, regulatory and commercial milestones for our products and products in development under our license agreements and acquisition agreements, assuming all milestones are achieved in accordance with the terms of these agreements, would be approximately \$1,624.0 million. Of this amount, approximately \$180.0 million relates to development milestones, \$482.0 million relates to regulatory approval milestones and \$962.0 million relates to commercial milestones.

In addition, of the total potential milestone payment obligations, based on our earliest anticipated timeline for the achievement of development, regulatory and commercial milestones, we expect that we would make total milestone payments under our license agreements and acquisition agreements of up to \$294.0 million during the remainder of 2015. The majority of these anticipated payments for 2015 relate to the achievement of regulatory approval milestones for cangrelor, IONSYS, Raplixa, RPX-602, and PreveLeak, and the remainder of these payments relate to the achievement of development and commercial milestones for our other products in development.

Our future capital requirements will depend on 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. If we lose our appeal of the adverse court decision we received in our patent infringement litigation with Hospira or if Mylan prevails in its appeal of the court decision we received in our patent infringement litigation with Mylan, or if we receive an adverse decision in any other patent infringement litigation relating to the '727 patent or the '343 patent, Angiomax could be subject to generic competition prior to May 1, 2019, and possibly as early as June 15, 2015;
- the extent to which our submissions and planned submissions for regulatory approval of products in development are approved on a timely basis, if at all;
- the extent to which our products other than Angiomax and our products in development are commercially successful in the United States;
- the extent to which we are successful in our efforts to commercialize our products and products in development, if and when approved, outside the United States;
- the consideration paid by us and to be 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, Orbactiv and our products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of our approved products in additional countries and for additional indications, and of our products in development globally;
- whether we develop and commercialize our products in development on our own or through licenses and collaborations with third parties and the terms and timing of such arrangements, if any;
- 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, including our obligations with respect to the 2017 notes and the 2022 notes and under the license agreements and acquisition agreements to which we are a party, but excluding any future material acquisition activity. 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 lower than anticipated sales of our marketed products, particularly if Angiomax becomes subject to generic competition in the United States earlier than May 1, 2019, or due to higher than anticipated costs associated with product launches, investments in research and development or otherwise, we likely will need to sell additional equity or debt securities or seek additional financing through other arrangements to increase our cash resources. Any sale of additional equity or debt securities may result in dilution to our stockholders. Public or private financing may not be available in amounts or on terms acceptable to

us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. Moreover, our ability to obtain additional debt financing may be limited by the 2017 notes and the 2022 notes, market conditions or otherwise. 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 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.

#### ***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.

Currently, we are party to other legal proceedings as described in Part I, Item 3. *Legal Proceedings*, of this Annual Report on Form 10-K. 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, leased office space for our principal office in Parsippany, New Jersey and our new leased office space in San Diego, California, royalties, milestone payments and other contingent payments due under our license and acquisition agreements. These obligations also include our obligations under the 2017 notes and 2022 notes.

Future estimated contractual obligations as of December 31, 2014 are:

<b>Contractual Obligations (in thousands)</b> <sup>(1) (2) (3)</sup>	<b>Total</b>	<b>Less Than</b>			<b>More Than</b>
		<b>1 Year</b>	<b>1 - 3 Years</b>	<b>4 - 5 Years</b>	<b>5 Years</b>
Inventory related commitments	\$ 53,347	\$ 52,174	\$ 913	\$ 260	\$ —
Long-term debt obligations, including interest	284,138	3,781	280,357	—	—
Research and development	77,833	72,617	5,162	54	—
Operating leases	87,059	8,221	15,791	14,507	48,540
Selling, general and administrative	3,830	2,589	1,241	—	—
<b>Total contractual obligations</b>	<b>\$ 506,207</b>	<b>139,382</b>	<b>\$ 303,464</b>	<b>\$ 14,821</b>	<b>\$ 48,540</b>

(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.

(2) This table does not include \$400.0 million aggregate principal amount of the 2022 notes issued by us in January 2015.

(3) Also excluded from the above table is a liability for uncertain tax positions totaling \$8.8 million. This liability has been excluded because we cannot currently make a reliable estimate of the period in which the liability will be payable, if ever.

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments totaling \$20.1 million, \$23.8 million and \$4.5 million for Angiomax, Orbactiv and Recothrom bulk drug substances related to 2015, respectively. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$9.6 million are non-cancellable.

Our long-term debt obligations reflect our obligations under the 2017 notes to pay interest on the \$275.0 million aggregate principal amount of the 2017 notes and to make principal payments on the 2017 notes at maturity or upon conversion.

We lease our principal office in Parsippany, New Jersey, the lease covers 173,146 square feet and expires January 2024. On October 1, 2014, we entered into an agreement to lease 63,000 square feet of office space with ARE-SD Region No. 35, LLC, or ARE, for new office and laboratory space in San Diego, California. This lease has a term of 144 months from the first day of the

first full month after the commencement date, which we currently expect to be on or about September 2016. The agreement is for the build out of the space with a targeted commencement date in September of 2016. The lease will qualify for operating lease treatment with recorded annual rent expense from commencement date to expiration of \$2.9 million, with adjustments for customary triple-net lease operating expenses. We expect our total obligation for this space to be \$35.3 million.

Approximately 88.8% of the total operating lease commitments above relate to our principal office building in Parsippany, New Jersey and our for office space in San Diego, California. Also included in total property lease commitments are automobile leases, computer leases and other property leases that we entered into while expanding our global infrastructure.

Aggregate rent expense under our property leases was approximately \$8.5 million in 2014, \$7.3 million in 2013 and \$5.8 million in 2012.

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. These contingent payments include royalty payments with respect to Angiomax under our license agreements with Biogen and HRI, royalty and/or milestone payments with respect to Cleviprex, cangrelor, Orbactiv, MDCO-216, IONSYS, Raplixa, PreveLeak and Carbavance and profit sharing agreement with Eagle with respect to our sales of ready-to-use Argatroban. We made a payment in February 2015 of \$127.7 million to BMS upon closing the acquisition Recothrom, respectively. In addition, we have agreed to pay BMS up to an additional \$4.9 million upon the delivery of certain additional inventory following the closing, subject to specified terms and conditions. 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. We may have to make these significant contingent cash payments in connection with our acquisition and licensing activities upon the achievement of specified regulatory, sales and other milestones as follows:

- In connection with our acquisition of Targanta, we are obligated to pay contingent cash payments up to \$49.4 million to the former shareholders of Targanta and up to \$25.0 million in additional payments to Eli Lilly and InterMune upon reaching specified milestones. 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 Orbactiv or the other compounds in any jurisdiction in which we hold license rights to a valid patent. We are required to make a cash payment to InterMune if and when we receive from the FDA all approvals necessary for the commercial launch of Orbactiv.
- 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 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 share equally with Eagle the gross profits, as defined in the license agreement, of our sales of ready-to-use Argatroban.
- In connection with our acquisition of Incline, we agreed to pay contingent payments of up to \$189.3 million, less certain expenses, upon achievement of specified regulatory and sales milestones with respect to IONSYS. We also agreed to make payments to third parties of up to \$113.0 million upon achievement of specified development milestones.
- Under the license agreement with Alnylam, we agreed to pay contingent payments of up to \$170.0 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 connection with our acquisition of ProFibrix, we agreed to pay contingent payments of up to \$140.0 million upon achievement of specified regulatory and sales milestones with respect to Raplixa.

- In connection with our acquisition of Rempex, we agreed to pay contingent payments of up to \$315.7 million, less certain expenses and employer taxes owing because of such payments, upon achievement of specified development, regulatory and sales milestones.
- In connection with our acquisition of Tenaxis, we agreed to pay contingent payments of up to \$112.0 million upon achievement of specified regulatory and sales milestones with respect to PreveLeak;
- In connection with our acquisition of Annovation, we agreed to pay contingent payments of up to \$26.3 million upon achievement of certain clinical and regulatory milestones and up to \$6.5 million in additional payments to other third parties.

In 2014, 2013 and 2012, we incurred aggregate royalties to Biogen and HRI of \$131.3 million, \$140.7 million and \$122.2 million, respectively, and royalties to AstraZeneca with respect to Cleviprex of \$0.8 million, \$1.0 million and 1.0 million, and royalties to BMS with respect to Recothrom of \$7.5 million and \$7.4 million, respectively. As of December 15, 2014, we no longer owe royalties to Biogen or HRI relating to sales of Angiomax in the United States.

### Recent Accounting Pronouncements

In May 2014, the FASB issued a comprehensive new revenue recognition Accounting Standards Update "Revenue from Contracts with Customers (Topic 606)", or ASU 2014-09. ASU 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. We expect to adopt this guidance when effective and are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

### Application of Critical Accounting Estimates

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

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

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

Our significant accounting policies are more fully described in note 2 to our consolidated financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, share-based compensation, income taxes, in-process research and development, contingent purchase price from business combinations and impairment of long-lived asset described below are "critical accounting estimates."

### Revenue Recognition

*Product Sales.* We distribute Angiomax, Recothrom, Cleviprex, Orbactiv, Minocin IV, the acute care generic products we market and our ready-to-use Argatroban in the United States through a sole source distribution model with ICS. Under this model, we record revenue upon shipment of Angiomax, Recothrom, Cleviprex, Minocin IV and ready-to-use Argatroban to ICS. ICS then sells these products to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals.

Our agreement with ICS, which we initially entered into in February 2007, provides that ICS will be our exclusive distributor of Angiomax, Recothrom, Cleviprex, Orbactiv, Minocin IV, the acute care generic products we market 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, Recothrom, Cleviprex, Minocin IV, the acute care generic products we market 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 these products subject to specified limitations in the agreement. The agreement terminates on February 28, 2019, 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.

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, 2014, we market and sell Angiomax in India, Australia and New Zealand. As of December 31, 2014, we sell Cleviprex outside the United States in Australia and in certain European countries. The Company sells PreveLeak in Europe.

We had deferred revenue of \$0.6 million as of December 31, 2014 and December 31, 2013 associated with sales of Angiomax, Cleviprex and PreveLeak to wholesalers outside of the United States. We recognize revenue from such sales when hospitals purchase the product.

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.

Beginning in 2014, we recognize revenue for Cleviprex and ready-to-use Argatroban as product is sold to ICS in the same manner as we recognize Angiomax and Recothrom revenue, as we believe there is now sufficient history to reasonably estimate expected returns and other adjustments to revenue. During 2014, we recognized one-time increase of \$0.7 million in net sales of Cleviprex and \$1.6 million in net sales of ready-to-use Argatroban, representing product sales previously deferred as of December 31, 2013, net of chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges. Prior to January 1, 2014, product sales from Cleviprex and ready-to-use Argatroban were recorded under a deferred revenue model as we did not have sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue.

In August 2014, the FDA, approved Orbactiv. In October 2014, we commercially launched Orbactiv in the United States. We recognize sales from Orbactiv and our acute care generic products under a deferred revenue model. Under the deferred revenue model, we did not recognize revenue upon product shipment to ICS. Instead, upon product shipment, we invoiced ICS, recorded deferred revenue at gross invoice sales price, classified 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.

We had deferred revenue of \$5.8 million as of December 31, 2014 associated with sales of Orbactiv in the United States. When such estimates of the expected returns and other adjustments can be reasonably estimable, we expect to recognize revenue from Orbactiv upon shipment to ICS in the same manner as we recognize Angiomax, Recothrom, Cleviprex, Minocin IV and ready-to-use Argatroban revenue. We recognized \$0.8 million of revenue associated with Orbactiv during 2014, 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.

At December 31, 2014 and December 31, 2013, our accrual for product returns was \$3.3 million and \$2.4 million, respectively. A 10% change in our accrual for product returns would have had an approximately \$0.3 million effect on our reported net revenue for the year ended December 31, 2014.

- *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.

We also participate in the 340B Drug Pricing Program under the Public Health Services Act. Under the 340B Drug Pricing 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.

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.

Our allowance for chargebacks was \$44.4 million and \$25.0 million at December 31, 2014 and December 31, 2013, respectively. A 10% change in our allowance for chargebacks would have had an approximate \$4.4 million effect on our reported net revenue for the year ended December 31, 2014. We did not have any significant allowance for rebates at December 31, 2014 and at December 31, 2013.

- *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 \$0.9 million and \$3.1 million at December 31, 2014 and December 31, 2013, respectively. A 10% change in our fee-for-service accruals and allowances would have had an approximately \$0.1 million effect on our net revenue for the year ended December 31, 2014.

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 2014, 2013 and 2012 (amounts in thousands):



	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for-Service
<b>Balance at January 1, 2012</b>	\$ 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)
<b>Balance at December 31, 2012</b>	2,010	1,113	14,843	—	3,577
Allowances for sales during 2013	15,943	2,524	130,374	—	12,059
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,871)	(1,204)	(10,244)	—	(3,049)
Actual credits issued for sales during 2013	(13,420)	—	(109,933)	—	(9,460)
<b>Balance at December 31, 2013</b>	2,662	2,433	25,040	—	3,127
Allowances for sales during 2014	18,299	5,836	175,001	—	12,453
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(2,411)	(1,724)	(25,888)	—	(3,246)
Actual credits issued for sales during 2014	(14,408)	(3,196)	(129,754)	—	(11,410)
<b>Balance at December 31, 2014</b>	<u>\$ 4,142</u>	<u>\$ 3,349</u>	<u>\$ 44,399</u>	<u>\$ —</u>	<u>\$ 924</u>

*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 2014, 2013 and 2012 was \$1.3 million, \$5.1 million and \$5.5 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, Cleviprex, Orbactiv and Minocin IV 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.

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, 2014, our inventory of Angiomax was \$68.3 million and we had inventory-related purchase commitments totaling \$20.1 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.

#### *Share-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 share-based awards under our 2013 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 share-based compensation in accordance with FASB Accounting Standards Codification 718-10, 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 share-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 share-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	Method of Estimating
• Estimated expected term of options	• Employees' historical exercise experience
• Expected volatility	• Historical price of our common stock
• Risk-free interest rate	• Yields of U.S. Treasury securities corresponding with the expected life of option grants
• Forfeiture rates	• 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*

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. 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.

Our annual effective tax rate is based on pre-tax earnings (loss) 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 record uncertain tax positions on the basis of a two-step process whereby (1) 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; and (2) for tax positions that meets the more-likely-than-not recognition threshold, we recognize the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement with the relevant tax authority. 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.

#### *In-Process Research and Development*

The cost of in-process research and development, or IPR&D, acquired directly in a transaction other than a business combination is capitalized if the projects have an alternative future use; otherwise they are expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method," which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

#### *Contingent Purchase Price from Business Combinations*

Subsequent to the acquisition date, the Company measures contingent consideration arrangements at fair value for each period with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses.

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

Long-lived assets, such as property, plant and equipment and certain other long-term assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of the assets exceed their estimated future undiscounted net cash flows, an impairment charge is recognized for the amount by which the carrying amount of the assets exceed the fair value of the assets.

#### ***Goodwill***

Goodwill represents the excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized, but subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We determine whether goodwill may be impaired by comparing the carrying value of its reporting unit to the fair value of its reporting unit.

#### **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, 2014, we held \$370.7 million in cash and cash equivalents, which had an average interest rate of approximately 0.35%. A 10 basis point change in such average interest rate would have had an approximate \$0.1 million impact on our interest income. At December 31, 2014, all cash and cash equivalents were due on demand or within one year and 95.8% 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, 2014, we had receivables denominated in currencies other than the U.S. dollar. A 10.0% change would have had an approximate \$0.7 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, 2014. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2014, 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.

#### ***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, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

None.

### PART III

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our proxy statement to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2014 in connection with our 2015 annual meeting of stockholders. We refer to such proxy statement herein as our 2015 Proxy Statement.

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

The information required by this item will be contained in our 2015 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, as amended, 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 2015 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 2015 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 2015 Proxy Statement under the caption “Information About Corporate Governance” and “Information About Our Executive Officers” and is incorporated herein by this reference.

#### **Item 14. Principal Accountant Fees and Services.**

The information required by this item will be contained in our 2015 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.

### PART IV

#### **Item 15. Exhibits and Financial Statement Schedules.**

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) *Financial Statements*. The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this Annual Report on Form 10-K. 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>
<u>Consolidated Balance Sheets</u>	<u>F - 5</u>
<u>Consolidated Statements of Income</u>	<u>F - 6</u>
<u>Consolidated Statements of Comprehensive Income</u>	<u>F - 7</u>
<u>Consolidated Statements of Stockholders’ Equity</u>	<u>F - 8</u>
<u>Consolidated Statements of Cash Flows</u>	<u>F - 9</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F - 10</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 on Form 10-K. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K.

**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 2, 2015.

**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.

<u>Signature</u>	<u>Title(s)</u>	
<u>/s/ Clive A. Meanwell</u> Clive A. Meanwell	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 2, 2015
<u>/s/ Glenn P. Sblendorio</u> Glenn P. Sblendorio	President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer); Director	March 2, 2015
<u>/s/ William W. Crouse</u> William W. Crouse	Director	March 2, 2015
<u>/s/ Robert J. Hugin</u> Robert J. Hugin	Director	March 2, 2015
<u>/s/ John C. Kelly</u> John C. Kelly	Director	March 2, 2015
<u>/s/ Armin M. Kessler</u> Armin M. Kessler	Director	March 2, 2015
<u>/s/ Robert G. Savage</u> Robert G. Savage	Director	March 2, 2015
<u>/s/ Hiroaki Shigeta</u> Hiroaki Shigeta	Director	March 2, 2015
<u>/s/ Melvin K. Spigelman</u> Melvin K. Spigelman	Director	March 2, 2015
<u>/s/ Elizabeth H.S. Wyatt</u> Elizabeth H.S. Wyatt	Director	March 2, 2015

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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, 2014, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria) (2013 Framework). 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, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2014 consolidated financial statements of The Medicines Company and our report dated March 2, 2015, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
March 2, 2015

**THE MEDICINES COMPANY  
CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2014	2013
(In thousands, except share and per share amounts)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 370,741	\$ 376,727
Accounts receivable, net of allowances of approximately \$47.0 million and \$28.6 million at December 31, 2014 and 2013	155,691	101,587
Inventory	81,450	87,105
Deferred tax assets	33,080	13,431
Prepaid expenses and other current assets	16,012	12,591
Total current assets	656,974	591,441
Fixed assets, net	40,060	39,268
Intangible assets, net	892,659	836,273
Goodwill	286,532	257,694
Restricted cash	1,446	1,574
Other assets	8,034	15,032
Total assets	<u>\$ 1,885,705</u>	<u>\$ 1,741,282</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 19,799	\$ 26,911
Accrued expenses	159,252	142,290
Current portion of contingent purchase price	210,422	—
Deferred revenue	14,350	5,052
Total current liabilities	403,823	174,253
Contingent purchase price	140,712	302,363
Convertible senior notes (due 2017)	246,676	236,088
Deferred tax liability	164,459	128,677
Other liabilities	9,944	7,740
Total liabilities	965,614	849,121
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; 67,667,468 issued and 65,474,486 outstanding at December 31, 2014 and 66,590,875 issued and 64,397,893 outstanding at December 31, 2013	68	66
Additional paid-in capital	1,045,078	991,982
Treasury stock, at cost; 2,192,982 at December 31, 2014 and December 31, 2013	(50,000)	(50,000)
Accumulated deficit	(77,109)	(44,899)
Accumulated other comprehensive income (loss)	2,528	(4,652)
Total The Medicines Company stockholders' equity	920,565	892,497
Non-controlling interest in joint venture	(474)	(336)
Total stockholders' equity	920,091	892,161
Total liabilities and stockholders' equity	<u>\$ 1,885,705</u>	<u>\$ 1,741,282</u>

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF INCOME**

	Year Ended December 31,		
	2014	2013	2012
(In thousands, except per share amounts)			
Net revenue	\$ 724,408	\$ 687,864	\$ 558,588
Operating expenses:			
Cost of revenue	287,630	262,785	177,339
Research and development	159,181	146,930	126,423
Selling, general and administrative	342,164	264,958	171,753
Total operating expenses	788,975	674,673	475,515
(Loss) income from operations	(64,567)	13,191	83,073
Settlement	25,736	—	—
Co-promotion and profit share income	24,236	17,383	10,000
Loss in equity investment	(1,711)	—	—
Interest expense	(15,701)	(15,531)	(8,005)
Investment impairment	(7,500)	—	—
Other income	322	1,577	1,140
(Loss) income before income taxes	(39,185)	16,620	86,208
Benefit (provision) for income taxes	6,837	(1,360)	(35,038)
(Loss) net income	(32,348)	15,260	51,170
Net loss attributable to non-controlling interest	138	252	84
Net (loss) income attributable to The Medicines Company	\$ (32,210)	\$ 15,512	\$ 51,254
Earnings per common share attributable to The Medicines Company:			
Basic	\$ (0.50)	\$ 0.27	\$ 0.96
Diluted	\$ (0.50)	\$ 0.25	\$ 0.93
Weighted average number of common shares outstanding:			
Basic	64,473	58,096	53,545
Diluted	64,473	62,652	55,346

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2014	2013	2012
Net (loss) income	\$ (32,348)	\$ 15,260	\$ 51,170
Other comprehensive (loss) income:			
Unrealized (loss) gain on available for sale securities		(10)	6
Foreign currency translation adjustment	7,180	(3,876)	(224)
Other comprehensive income (loss)	7,180	(3,886)	(218)
Comprehensive (loss) income	\$ (25,168)	\$ 11,374	\$ 50,952

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
For The Years Ended December 31, 2012, 2013 and 2014

	Common Stock		Treasury Stock		Additional Paid-in Capital		Accumulated Deficit		Accumulated Comprehensive (Loss) Income		Non-controlling Interest in JV		Total Stockholders' Equity	
	Shares	Amount	Shares	Amount	Capital	Deficit	(Loss)	Income	Interest	Equity				
Balance at January 1, 2012	54,312	\$ 54	—	\$ —	\$ 623,801	\$ (111,665)	\$ (548)	\$ —	\$ —	\$ 511,642				
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)				
Currency translation adjustment						(224)								(224)
Unrealized loss on available for sale securities (net of tax)						6				6				6
Balance at December 31, 2012	56,152	\$ 56	(2,193)	\$ (50,000)	\$ 697,427	\$ (60,411)	\$ (766)	\$ (84)	\$ (84)	\$ 586,222				
Employee stock purchases	3,547	4			74,209					74,213				
Issuance of restricted stock awards	237	—								—				
Issuance of common stock	6,653	6			189,593					189,599				
Non-cash stock compensation					23,078					23,078				
Excess tax benefit from share-based compensation arrangements					7,675					7,675				
Net income						15,512				(252)				15,260
Currency translation adjustment						(3,876)				(3,876)				(3,876)
Unrealized loss on available for sale securities (net of tax)						(10)				(10)				(10)
Balance at December 31, 2013	66,589	\$ 66	(2,193)	\$ (50,000)	\$ 991,982	\$ (44,899)	\$ (4,652)	\$ (336)	\$ (336)	\$ 892,161				
Employee stock purchases	864	1			17,342					17,343				
Issuance of restricted stock awards	214	1								1				1
Non-cash stock compensation					34,311					34,311				34,311
Excess tax benefit from share-based compensation arrangements					1,443					1,443				1,443
Net (loss) income attributable to The Medicines Company						(32,210)				(138)				(32,348)
Currency translation adjustment						7,180				7,180				7,180
Balance at December 31, 2014	67,667	\$ 68	(2,193)	\$ (50,000)	\$ 1,045,078	\$ (77,109)	\$ 2,528	\$ (474)	\$ (474)	\$ 920,091				

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2014	2013	2012
	(In thousands)		
Cash flows from operating activities:			
Net (loss) income attributable to The Medicines Company	\$ (32,348)	\$ 15,260	\$ 51,170
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	34,398	32,238	7,270
Impairment charges	31,133	—	—
Amortization of net premiums and discounts on available for sale securities	—	209	734
Amortization of long term debt financing costs	1,332	1,179	598
Amortization of debt discount	10,588	9,978	5,306
Unrealized foreign currency transaction (gains) losses, net	(833)	143	(573)
Non-cash stock compensation expense	34,311	23,078	14,981
Loss on disposal of fixed assets	35	39	69
Deferred tax provision (benefit)	(5,565)	(10,272)	30,376
Excess tax benefit from share-based compensation arrangements	(1,443)	(7,675)	(1,558)
Change in contingent consideration obligation	20,823	16,942	(1,460)
Loss in equity method investment	1,711	—	—
Changes in operating assets and liabilities:			
Accrued interest receivable	1	347	26
Accounts receivable	(54,739)	(15,017)	(11,120)
Inventory	5,627	(10,130)	(31,152)
Prepaid expenses and other current assets	(3,560)	39	1,516
Accounts payable	(6,866)	(1,319)	18,903
Accrued expenses	24,058	31,192	(40,160)
Deferred revenue	5,257	3,854	1,685
Other liabilities	3,394	1,335	(265)
Net cash provided by operating activities	67,314	91,420	46,346
Cash flows from investing activities:			
Purchases of available for sale securities	—	—	(65,354)
Proceeds from maturities and sales of available for sale securities	—	50,656	38,881
Purchases of fixed assets	(7,289)	(13,574)	(1,005)
Payments for intangible assets	(15,000)	—	(36,678)
Other investments	(3,625)	1,125	(2,500)
Cash used for acquisitions, net	(58,934)	(542,579)	—
Decrease in restricted cash	92	11	3,148
Net cash used in investing activities	(84,756)	(504,361)	(63,508)
Cash flows from financing activities:			
Proceeds from issuances of common stock	17,343	74,212	22,935
Proceeds from equity offering, net	—	189,600	—
Milestone payments to Rempex shareholders	(9,953)	—	—
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	1,443	7,675	1,558
Net cash provided by financing activities	8,833	271,487	220,921
Effect of exchange rate changes on cash	2,623	(1,265)	305
(Decrease) increase in cash and cash equivalents	(5,986)	(142,719)	204,064
Cash and cash equivalents at beginning of period	376,727	519,446	315,382
Cash and cash equivalents at end of period	\$ 370,741	\$ 376,727	\$ 519,446
Supplemental disclosure of cash flow information:			
Taxes paid	\$ 1,371	\$ 9,137	\$ 1,709
Interest paid	\$ 3,782	\$ 4,374	\$ 1,786

See accompanying notes to consolidated financial statements.



**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 contributing to the economics of healthcare by focusing on leading acute/intensive care hospitals worldwide. The Company markets Angiomax<sup>®</sup> (bivalirudin), Cleviprex<sup>®</sup> (clevidipine) injectable emulsion, Minocin<sup>®</sup> (minocycline) for injection, Orbactiv<sup>®</sup> (oritavancin), PreveLeak<sup>™</sup> and Recothrom<sup>®</sup> Thrombin topical (Recombinant). The Company also has a pipeline of acute and intensive care hospital products in development, including four registration stage product candidates for which it has submitted applications for regulatory approval in the United States, cangrelor, IONSYS<sup>®</sup> (fentanyl iontophoretic transdermal system), Raplixa<sup>™</sup>, formerly referred to as Fibrocaps<sup>™</sup>, and RPX-602, and four research and development product candidates, ABP-700, ALN-PCSSc, Carbavance<sup>™</sup> and MDCO-216. The Company refers to its registration stage product candidates and its research and development product candidates as its products in development. The Company has the right to develop, manufacture and commercialize ALN-PCSSc under its collaboration agreement with Alnylam Pharmaceuticals, Inc. (Alnylam). The Company believes that these 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 products in development, the Company sells a ready-to-use formulation of Argatroban and has a portfolio of ten generic drugs, which it refers to as its acute care generic products, that the Company has the non-exclusive right to market in the United States. The Company is currently selling three of its acute care generic products, midazolam, ondansetron and rocuronium.

**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 records net income (loss) attributable to non-controlling interest in the Company's consolidated financial statements equal to percentage of ownership interest retained in the respective operations by the non-controlling parties. The Company has no unconsolidated subsidiaries.

***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% as of December 31, 2014 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, 2014, the loss attributable to the noncontrolling interest in the Medicines Company (India) Private Limited was approximately \$0.1 million.

***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 FASB Accounting Standards Codification (ASC) 325-20, "Cost Method Investments" (ASC 325-20). Under the cost method, an investment is carried at cost until it is sold or there is evidence that changes in the business environment or other facts and circumstances suggest it may be other than temporarily impaired based on criteria outlined in ASC 325-20. Investments in which the Company has at least a 20%, but not more than a 50%, interest are generally accounted for under the equity method. These non-marketable securities have been classified as investments and included in other

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

assets on the consolidated balance sheets. The Company's proportionate share of the operating results is recorded as loss in equity investment in the Company's consolidated statement of income.

***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, Orbactiv, Minocin IV 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.

***Fixed Assets***

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms. Repairs and maintenance costs are expensed as incurred.

***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.

***Intangible Assets***

Intangible assets with definite useful lives are amortized over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

***In-Process Research and Development***

The cost of in-process research and development (IPR&D) acquired directly in a transaction other than a business combination is capitalized if the projects have an alternative future use; otherwise it is expensed. The fair values of IPR&D projects acquired in business combinations are capitalized. Several methods may be used to determine the estimated fair value of the IPR&D acquired in a business combination. The Company utilizes the "income method," which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each project independently. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.

***Goodwill***

Goodwill represents the excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized, but subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. 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.

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

Long-lived assets, such as property, plant and equipment, goodwill, indefinite lived intangible assets and certain other long-term assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of the assets exceed their estimated future undiscounted net cash flows, an impairment charge is recognized for the amount by which the carrying amount of the assets exceed the fair value of the assets. 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

not be recoverable. 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 2014.

***Contingent Purchase Price from Business Combinations***

Subsequent to the acquisition date, the Company measures the fair value of the acquisition-related contingent consideration at each reporting period, with changes in fair value recorded in the consolidated statements of (loss) income. Changes in the fair value of the acquisition-related contingent consideration obligations result from several factors including changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving specified milestone criteria. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting

***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 and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments with high quality institutions. At December 31, 2014 and 2013, approximately \$6.0 million and \$45.9 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, Minocin IV, Orbactiv, Recothrom, the acute care generic products and ready-to-use Argatroban in the United States to a sole source distributor, Integrated Commercialization Solutions, Inc. (ICS). ICS accounted for 95%, 89% and 90% of the Company's net revenue for 2014, 2013 and 2012, respectively. At December 31, 2014 and 2013, amounts due from ICS represented approximately \$193.4 million and \$120.9 million, or 95% and 92%, of gross accounts receivable, respectively. At December 31, 2014 and 2013, the Company did not maintain an allowance for doubtful accounts for its ICS accounts receivable.

***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.

***Revenue Recognition***

**Product Sales.** The Company distributes Angiomax, Recothrom, Cleviprex, Orbactiv, Minocin IV, the acute care generic products it markets and its ready-to-use Argatroban in the United States through a sole source distribution model with Integrated Commercialization Solutions (ICS). Under this model, the Company records revenue upon shipment of Angiomax, Recothrom, Cleviprex, Minocin IV and ready-to-use Argatroban to ICS. ICS then sells these products to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals.

The Company's agreement with ICS, which it initially entered into in February 2007, provides that ICS will be the Company's exclusive distributor of Angiomax, Recothrom, Cleviprex, Orbactiv, Minocin IV, the acute care generic products we market 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, Recothrom, Cleviprex, Minocin IV, the acute care generic products we market and ready-

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 these products, subject to specified limitations in the agreement. The agreement terminates on February 28, 2019 and 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, the Company amended its 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.

In Europe, the Company markets and sells Angiomax, which the Company markets under the trade name Angiox, with a sales force that is experienced in selling to hospital customers. As of December 31, 2014, the Company markets and sells Angiomax in India, Australia and New Zealand. The Company sells Cleviprex outside the United States in Australia and in certain European countries. The Company only sells PreveLeak in Europe.

The Company had deferred revenue of \$0.6 million and \$0.8 million as of December 31, 2014 and December 31, 2013, respectively, associated with sales of Angiomax, Cleviprex and PreveLeak 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.

Beginning in 2014, the Company is recognizing revenue for Cleviprex and ready-to-use Argatroban as product is sold to ICS in the same manner as it recognizes Angiomax and Recothrom revenue, as the Company believes there is now sufficient history to reasonably estimate expected returns and other adjustments to revenue. During 2014, the Company recognized one-time increase of \$0.7 million in net sales of Cleviprex and \$1.6 million in net sales of ready-to-use Argatroban, representing product sales previously deferred as of December 31, 2013, net of chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges. Prior to January 1, 2014, product sales from Cleviprex and ready-to-use Argatroban were recorded under a deferred revenue model as the Company did not have sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue.

In August 2014, the U.S Food and Drug Administration (FDA) approved Orbactiv. In October 2014, the Company commercially launched Orbactiv in the United States. The Company recognizes sales from Orbactiv and the acute care generic products it markets 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 \$5.8 million as of December 31, 2014 associated with sales of Orbactiv in the United States. When estimates of the expected returns and other adjustments can be reasonably estimated, the Company expects to recognize revenue from Orbactiv upon shipment to ICS in the same manner as the Company recognizes Angiomax, Recothrom, Cleviprex, Minocin IV and ready-to-use Argatroban revenue. The Company recognized \$0.8 million of revenue associated with Orbactiv during 2014, related to purchases by hospitals.

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

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The nature of the Company's allowances and accruals require critical estimates, and the specific considerations the Company uses in estimating its 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.

At December 31, 2014 and December 31, 2013, the Company's accrual for product returns was \$3.3 million and \$2.4 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.

The Company also participates in the 340B Drug Pricing Program under the Public Health Services Act. Under the 340B Drug Pricing Program, the Company offers qualifying entities a discount off the commercial price of Angiomax for patients undergoing percutaneous coronary intervention, or PCI, on an outpatient basis.

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 \$44.4 million and \$25.0 million at December 31, 2014 and December 31, 2013, respectively. The Company did not have any significant allowance for rebates at December 31, 2014 and at December 31, 2013.

- **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 \$0.9 million and \$3.1 million at December 31, 2014 and December 31, 2013, 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.

The following table provides a summary of activity with respect to the Company's sales allowances and accruals during 2014, 2013 and 2012 (amounts in thousands):

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Cash Discounts	Returns	Chargebacks	Rebates	Fees-for-Service
<b>Balance at January 1, 2012</b>	\$ 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)
<b>Balance at December 31, 2012</b>	2,010	1,113	14,843	—	3,577
Allowances for sales during 2013	15,943	2,524	130,374	—	12,059
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(1,871)	(1,204)	(10,244)	—	(3,049)
Actual credits issued for sales during 2013	(13,420)	—	(109,933)	—	(9,460)
<b>Balance at December 31, 2013</b>	2,662	2,433	25,040	—	3,127
Allowances for sales during 2014	18,299	5,836	175,001	—	12,453
Allowances for prior year sales	—	—	—	—	—
Actual credits issued for prior year's sales	(2,411)	(1,724)	(25,888)	—	(3,246)
Actual credits issued for sales during 2014	(14,408)	(3,196)	(129,754)	—	(11,410)
<b>Balance at December 31, 2014</b>	\$ 4,142	\$ 3,349	\$ 44,399	\$ —	\$ 924

**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 2014, 2013 and 2012 was \$1.3 million, \$5.1 million and \$5.5 million, respectively.

**Cost of Revenue**

Cost of revenue consists of expenses in connection with the manufacture of Angiomax, Cleviprex, ready-to-use Argatroban, Orbactiv and Minocin IV, royalty expenses under the Company's agreements with Biogen Idec (Biogen) and Health Research Inc. (HRI) related to Angiomax, with AstraZeneca AB (AstraZeneca) related to Cleviprex, with Eli Lilly (Lilly) related to Orbactiv and with Eagle related to ready-to-use Argatroban and the logistics costs related to Angiomax, Recothrom, Cleviprex, ready-to-use Argatroban, Orbactiv and Minocin IV including distribution, storage and handling costs. Cost of revenue also includes expenses related to the Company's license agreement with Bristol-Myers Squibb Company (BMS) for Recothrom and expenses related to the Company's supply agreement for Recothrom with BMS including product cost and logistics as well as royalties and amortization related to Recothrom.

**Advertising Costs**

The Company expenses advertising costs as incurred. Advertising costs were approximately \$1.1 million, \$0.4 million and \$0.2 million for the years ended December 31, 2014, 2013, and 2012, respectively.

**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. Payments for a product license prior to regulatory approval of the product and payments for milestones 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.

The Company performs research and development for US government agencies under a cost-reimbursable contract in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. The Company recognizes the reimbursements under research contracts when a contract has been executed, the contract price is fixed and determinable, delivery of services or

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

products has occurred and collection of the contract price is reasonably assured. The reimbursements are classified as an offset to research and development expenses. Payments received in advance of work performed are deferred. The Company recorded approximately \$9.5 million of reimbursements by the government as a reduction of research and development expenses for the year ended December 31, 2014.

**Share-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 principally on historic volatility of the Company's common stock. 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. 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. Revenues and expenses and other 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 accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company records net deferred tax assets to the extent it believes these assets will more likely than not be realized. On a periodic basis, the Company evaluates the realizability of its deferred tax assets net of deferred tax liabilities and adjusts such amounts in light of changing facts and circumstances, including but not limited to its 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. The Company considers 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.

The Company's 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 it operates.

In accordance with ASC 740, the Company records uncertain tax positions on the basis of a two-step process whereby (1) it determines whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position; and (2) for tax positions that meets the more-likely-than-not recognition threshold, the Company recognizes the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement with the relevant tax authority. Significant judgment is required in evaluating the Company's tax position. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution. The Company's liability for uncertain tax positions is reflected as a reduction to its deferred tax assets in its consolidated balance sheet.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**Comprehensive Income (Loss)**

The Company's accumulated comprehensive income (loss) is comprised of unrealized gains and losses on available for sale securities (if any), which are recorded and presented net of income tax, and foreign currency translation.

**Recent Accounting Pronouncements**

In July 2013, the FASB issued Accounting Standards Update "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" (ASU 2013-11). ASU 2013-11 requires an entity to present an unrecognized tax benefit as a reduction of a deferred tax asset for a net operating loss (NOL) carryforward, or similar tax loss or tax credit carryforward, rather than as a liability when (1) the uncertain tax position would reduce the NOL or other carryforward under the tax law of the applicable jurisdiction and (2) the entity intends to use the deferred tax asset for that purpose. ASU 2013-11 is effective prospectively for fiscal years and interim periods within those years, beginning after December 15, 2013 for public entities. The adoption of ASU 2013-11 did not have a significant impact on our consolidated financial statements.

In May 2014, the FASB issued a comprehensive new revenue recognition Accounting Standards Update "Revenue from Contracts with Customers (Topic 606)" (ASU 2014-09). ASU 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

**3. Inventory**

The major classes of inventory were as follows:

Inventory	2014	2013
	(In thousands)	
Raw materials	\$ 40,533	\$ 42,402
Work-in-progress	34,095	27,911
Finished goods	6,822	16,792
<b>Total</b>	<b>\$ 81,450</b>	<b>\$ 87,105</b>

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.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**4. Fixed Assets**

Fixed assets consist of the following:

	Estimated Life (Years)	December 31,	
		2014	2013
(In thousands)			
Furniture, fixtures and equipment	3-7	\$ 26,895	\$ 23,267
Computer software	3	3,777	2,237
Computer hardware	3	4,798	3,469
Leasehold improvements	5-15	31,426	31,735
		66,896	60,708
Less: Accumulated depreciation		(26,836)	(21,440)
		<u>\$ 40,060</u>	<u>\$ 39,268</u>

Depreciation expense was approximately \$5.7 million, \$3.9 million and \$2.9 million for the years ended December 31, 2014, 2013 and 2012, respectively.

**5. Cash, Cash Equivalents and Restricted Cash**

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 \$364.7 million and \$330.8 million at December 31, 2014 and December 31, 2013, respectively. Cash and cash equivalents at December 31, 2014 and December 31, 2013 included investments of \$6.0 million and \$45.9 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.

At December 31, 2014 and December 31, 2013 the Company did not hold any available for sale securities.

**Restricted Cash**

The Company had restricted cash of \$1.4 million and \$1.6 million at December 31, 2014 and at December 31, 2013, which is included in restricted cash on the consolidated balance sheets. Restricted cash of \$1.0 million at December 31, 2014 and December 31, 2013 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, 2014 and December 31, 2013 restricted cash of \$0.1 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, 2014 and December 31, 2013 restricted cash of \$0.3 million, respectively, related to certain foreign tender requirements.

**6. Non Marketable Investments**

In December 2012, 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. 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 held less than 10% of the issued and outstanding shares of GeNO and does not have significant influence over the company. During the three month period ended September 30, 2014 the Company's investment in the common stock of GeNO, LLC became diluted, resulting in the determination by the Company that the investment's fair value was zero. As a result the Company recorded an investment impairment charge of \$7.5 million representing an other-than-temporary decline in the value of the Company's investment in common stock of GeNO, LLC.

In the third quarter 2014, the Company acquired additional ownership interests in Annovation, increasing the Company's equity ownership interest in Annovation to 36%. The Company has determined that its current ownership provides it with the

ability to exercise significant influence, but not control, over Annovation's operating activities and, as a result, has accounted for its investment under the equity method. The investment is included in other assets on the consolidated balance sheet. The Company's proportionate share of the operating results of its equity investment is recorded as a loss in equity investment in the Company's consolidated statement of income. The retroactive application of the equity method resulted in an immaterial adjustment to the Company's financial statements for the year ended December 31, 2014.

**7. Acquisitions**

*Incline Therapeutics, Inc.*

In January 2013, the Company acquired 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 the holders of Incline's capital stock and the holders of options to purchase shares of Incline's capital stock (collectively, the Incline equityholders) an aggregate of approximately \$155.2 million in cash. In addition, the Company also paid approximately \$13.0 million to Cadence Pharmaceuticals, Inc. (Cadence) to terminate Cadence's option to acquire Incline pursuant to an agreement between Cadence and Incline and deposited an additional \$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.

The Company also agreed to pay up to \$205 million in cash in the aggregate, less certain transaction expenses and taxes, upon its entering into a license agreement in Japan and achieving certain regulatory approval and certain sales milestones with respect to IONSYS.

The Company accounted for the transaction as a business combination. The results of Incline's operations have been included in the consolidated statements of income from the date of acquisition.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Incline transaction to the underlying assets acquired and liabilities assumed by the Company, based upon estimated fair values of those assets and liabilities at the date of acquisition and classified the fair value of acquired IPR&D as an indefinite-lived asset until the successful completion or abandonment of the associated research and development efforts.

The Company recognized as goodwill from the transaction an amount equal to the excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed by the Company. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax deduction. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The Company has recorded the goodwill attributable to the acquisition as a non-current asset on its consolidated balance sheets. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

Acquisition related costs during 2013 of approximately \$2.2 million for advisory, legal and regulatory costs incurred in connection with the Incline acquisition have been expensed in selling, general and administrative expenses.

Total purchase price is summarized as follows:

	(in thousands)
Upfront cash consideration	\$ 186,699
Fair value of contingent purchase price	87,200
<b>Total purchase price</b>	<b>\$ 273,899</b>

Below is a summary which details the allocation of assets acquired and liabilities assumed as a result of this acquisition:

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

<b>Assets Acquired:</b>	(in thousands)
Cash and cash equivalents	\$ 1,563
Prepaid expenses and other current assets	624
Fixed assets, net	12,577
In-process research and development	250,000
Goodwill	102,613
Other assets	34
<b>Total Assets</b>	<b>\$ 367,411</b>
<b>Liabilities Assumed:</b>	
Accrued expenses	\$ 1,413
Contingent purchase price	87,200
Deferred tax liabilities	92,099
<b>Total Liabilities</b>	<b>\$ 180,712</b>
Total cash price paid upon acquisition	<u>\$ 186,699</u>

*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 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 \$105.0 million and a one-time option fee equal to \$10.0 million.

The Company did 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 any significant tangible assets related to the Recothrom business. Under the master transaction agreement, the Company paid BMS quarterly tiered royalty payments during the collaboration term equal to a percentage of worldwide net sales of Recothrom.

Under the terms of the agreement, 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.

On February 6, 2015, the Company completed the acquisition of Recothrom assets from Bristol-Myers Squibb Company, or BMS. Please refer to Note 22 Subsequent Events.

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 Recothrom to the Company during the collaboration term at specified purchase prices.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Recothrom transaction to the underlying assets acquired by the Company based primarily upon the estimated fair values of those assets at the date of acquisition.

The Company recognized as goodwill from the transaction an amount equal to the excess of purchase price over the fair value amounts assigned to the assets acquired by the Company. The goodwill recorded as part of the acquisition is primarily related to cost synergies and the acquired assembled workforce. The Company expects this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

The Company accounted for the transaction as a business combination since it acquired the biologics license application for Recothrom and certain related regulatory assets, employees and an option to acquire 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 (inputs), including the infrastructure to the sell the product (processes) and net sales of Recothrom (outputs). In addition, the Company has control over sales and marketing of the product during the collaboration period.

Acquisition related costs during 2013 of approximately \$1.6 million for advisory, legal and regulatory costs incurred in connection with the Recothrom acquisition have been expensed in selling, general and administrative expenses.

Below is a summary which details the purchase price allocation of assets acquired as a result of this acquisition:

<b>Assets Acquired:</b>	(in thousands)
Product license	\$ 32,000
Option	62,000
Goodwill	21,000
<b>Total Assets</b>	<b>\$ 115,000</b>
Total cash price paid upon acquisition	<u>\$ 115,000</u>

*ProFibrix B.V.*

In June 2013, the Company entered into a share purchase agreement (Purchase Agreement) with ProFibrix B.V., the equityholders of ProFibrix, certain members of the management team of ProFibrix in their capacities as warrantors of certain information in the Purchase Agreement, and the holders of options to acquire equity interests in ProFibrix and Stichting ProFibrix Sellers Representative, solely in its capacity as representative. In connection with the signing of the Purchase Agreement, the Company paid ProFibrix a \$10.0 million option payment for the right to acquire ProFibrix in the event that the Company was satisfied with the results of the then pending FINISH-3 Phase 3 clinical trial of Raplixa, a dry powder topical formulation of fibrogen and thrombin being developed for use as an aid to stop mild to moderate bleeding during surgery. On July 20, 2013, ProFibrix delivered to the Company the results of the Phase 3 trial. Following the Company's review of the Phase 3 trial results, on August 2, 2013, the Company notified ProFibrix that it wished to proceed with the closing of its acquisition of ProFibrix. On August 5 2013, the Company completed its acquisition of ProFibrix, and ProFibrix became a wholly owned subsidiary of the Company.

Upon the closing of the transactions contemplated by the Purchase Agreement, the Company paid an aggregate purchase price of \$90.9 million in cash in connection with its acquisition of all the outstanding equity of ProFibrix. The Company deposited \$9.0 million of the purchase price into an escrow fund for the purpose of (i) securing the indemnification obligations of the ProFibrix equityholders and optionholders to the Company for any and all losses for which the Company is entitled to indemnification under the Purchase Agreement, and (ii) providing 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 Purchase Agreement, the Company is also obligated to pay up to an aggregate of \$140.0 million in cash to the ProFibrix equityholders and optionholders upon the achievement of certain U.S. and European regulatory approvals prior to January 1, 2016 and certain U.S. and European sales milestones during the 24 month period that follows the initial commercial sale of Raplixa. As a result of the Company's acquisition of ProFibrix, the Company acquired a portfolio of patents and patent applications, including patents licensed from Quadrant Drug Delivery Limited (Quadrant), which included the U.S. patent directed to the composition of matter of Raplixa. Under the terms of a license agreement between ProFibrix and Quadrant,

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the Company is required to pay low single digit percentage royalties based on annual worldwide net sales of licensed products, including Raplix, by the Company or its affiliates and sublicensees. The royalties are subject to reduction in specified circumstances.

The Company accounted for the transaction as a business combination and the results of ProFibrix's operations have been included in the consolidated statements of income from the date of acquisition.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the ProFibrix transaction to the underlying assets acquired and liabilities assumed by the Company, based upon estimated fair values of those assets and liabilities at the date of acquisition and will classify the fair value of acquired IPR&D as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

The Company recognized as goodwill from the transaction an amount equal to the excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed by the Company. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax deduction. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The Company has recorded the goodwill attributable to the acquisition as a non-current asset on its consolidated balance sheets. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

Acquisition related costs during 2013 of approximately \$3.1 million for advisory, legal and regulatory costs incurred in connection with the ProFibrix acquisition have been expensed in selling, general and administrative expenses.

Total purchase price is summarized as follows:

	(in thousands)
Upfront cash consideration	\$ 105,395
Fair value of contingent purchase price	82,550
<b>Total purchase price</b>	<b>\$ 187,945</b>

Below is a summary which details the allocation of assets acquired and liabilities assumed as a result of this acquisition:

	(in thousands)
<b>Assets Acquired:</b>	
Cash	\$ 7,880
Prepaid assets	528
Fixed assets, net	124
In-process research and development	176,000
Goodwill	52,037
<b>Total Assets</b>	<b>\$ 236,569</b>
<b>Liabilities Assumed:</b>	
Accounts payable	\$ 1,074
Accrued expenses	3,544
Contingent purchase price	82,550
Deferred tax liabilities	44,006
<b>Total Liabilities</b>	<b>\$ 131,174</b>
Total cash price paid upon acquisition	<b>\$ 105,395</b>

*Rempex Pharmaceuticals, Inc.*

In December 2013, the Company acquired Rempex Pharmaceuticals, Inc. (Rempex), a company focused on the discovery and development of new antibacterial drugs to meet the growing clinical need created by multi-drug resistant gram-negative

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

bacterial pathogens. As a result of the transaction, the Company acquired Rempex's marketed product, Minocin IV, a broad-spectrum tetracycline antibiotic, and Rempex's portfolio of product candidates, including RPX-602, a proprietary reformulation of Minocin IV, Carbavance, an investigational agent that combines RPX-7009, a proprietary, novel beta-lactamase inhibitor, with a marketed carbapenem antibiotic, and Rempex's other product candidates.

At the closing, the Company paid to the holders of Rempex's capital stock, the holders of options to purchase shares of Rempex's capital stock and the holders of certain phantom stock units (collectively, the Rempex equityholders) an aggregate of approximately \$140.0 million in cash, and an additional \$0.3 million in purchase price adjustments. The amount paid to the Rempex equityholders at the closing was subject to a post-closing purchase price adjustment process with respect to the net amount of cash, unpaid transaction expenses and other debt and liabilities of Rempex as of the date of the closing.

In addition, the Company agreed to pay to the Rempex equityholders milestone payments subsequent to the closing, if the Company achieves certain development and regulatory approval milestones and commercial sales milestones with respect to Rempex's Minocin IV product, Rempex's RPX-602 product candidate, a proprietary reformulation of Minocin IV, Rempex's Carbavance product candidate, an investigational agent that is a combination of a novel beta-lactamase inhibitor with a marketed carbapenem antibiotic, and certain of Rempex's other product candidates, at the times and on the conditions set forth in the Merger Agreement. In the event that all of the milestones set forth in the Merger Agreement are achieved in accordance with the terms of the Merger Agreement, the Company will pay the Rempex equityholders an additional \$214.0 million in cash in the aggregate for achieving development and regulatory milestones and an additional \$120.0 million in cash in the aggregate for achieving commercial milestones, in each case, less certain transaction expenses and employer taxes owing because of the milestone payments. In the event that any milestone payments become due within eighteen months following the Closing, the Company will enter into an escrow agreement (the Escrow Agreement) and will deposit the first \$14.0 million of the aggregate milestone payments into an escrow fund for the purposes of securing the indemnification rights of the Company for any and all losses for which it is entitled to indemnification pursuant to the Merger Agreement or the Escrow Agreement and to provide the source of recovery for any amounts payable to the Company as a result of a post-closing purchase price adjustment process. To the extent that any amounts remain in the escrow fund after June 3, 2015 and not subject to claims by the Company, such amounts will be released to the Rempex Equityholders, subject to certain conditions set forth in the Merger Agreement.

The Company accounted for the transaction as a business combination and the results of Rempex operations have been included in the consolidated statements of income from the date of acquisition. In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Rempex transaction to the underlying assets acquired and liabilities assumed by the Company, based upon estimated fair values of those assets and liabilities at the date of acquisition and will classify the fair value of acquired IPR&D as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

The Company recognized as goodwill from the transaction an amount equal to the excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed by the Company. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the IPR&D intangible assets which have no tax basis and, therefore, will not result in a future tax deduction. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The Company has recorded the goodwill attributable to the acquisition as a non-current asset on its consolidated balance sheets. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

Acquisition related costs during 2013 of approximately \$2.6 million for advisory, legal and regulatory costs incurred in connection with the Rempex acquisition have been expensed in selling, general and administrative expenses.

Total purchase price is summarized as follows:

	(in thousands)
Upfront cash consideration	\$ 140,251
Fair value of contingent cash payment	96,700
<b>Total purchase price</b>	<b>\$ 236,951</b>

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Below is a summary which details the allocation of assets acquired and liabilities assumed as a result of this acquisition:

<b>Assets Acquired:</b>	<i>(In thousands)</i>
Cash and cash equivalents	\$ 4,218
Accounts receivable, net	399
Inventory	566
Prepaid expenses and other current assets	2,465
Fixed assets, net	331
Intangible assets	530
In-process research and development	224,680
Goodwill	68,632
<b>Total Assets</b>	<b>301,821</b>
<b>Liabilities Assumed:</b>	
Accounts payable	1,413
Accrued expenses	5,867
Deferred tax liabilities	57,590
<b>Total Liabilities</b>	<b>64,870</b>
<b>Total purchase price</b>	<b>\$ 236,951</b>

Tenaxis Medical, Inc.

On April 21, 2014, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Tenaxis, Napa Acquisition Corp., a Delaware corporation and wholly owned subsidiary of the Company, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the representative and agent of the stockholders and optionholders of Tenaxis (the Representative). On May 1, 2014, the Company completed its acquisition of Tenaxis and Tenaxis became a wholly owned subsidiary of the Company.

Tenaxis's sole product, PreveLeak, is a vascular and surgical sealant that mechanically seals both human tissue and artificial grafts. In the United States, PreveLeak received premarket approval from the U.S. Food and Drug Administration in March 2013 for use as a vascular sealant, however PreveLeak has not yet been commercialized in the United States. In the European Union, the product is approved for sale with a European CE Mark as a surgical sealant indicated for vascular, cardiac and soft tissue reconstructions to achieve hemostasis by mechanically sealing areas of leakage. Pursuant to this approval, PreveLeak has been sold in the European Union since September 2008.

Under the Merger Agreement, the Company paid to the holders of Tenaxis's capital stock, the holders of options to purchase shares of Tenaxis's capital stock (whether or not such capital stock or options were vested or unvested as of immediately prior to the closing) and the holders of certain warrants and side letters (collectively, the Tenaxis Equityholders) an aggregate of \$58.9 million in cash, subject to customary adjustments at and after the closing. At the closing, the Company deposited approximately \$5.4 million in cash from the \$58.9 million purchase price into an escrow fund for the purposes of securing the indemnification obligations of the Tenaxis 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. To the extent that any amounts remain in the escrow fund after October 1, 2015 and not subject to claims by the Company, such amounts will be released to the Tenaxis Equityholders, subject to certain conditions set forth in the merger agreement.

In addition, the Company has agreed to pay to the Tenaxis Equityholders milestone payments subsequent to the closing, if the Company achieves certain regulatory approval milestones and commercial net sales milestones with respect to PreveLeak, at the times and on the conditions set forth in the Merger Agreement. In the event that all of the milestones set forth in the Merger Agreement are achieved in accordance with the terms of the Merger Agreement, the Company will pay the Tenaxis Equityholders up to an additional \$112 million in cash in the aggregate.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company accounted for the transaction as a business combination. During the third quarter of 2014, the purchase price adjustment process was finalized and resulted in an insignificant adjustment to the purchase price. The results of Tenaxis operations have been included in the consolidated statements of income from the date of acquisition.

In accordance with the acquisition method of accounting, the Company allocated the acquisition cost for the Tenaxis transaction to the underlying assets acquired and liabilities assumed by the Company, based upon estimated fair values of those assets and liabilities at the date of acquisition and plan to classify the fair value of developed product rights as an intangible asset with the amortization recorded through the life of the products patents.

The Company recognized as goodwill from the transaction an amount equal to the excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed by the Company. The goodwill recorded as part of the acquisition is primarily related to establishing a deferred tax liability for the developed product intangible asset which has no tax basis and, therefore, will not result in a future tax deduction. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The Company has recorded the goodwill attributable to the acquisition as a non-current asset on its consolidated balance sheets. The goodwill attributable to the acquisition is not amortized, but the Company reviews its goodwill annually for impairment.

Acquisition related costs during 2014 of approximately \$0.6 million for advisory, legal and regulatory costs incurred in connection with the Tenaxis acquisition have been expensed in selling, general and administrative expenses.

Total purchase price is summarized as follows:

	<i>(In thousands)</i>
Upfront cash consideration	\$ 58,871
Fair value of contingent purchase price	37,900
<b>Total purchase price</b>	<b>\$ 96,771</b>

Below is a summary which details the allocation of assets acquired and liabilities assumed as a result of this acquisition:

<b>Assets Acquired:</b>	<i>(In thousands)</i>
Cash and cash equivalents	\$ 914
Inventory	307
Developed product rights	93,900
Goodwill	25,063
Other assets	131
<b>Total assets</b>	<b>\$ 120,315</b>
<b>Liabilities assumed:</b>	
Accounts payable	161
Contingent purchase price	37,900
Deferred tax liability	23,160
Other liabilities	223
<b>Total liabilities</b>	<b>\$ 61,444</b>
<b>Total cash price paid upon acquisition</b>	<b>\$ 58,871</b>



THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following unaudited pro forma financial information reflects the consolidated statements of income of the Company for the years ended December 31, 2014 as if the acquisition of Tenaxis had occurred as of January 1, 2013, and as if the 2013 acquisitions had occurred as of January 1, 2012.

	Year Ended December 31,	
	2014	2013
	(in thousands, except per share amounts)	
Net revenue	\$ 724,599	\$ 695,473
Net loss	\$ (35,023)	\$ (32,743)
Basic loss per common share	\$ (0.54)	\$ (0.56)
Diluted loss per common share	\$ (0.54)	\$ (0.56)

8. 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, 2014			As of December 31, 2013			
	Weighted Average Remaining Useful Life	Gross Carrying Amount	Accumulated Amortization and other charges	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
	(In thousands)						
Amortizable intangible assets							
Customer relationships <sup>(1)</sup>	—	\$ 7,457	\$ (7,457)	\$ —	\$ 7,457	\$ (5,631)	\$ 1,826
Selling rights agreements <sup>(1)</sup>	0.1	9,125	(8,961)	164	9,125	(5,870)	3,255
Trademarks <sup>(1)</sup>	—	3,024	(3,024)	—	3,024	(2,284)	740
Product licenses <sup>(2)</sup>	0.5	71,000	(65,602)	5,398	71,530	(25,067)	46,463
Developed product rights <sup>(3)</sup>	11.9	180,930	(6,513)	174,417	2,000	(191)	1,809
<b>Total</b>	<b>12.5</b>	<b>\$271,536</b>	<b>\$ (91,557)</b>	<b>\$179,979</b>	<b>\$ 93,136</b>	<b>\$ (39,043)</b>	<b>\$ 54,093</b>

- (1) The Company amortizes intangible assets related to Angiox through the end of its patent life.
- (2) The Company amortizes intangible assets related to the product licenses over their expected useful lives.
- (3) The Company amortizes intangible assets related to developed product rights over the remaining life of the patents.

In the third quarter of 2014, the Company paid to third parties \$15.0 million upon regulatory approval of Orbactiv. In addition, in the second quarter of 2014 the Company completed its acquisition of Tenaxis and Tenaxis became a wholly owned subsidiary of the Company. The Company classified the \$15.0 million payment to third parties and the intangible assets obtained from Tenaxis as developed products rights. In the fourth quarter of 2014, the Company reclassified in-process research and development of \$69.5 million related to Orbactiv, to developed product rights and commenced amortizing.

Amortization expense was \$52.5 million, \$28.5 million and \$4.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. The Company expects annual amortization expense related to these intangible assets to be \$14.6 million, \$13.2 million, \$13.3 million, \$13.3 million and \$12.9 million for the years ending December 31, 2015, 2016, 2017, 2018 and 2019, respectively, with the balance of \$112.6 million being amortized thereafter. Amortization of customer relationships, distribution

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

agreements and trademarks are recorded in selling, general and administrative expense on the consolidated statements of income. Amortization of developed product and product licenses 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, 2014			As of December 31, 2013		
	Gross Carrying Amount	Adjustments	Net Carrying Amount	Gross Carrying Amount	Adjustments	Net Carrying Amount
	(In thousands)					
Intangible assets not subject to amortization:						
In-process research and development	\$ 650,680	\$ —	\$ 650,680	720,180	\$ —	\$ 720,180
Recothrom option	62,000	—	62,000	62,000	—	62,000
<b>Total</b>	<b>\$712,680</b>	<b>\$ —</b>	<b>\$712,680</b>	<b>\$782,180</b>	<b>\$ —</b>	<b>\$782,180</b>

The changes in the carrying amount of goodwill for the years ended December 31, 2014 and December 31, 2013 are as follows:

	December 31, 2014	December 31, 2013
	(In thousands)	
Balance at beginning of period	\$ 257,694	\$ 14,671
Goodwill resulting from the acquisition of Tenaxis	25,063	—
Goodwill resulting from the acquisition of Incline	—	102,613
Goodwill resulting from the acquisition of Recothrom	—	21,000
Goodwill resulting from the acquisition of ProFibrix	—	52,037
Goodwill resulting from the acquisition of Rempex	—	68,632
Translation adjustments	3,775	(1,259)
Balance at end of period	<b>\$ 286,532</b>	<b>\$ 257,694</b>

9. Accrued Expenses

Accrued expenses consisted of the following at December 31, 2014 and 2013:

	2014	2013
	(In thousands)	
Royalties	\$ 26,821	\$ 44,260
Research and development services	29,726	14,846
Compensation related	43,992	35,492
Product returns, rebates and other fees	6,495	5,699
Legal, accounting and other	14,045	14,487
Manufacturing, logistics and related fees	30,919	23,722
Sales and marketing	6,939	3,469
Interest	315	315
<b>Total</b>	<b>\$ 159,252</b>	<b>\$ 142,290</b>

10. Convertible Senior Notes

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 2017 notes). The 2017 notes bear cash interest at a rate of 1.375% per year, payable semi-annually on

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

June 1 and December 1 of each year, beginning on December 1, 2012. The 2017 notes will mature on June 1, 2017. 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 2017 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 2017 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 2017 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 2017 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 the 2017 notes will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a 2017 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 2017 note.

The conversion rate for the 2017 notes was initially, and remains, 35.8038 shares of the Company's common stock per \$1,000 principal amount of 2017 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 2017 notes prior to maturity and is not required to redeem or retire the 2017 notes periodically. However, upon the occurrence of a "fundamental change" (as defined in the Indenture), subject to certain conditions, in lieu of converting their 2017 notes, holders may require the Company to repurchase for cash all or part of their 2017 notes at a repurchase price equal to 100% of the principal amount of the 2017 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 2017 notes in connection with such change of control in certain circumstances.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Indenture contains customary events of default with respect to the 2017 notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2017 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 2017 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) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 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 2017 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 2017 notes, the Company separated the 2017 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 2017 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 2017 notes, the Company allocated the total costs incurred to the liability and equity components of the 2017 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 2017 notes.

The Notes consisted of the following:

Liability component	December 31, 2014	December 31, 2013
	(in thousands)	
Principal	\$ 275,000	\$ 275,000
Less: Debt discount, net <sup>(1)</sup>	(28,324)	(38,912)
<b>Net carrying amount</b>	<b>\$ 246,676</b>	<b>\$ 236,088</b>

<sup>(1)</sup> Included in the 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 \$262.0 million as of December 31, 2014. 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, 2014, the remaining contractual life of the Notes is approximately 2.4 years.

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

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Contractual interest expense	\$ 3,781	\$ 3,781	\$ 2,101
Amortization of debt issuance costs	1,332	1,179	598
Amortization of debt discount	10,588	9,978	5,306
	<u>\$ 15,701</u>	<u>\$ 14,938</u>	<u>\$ 8,005</u>
Effective interest rate of the liability component	<u>6.02%</u>	<u>6.02%</u>	<u>6.02%</u>

*Note Hedges.* In June 2012, the Company paid an aggregate amount of \$58.2 million for the 2017 Note Hedges, which was recorded as a reduction of additional paid-in-capital in stockholders' equity. The 2017 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 2017

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

notes, have a strike price that corresponds to the initial conversion price of the 2017 notes and are exercisable upon conversion of the 2017 notes. The 2017 Note Hedges will expire upon the maturity of the 2017 notes. The 2017 Note Hedges are expected generally to reduce the potential dilution with respect to shares of the Company's common stock upon conversion of the 2017 notes in the event that the market price per share of the Company's common stock, as measured under the terms of the 2017 Note Hedges, at the time of exercise is greater than the strike price of the 2017 Note Hedges. The 2017 Note Hedges are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the 2017 notes or the Warrants. Holders of the 2017 notes and Warrants will not have any rights with respect to the 2017 Note Hedges. As of December 31, 2014, the fair value of the 2017 Note Hedges was \$58.1 million. The Company estimates the fair value of its 2017 Note Hedges using Monte Carlo simulation models of its stock price (Level 2).

*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 are separate transactions entered into by the Company with the Hedge Counterparties and are not part of the terms of the 2017 notes or 2017 Note Hedges. Holders of the 2017 notes and 2017 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.

The Warrants were anti-dilutive for the years ended December 31, 2014 and 2013.

**11. 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 864,457 shares, 3,547,431 shares, and 1,487,642 shares of common stock during the years ended December 31, 2014, 2013 and 2012, 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 \$17.3 million, \$74.2 million, and \$22.9 million during the years ended December 31, 2014, 2013 and 2012, respectively, and are included within the financing activities section of the consolidated statements of cash flows. The Company issued 212,136 shares, 237,413 shares and 352,391 shares under restricted stock awards during the years ended December 31, 2014, 2013 and 2012, 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 2017 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 2013 for an aggregate cost of \$50.0 million.

As of December 31, 2014, there were 2,192,982 shares of the Company's common stock held in treasury.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**12. Share-Based Compensation***Stock Plans*

The Company has adopted the following stock incentive plans:

- the 2013 Stock Incentive Plan (the 2013 Plan),
- 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.

*2013 Plan*

In April 2013, the Board of Directors adopted, subject to stockholder approval, the 2013 Plan, which provides for the grant of stock options, restricted stock awards, restricted stock units, stock appreciation rights, other share-based awards and cash-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 2013 Plan on May 30, 2013.

The Company may issue up to 13,166,879 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2013 Plan. The total number of shares of the Company's common stock available for issuance under the 2013 Plan is equal to 3,700,000 shares plus the remaining number of shares of the Company's common stock available for issuance under the 2004 Plan as of May 30, 2013 (the date the plan was approved by the Company's stockholders), plus the number of shares of the Company's common stock subject to awards granted under the 2004 Plan which may expire, terminate or be surrendered, canceled, forfeited or repurchased by the Company. Shares issued under the 2013 Plan may be authorized but unissued shares or treasury shares, or may be issued from shares that are returned to the 2013 Plan (provided that open-market purchases of shares using the proceeds from the exercise of awards do not increase the number of shares available for future grants). The 2013 Plan uses a "fungible share" concept under which the awards of options and stock appreciation rights cause one share per share subject to such award to be removed from the available share pool, while the award of restricted stock, restricted stock units, or other share-based awards where the purchase price for the award is less than 100% of the fair market value of the Company's common stock on the date of grant will be counted against the pool as 1.7 shares, which was changed to 1.98 shares, effective May 2014, for each share subject to such award. Shares subject to awards under the 2013 Plan and the 2004 Plan that are forfeited, canceled or otherwise expire without having been exercised or settled, or that are settled by cash or other non-share consideration, will become available for issuance pursuant to a new award under the 2013 Plan and will be credited back to the pool at the same rates at which they left the plan. Shares are subtracted for exercises of stock appreciation rights using the proportion of the total stock appreciation rights that is exercised, rather than the number of shares actually issued. The Board of Directors has delegated its authority under the 2013 Plan to the Compensation Committee of the Board of Directors (the Compensation Committee), consisting of independent directors, which administers the 2013 Plan, including granting options and other awards under the 2013 Plan. In addition, pursuant to the terms of the 2013 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 2013 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 2013 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 2013 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

- \$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.

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, 2014, the Company had granted an aggregate of 3,902,596 shares as restricted stock or subject to issuance upon exercise of stock options under the 2013 Plan, of which 3,560,018 shares remained subject to outstanding options.

*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 share-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, 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, 2014, an aggregate of 69,671 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 share-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, 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, 2014, an aggregate of 24,700 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 share-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 sub limit 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 canceled 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 Company ceased making grants under the 2004 Plan following adoption of an amendment to the 2013 Plan at its annual stockholders' meeting in May 2013.

As of December 31, 2014, the Company had granted an aggregate of 12,290,910 shares as restricted stock or subject to issuance upon exercise of stock options under the 2004 Plan, of which 5,294,384 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 canceled 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, 2014, an aggregate of 1,099,241 shares had been issued under the 2001 Plan and options to purchase an aggregate of 11,500 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, 2014, an aggregate of 177,086 shares had been issued under the 2000 Directors Plan and no 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 share-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 canceled 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, 2014, an aggregate of 5,046,587 shares had been issued under the 1998 Plan and options to purchase an aggregate of 24,490 shares remained outstanding.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2014:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2012	9,136,677	18.51		
Granted	1,619,702	17.04		
Exercised	(1,342,739)	11.04		
Forfeited and expired	(301,608)	17.3		
Outstanding, December 31, 2012	9,112,032	18.61		
Granted	2,263,649	32.2		
Exercised	(3,425,586)	20.79		
Forfeited and expired	(333,691)	23.29		
Outstanding, December 31, 2013	7,616,404	\$ 22.83		
Granted	2,825,451	27.8		
Exercised	(708,590)	19.25		
Forfeited and expired	(748,502)	30.12		
Outstanding, December 31, 2014	8,984,763	\$ 24.07	6.48	\$ 45,251,635
Vested and expected to vest, December 31, 2014	8,670,134	\$ 23.92	6.39	\$ 44,766,760
Exercisable, December 31, 2014	5,207,526	\$ 21.15	4.84	\$ 38,634,832
Available for future grant at December 31, 2014	2,656,366			

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, 2014, 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, 2014, 2013 and 2012 was \$12.34, \$13.76, and \$8.95, respectively. The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was \$8.2 million, \$43.5 million, and \$10.4 million, respectively.

In accordance with ASC 718-10, the Company recorded approximately \$34.3 million, \$23.0 million and \$15.0 million of share-based compensation expense related to the options, restricted stock and ESPP for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, there was approximately \$33.6 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 1.45 years.

The Company recorded approximately \$32.8 million, \$15.9 million, and \$9.6 million in compensation expense related to options in the years ended December 31, 2014, 2013 and 2012.

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.

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	Years Ended December 31,		
	2014	2013	2012
Expected dividend yield	—%	—%	—%
Expected stock price volatility	50.25%	48.3%	46.5%
Risk-free interest rate	1.543%	1.079%	0.825%
Expected option term (years)	4.96	5.07	4.95

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,		
	2014	2013	2012
Expected dividend yield	—%	—%	—%
Expected stock price volatility	38.97%	32.46%	36.25%
Risk-free interest rate	0.07%	0.09%	14%
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, 2014:

	Number of Shares	Weighted Average Grant-Date Fair Value
Outstanding, January 1, 2012	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
Awarded	266,388	31.80
Vested	(247,945)	17.61
Forfeited	(28,975)	22.88
Outstanding, December 31, 2013	602,579	24.97
Awarded	306,161	29.84
Vested	(238,028)	23.69
Forfeited	(94,025)	28.59
Outstanding, December 31, 2014	576,687	\$ 27.50

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 \$0.3 million, \$6.1 million and \$4.7 million was recognized related to restricted stock awards in the years ended December 31, 2014, 2013 and 2012, respectively. The remaining expense of approximately \$6.4 million will be recognized over a period of 1.13 years. The total fair value of the restricted stock that vested during the years ended December 31, 2014, 2013 and 2012 was \$7.1 million, \$7.5 million and \$4.0 million, respectively.

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2000 ESPP

In May 2000, the Board of Directors and the Company's stockholders approved the 2000 ESPP. The 2000 ESPP provided for the issuance of up to 805,500 shares of common stock. The 2000 ESPP permitted eligible employees to purchase shares of common stock at the lower of 85% of the fair market value of the common stock at the beginning or at the end of each offering period. Employees who owned 5% or more of the common stock were not eligible to participate in the 2000 ESPP. Participation was voluntary.

As of December 31, 2014, 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 155,867 shares, and 121,845 shares under the 2010 ESPP during the year ended December 31, 2014 and 2013, and currently has 388,340 shares in reserve for future issuance under the 2010 ESPP. The Company recorded approximately \$1.2 million, and \$1.0 million in compensation expense related to the 2010 ESPP in the year ended December 31, 2014 and 2013.

Common Stock Reserved for Future Issuance

At December 31, 2014, there were 388,340 shares of common stock available for grant under the 2010 ESPP and 2,656,366 shares of common stock available for grant under the 2013 Plan.

13. Earnings per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2014, 2013 and 2012.

	Years Ended December 31,		
	2014	2013	2012
	(In thousands, except per share amounts)		
<b>Basic and diluted</b>			
Net income attributable to The Medicines Company	\$ (32,210)	\$ 15,512	\$ 51,254
Net weighted average common shares outstanding, basic	64,473	58,096	53,545
Plus: net effect of dilutive stock options, warrants, restricted common shares and shares issuable upon conversion of Notes	—	4,556	1,801
Weighted average common shares outstanding, diluted	64,473	62,652	55,346
Income per common share attributable to The Medicines Company, basic	\$ (0.50)	\$ 0.27	\$ 0.96
Income per common share attributable to The Medicines Company, diluted	\$ (0.50)	\$ 0.25	\$ 0.93

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, 2014, 2013 and 2012, options to purchase 3,910,115 shares, 1,335,570 shares, and 3,171,163 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 year ended December 31, 2014, there were 5,791 shares of unvested restricted stock excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive. For the years ended December 2013 no shares of unvested restricted stock were excluded from the calculation of diluted earnings per common share. For the years ended December

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2012, 77,235 shares, 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 the 2017 notes. As the Company is required to pay cash for the principal amount of the 2017 notes upon conversion, there is no impact to earnings per share. At December 31, 2014, 383,844 shares for the excess premium calculation on these notes were not included in the diluted shares for the purposes of calculating the total shares outstanding under the basic and diluted net loss per share as the effect would be anti-dilutive as the Company recorded a loss during for the year ended December 31, 2014.

In connection with the issuance of the 2017 notes, the Company entered into the 2017 Note Hedges with several of the initial purchasers of the Notes, their affiliates and other financial institutions (the Hedge Counterparties). The 2017 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 2017 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 2017 notes in the event that the market price per share of the Company's common stock, as measured under the terms of the 2017 Note Hedges, is greater than the strike price of the 2017 Note Hedges, which initially corresponded to the conversion price of the 2017 notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the 2017 notes.

In addition, in connection with the 2017 Note Hedges, the Company entered into warrant transactions with the Hedge Counterparties, pursuant to which the Company sold 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, 2014 and December 31, 2013, 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 shares of common stock issuable upon the exercise of the warrants included in diluted shares for the December 2013, were 107,263 shares. 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.

14. Income Taxes

The benefit from (provision for) income taxes in 2014, 2013 and 2012 consists of current and deferred federal, state and foreign taxes based on income as follows:

	2014	2013	2012
	(In thousands)		
<b>Current:</b>			
Federal	\$ 1,388	\$ (8,889)	\$ (2,492)
State	(160)	(287)	(1,309)
Foreign	44	(2,456)	(863)
	1,272	(11,632)	(4,664)
<b>Deferred:</b>			
Federal	5,357	(10,726)	(26,388)
State	208	20,999	(3,920)
Foreign	—	(1)	(66)
	5,565	10,272	(30,374)
<b>Total benefit from (provision for) income taxes</b>	<b>\$ 6,837</b>	<b>\$ (1,360)</b>	<b>\$ (35,038)</b>

The components of (loss) income before income taxes consisted of:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	2014	2013	2012
	(In thousands)		
Domestic	\$ (19,730)	\$ 17,516	\$ 92,998
International	(19,318)	(644)	(6,790)
Total	<u>\$ (39,048)</u>	<u>\$ 16,872</u>	<u>\$ 86,208</u>

The difference between tax expense and the amount computed by applying the statutory federal income tax rate of 35% in 2014, 2013, and 2012 to income before income taxes is as follows:

	Year Ended December 31,		
	2014	2013	2012
	(In thousands)		
Statutory rate applied to pre-tax income	\$ (13,667)	\$ 5,905	\$ 30,202
Add (deduct):			
State income taxes, net of federal benefit	(31)	(13,463)	3,399
Foreign	6,946	1,854	2,136
Revaluation of contingent purchase price	3,742	5,930	(511)
Tax credits	(2,598)	(6,052)	(1,712)
Lobbying costs	60	—	171
Acquisition costs	198	3,024	—
Meals and entertainment	502	468	386
Uncertain tax positions	(101)	2,574	542
Other	1,461	1,120	425
Deferred Tax Asset Adjustment	(3,349)	—	—
Income tax provision (benefit)	<u>\$ (6,837)</u>	<u>\$ 1,360</u>	<u>\$ 35,038</u>

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

	December 31,	
	2014	2013
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 81,603	\$ 49,451
Tax credits	17,451	13,279
Intangible assets	7,828	29,370
Stock based compensation	22,427	16,371
Other	20,103	16,174
Total deferred tax assets	149,412	124,645
Valuation allowance	(43,874)	(4,186)
Total deferred tax assets net of valuation allowance	105,538	120,459
Deferred tax liabilities:		
Fixed assets	\$ (5,099)	\$ (4,044)
Indefinite lived intangible assets	(231,818)	(231,662)
Total deferred tax liabilities	(236,917)	(235,706)
Net deferred tax liabilities	<u>\$ (131,379)</u>	<u>\$ (115,247)</u>

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At December 31, 2014 and 2013, the Company's current net deferred tax asset was \$33.1 million and \$13.5 million respectively, and its non-current deferred tax liability was \$164.5 million and \$128.7 million, respectively.

During 2014 the Company recorded a net increase to its valuation allowance of \$39.7 million. At December 31, 2014 and 2013, the Company recorded a valuation allowance of \$43.9 million and \$4.2 million respectively, principally against net operating loss carryforwards in foreign jurisdictions. 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 its deferred tax assets. 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 patent rights relating to Angiomax. Any changes to the valuation allowance or deferred tax assets in the future would impact the Company's effective tax rate.

In 1998 and 2002, the Company experienced a change in ownership as defined in Section 382 of the Internal Revenue Code. 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. During 2013 the Company acquired the stock of Incline and Rempex and became the successor of certain net operating losses and tax credit carryforwards. These tax attributes are also subject to a limitation under Internal Revenue Code Section 382 and these amounts combined with those of the Company in the table below have been reduced appropriately for such utilization limitations. In addition, utilization of these net operating loss and tax credit carryforwards is dependent upon the Company achieving profitable results. To the extent the Company's use of net operating loss and tax credit carryforwards is further limited by Section 382 as a result of any future ownership changes, the Company's income would be subject to cash payments of income tax earlier than it would if the Company was able to fully use its net operating loss and tax credit carryforwards in the U.S. The Company is also subject to US alternative minimum tax.

At December 31, 2014, 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	Federal Research and Development Tax Credit Carryforwards
	(In thousands)	
2018-2024	\$ —	\$ —
2027	6,256	840
2028	40,193	2,108
2029	9,742	1,148
2030	5,281	1,162
2031	3,292	3,097
2032	2,917	3,622
2033	38,155	3,239
2034	4,449	3,000
	<u>\$ 110,285</u>	<u>\$ 18,216</u>

At December 31, 2014 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 \$169.8 million expiring between 2014 and 2032.

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 2011. However applicable taxing authorities can review and adjust net operating loss or tax credit carryforwards originating in a closed tax year if utilized in an open tax year. The Company's 2011 corporate return is currently under examination by the Internal Revenue Service and the Italian Agency of

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Revenue. While tax examinations are often complex, as tax authorities may disagree with the treatment of items reported requiring several years to resolve, the Company believes that it has adequately provided for all uncertain tax provisions for open tax years by tax jurisdiction. 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, 2014. The Company has increased its ASC 740-10 liability for prior year tax positions due to the acquisitions of Incline, ProFibrix, Rempex and Tenaxis. The total amount of unrecognized tax benefits that, if recognized, would affect the Company's effective tax rate was \$8.1 million and \$8.8 million as of December 31, 2013 and December 31, 2014, respectively. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	Gross Unrecognized Tax Benefits (In thousands)
Balance at January 1, 2013	\$ 2,433
Additions related to current year tax positions	600
Additions for prior year tax positions	5,090
Balance at December 31, 2013	8,123
Additions related to current year tax positions	519
Additions for prior year tax positions	818
Reductions for prior year tax positions	(621)
Balance at December 31, 2014	\$ 8,839

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, 2014, the Company's accumulated foreign unremitted earnings have been immaterial. The Company's policy is to invest indefinitely its unremitted foreign earnings outside the United States.

On September 13, 2013, Treasury and the Internal Revenue Service issued final regulations regarding the deduction and capitalization of expenditures related to tangible property. The final regulations under Internal Revenue Code Sections 162, 167 and 263(a) apply to amounts paid to acquire, produce, or improve tangible property as well as dispositions of such property and are generally effective for tax years beginning on or after January 1, 2014. The Company has adopted these regulations and determined they do not have a material impact on its consolidated results of operations, cash flows or financial position.

**15. 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:

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**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 Company's business combinations. The fair value of the certain development or regulatory milestone based contingent purchase prices were determined in a discounted cash flow framework by probability weighting the future contractual payment with management's assessment of the likelihood of achieving these milestones and present valuing them using a risk adjusted discount rate. Certain sales milestone based payments were determined in a discounted cash flow framework where risk-adjusted revenue scenarios were estimated using Monte Carlo simulation models to compute contractual payments which were present valued using a risk adjusted discount rate.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at December 31, 2014 and 2013 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:

Assets and Liabilities	As of December 31, 2014				As of December 31, 2013			
	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, 2014	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, 2013
(In thousands)								
Assets:								
Money market	\$ 6,030	\$ —	\$ —	\$ 6,030	\$ 45,950	\$ —	\$ —	\$ 45,950
Total assets at fair value	\$ 6,030	\$ —	\$ —	\$ 6,030	\$ 45,950	\$ —	\$ —	\$ 45,950
Liabilities:								
Contingent purchase price	\$ —	\$ —	\$351,134	\$351,134	\$ —	\$ —	\$302,363	\$302,363
Total liabilities at fair value	\$ —	\$ —	\$351,134	\$351,134	\$ —	\$ —	\$302,363	\$302,363

*Level 3 Disclosures*

The Company measures its 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.



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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, 2014 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
<b>Targanta:</b>				
Contingent purchase price	\$ 6,334	Probability-adjusted discounted cash flow	Probabilities of success	20%
			Periods in which milestones are expected to be achieved	2019
			Discount rate	11%
<b>Incline:</b>				
Contingent purchase price	\$ 123,800	Probability-adjusted discounted cash flow	Probabilities of success	64% - 100% (83%)
			Periods in which milestones are expected to be achieved	2015-2018
			Discount Rate	18%
<b>ProFibrix:</b>				
Contingent purchase price	\$ 88,600	Probability-adjusted discounted cash flow	Probability of success	5% - 95% (92%)
			Period in which milestones are expected to be achieved	2015 - 2017
			Discount rate	2.5% - 24.1%
<b>Rempex:</b>				
Contingent purchase price: commercial milestone	\$ 80,800	Probability-adjusted discounted cash flow	Probability of success	11% -95% (63%)
			Period in which milestones are expected to be achieved	2015 - 2019
			Discount rate	1.5% - 3.7%
Contingent purchase price: sales milestone	\$ 10,900	Risk adjusted revenue simulation	Probability of success	9% - 49% (17%)
			Period in which milestones are expected to be achieved	2016 - 2022
			Discount rate	1.5% - 4.5%
<b>Tenaxis:</b>				
Contingent purchase price	\$ 40,700	Probability-adjusted discounted cash flow	Probability of success	5% - 100% (84%)
			Periods in which milestones are expected to be achieved	2015 - 2026
			Discount rate	1% - 20%

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	Fair Value as of December 31, 2013 (in thousands)	Valuation Technique	Unobservable Input	Range (Weighted Average)
<b>Targanta:</b>				
Contingent purchase price	\$ 5,573	Probability-adjusted discounted cash flow	Probabilities of success	20%
			Periods in which milestones are expected to be achieved	2019
			Discount rate	11%
<b>Incline:</b>				
Contingent purchase price	\$ 115,890	Probability-adjusted discounted cash flow	Probabilities of success	60% - 85% (79%)
			Periods in which milestones are expected to be achieved	2013-2017
			Discount Rate	18%
<b>ProFibrix:</b>				
Contingent purchase price	\$ 84,000	Probability-adjusted discounted cash flow	Probability of success	5% - 95% (91%)
			Period in which milestones are expected to be achieved	2015 - 2017
			Discount rate	4.9% - 17.5%
<b>Rempex:</b>				
Contingent purchase price: commercial milestone	\$ 87,900	Probability-adjusted discounted cash flow	Probability of success	11% -95% (63%)
			Period in which milestones are expected to be achieved	2014 - 2019
			Discount rate	1.5% - 4.38%
Contingent purchase price: sales milestone	\$ 9,000	Risk adjusted revenue simulation	Probability of success	9% - 49% (18%)
			Period in which milestones are expected to be achieved	2016 - 2022
			Discount rate	2% - 5.4%

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, Incline, ProFibrix, Rempex and Tenaxis. 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, Incline, ProFibrix, Rempex and Tenaxis agreements, 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, 2014 and 2013 were as follows:

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	December 31,	
	2014	2013
	(in thousands)	
Balance at beginning of period	\$ 302,363	\$ 18,971
Fair value of contingent purchase price with respect to Incline as of January 4, 2013	—	87,200
Fair value of contingent purchase price with respect to ProFibrix as of August 5, 2013	—	82,550
Fair value of contingent purchase price with respect to Rempex as of December 3, 2013	—	96,700
Fair value of contingent purchase price with respect to Tenaxis as of May1, 2014	37,900	—
Fair value adjustment to contingent purchase price included in net income (loss)	10,871	16,942
Balance at end of period	\$ 351,134	\$ 302,363

For the year ended December 31, 2014, the changes in the carrying value of the contingent purchase price obligations resulted from the initial estimate of the fair value of the contingent consideration related to the Company's purchase of Tenaxis and subsequent changes in the fair value of the contingent consideration due to either the passage of time, changes in discount rates or changes in probabilities of success, milestones payments and a settlement and amendment to the merger agreement relating to Incline. In December 2014, the Incline merger agreement was amended to revise to certain milestone triggers, reduce the total potential milestone payments and release the escrow fund to the Company.

No other changes in valuation techniques or inputs occurred during the year ended December 31, 2014.

No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the year ended December 31, 2014.

**16. Restructuring Costs and Other, Net**

On October 22, 2014, the Company commenced implementation of a reorganization of its European operations intended to improve efficiency and better align the Company's costs and employment structure with its strategic plans. The reorganization includes a workforce reduction and the consolidation of European sites into a single location in Zurich, Switzerland. As a result of the workforce reduction, the Company reduced its personnel by 46 employees. Upon signing release agreements, impacted employees were eligible to receive severance payments in specified amounts, and general benefits and outplacement services for specified periods in accordance with our policies and local requirements. The Company completed its reorganization of its European operations in December 2014.

In the year ended December 31, 2014, the Company recorded, in the aggregate, a one-time charge of approximately \$9.0 million associated with this reorganization of its European operations. Of the approximately \$9.0 million of charges related to the 2014 European reorganization, \$0.5 million were non-cash charges. Lease charges were recorded in selling, general and administrative expenses. The Company recorded \$8.7 million associated with the workforce reduction. The Company recorded these charges in research and development expense and selling general and administrative expense based on responsibilities of the impacted employees. Of the charges related to the 2014 workforce reduction, \$0.3 million were non-cash charges. The Company paid \$0.6 million during the 2014 fourth quarter and the Company expects to pay the remainder during 2015.

In February 2013, the Company commenced a workforce reduction to improve efficiency and better align its costs and employment structure with its strategic plans. As a result of the workforce reduction, the Company reduced its personnel by 66 employees. Upon signing release agreements, impacted employees received severance payments and fully paid health care coverage and outplacement services for specified periods. The Company completed this workforce reduction in March 2013.

THE MEDICINES COMPANY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The Company recorded, in the aggregate, one-time charges of \$6.4 million associated with the workforce reduction. The Company recorded these charges in cost of revenue, research and development expense and selling general and administrative expense based on the responsibilities of the impacted employees.

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. Upon signing release agreements, the terminated employees received severance and other benefits. The Company recorded, in the aggregate, charges of \$2.2 million in 2012 associated with the 2011 Leipzig closure. These charges were recorded in research and development expenses in the Company's consolidated statement of income. Of these charges, \$0.3 million related to asset write-offs were non-cash charges. The Company paid \$0.3 million during 2011 and \$0.8 million during 2012. During 2012, the Company recorded additional charges of \$0.2 million relating to the 2011 Leipzig closure due to the Saxony government in Leipzig recalling subsidies higher than originally estimated that were received by the Company during past three years. In the second quarter of 2013, the Company received notification from the Saxony government that no additional liabilities were due for these subsidies.

The following table sets forth details regarding the activities described above during the year ended December 31, 2014 and 2013 are as follows:

	Balance as of January 1, 2014	Expenses, Net	Cash	Noncash	Balance as of December 31, 2014
	(In thousands)				
Employee severance and other personnel benefits:					
2014 European workforce reduction	\$ —	\$ 8,660	\$ (632)	\$ (334)	\$ 7,694
2013 workforce reduction	370	—	—	(370)	—
2014 European leases and equipment write-off	—	347	—	(147)	200
<b>Total</b>	<b>\$ 370</b>	<b>\$ 9,007</b>	<b>\$ (632)</b>	<b>\$ (851)</b>	<b>\$ 7,894</b>

	Balance as of January 1, 2013	Expenses, Net	Cash	Noncash	Balance as of December 31, 2013
	(In thousands)				
Employee severance and other personnel benefits:					
2011 Leipzig closure and other associated costs	\$ 1,009	\$ —	\$ —	\$ (1,009)	\$ —
2013 workforce reduction	—	6,358	(5,699)	(289)	370
<b>Total</b>	<b>\$ 1,009</b>	<b>\$ 6,358</b>	<b>\$ (5,699)</b>	<b>\$ (1,298)</b>	<b>\$ 370</b>

**17. 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 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, leased office space for our principal office in Parsippany, New Jersey and additional leased office space in San Diego, California, royalties, milestone payments and other contingent payments due under the Company's license and acquisition agreements.

Future estimated contractual obligations as of December 31, 2014 are:

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Contractual Obligations <sup>(1)(2)</sup>	2015	2016	2017	2018	2019	Later Years	Total
	(In thousands)						
Inventory related commitments	\$ 52,174	\$ 783	\$ 130	\$ 130	\$ 130	\$ —	\$ 53,347
Long-term debt obligations	3,781	3,781	276,576	—	—	—	284,138
Research and development	72,617	1,952	3,210	44	10	—	77,833
Operating leases	8,221	7,556	8,235	7,230	7,277	48,540	87,059
Selling, general and administrative	2,589	1,167	74	—	—	—	3,830
Total contractual obligations	<u>\$ 139,382</u>	<u>\$ 15,239</u>	<u>\$ 288,225</u>	<u>\$ 7,404</u>	<u>\$ 7,417</u>	<u>\$ 48,540</u>	<u>\$ 506,207</u>

(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.

(2) This table does not include \$400.0 million aggregate principal amount of the convertible senior notes due 2022 issued by us in January 2015 (see Footnote No. 22).

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments for 2015 totaling \$20.1 million, \$23.8 million and \$4.5 million for Angiomax, Orbactiv and Recothrom bulk drug substances, respectively. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$9.6 million are non-cancellable.

The Company's long-term debt obligations reflect its obligations under the 2017 Notes to pay interest on the \$275.0 million aggregate principal amount of the 2017 Notes and to make principal payments on the 2017 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. On October 1, 2014, the Company entered into an agreement to lease 63,000 square feet of office space with ARE-SD Region No. 35, LLC, or ARE, for new office and laboratory space in San Diego. This lease has a term of 144 months from the first day of the first full month after the commencement date, which is currently expect to be on or about September 2016.

The agreement is for the build out of the space with a targeted commencement date in September of 2016. The lease will qualify for operating lease treatment with recorded annual rent expense from commencement date to expiration of \$2.9 million, with adjustments for customary triple-net lease operating expenses. The Company's expected total obligation for this space is \$35.3 million.

Approximately 88.8% of the total operating lease commitments above relate to the Company's principal office building in Parsippany, New Jersey and the Company's office in San Diego, California. Also included in total property lease commitments are automobile leases, computer leases and other property leases that the Company entered into while expanding its global infrastructure.

Aggregate rent expense under the Company's property leases was approximately \$8.5 million in 2014, \$7.3 million in 2013 and \$5.8 million in 2012.

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/or milestone payments with respect to Cleviprex, cangrelor, Orbactiv, MDCO-216, IONSYS, Raplixa, PreveLeak and Carbavance and profit sharing with respect to the Company's sales of ready-to-use Argatroban. The Company made payments in February 2015 of \$28.4 million to the equityholders of Annovation and \$127.7 million to BMS when the Company exercised the options granted to it (see Footnote No. 22). The Company may be obligated to pay Annovation's equityholders up to an additional \$26.3 million upon achievement of certain clinical and regulatory milestones and up to \$6.5 million in additional payments to other third parties.

The Company may have to make these significant contingent cash payments in connection with its acquisition and licensing activities upon the achievement of specified regulatory, sales and other milestones as follows:

- \$49.4 million due to the former shareholders of Targanta and up to \$25.0 million in additional payments to other third parties;

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

- up to \$189.3 million due to the former shareholders of Incline and up to \$113.0 million in additional payments to other third parties;
- up to \$140.0 million due to the former shareholders of ProFibrix;
- up to \$315.7 million due to the former shareholders of Rempex;
- up to \$112.0 million due to the former shareholders of Tenaxis;
- up to \$170.0 million due to the Alnylam license and collaboration agreement;
- up to \$422.0 million due to the Company's license agreement with Pfizer Inc. related to MDCO-216; and
- up to \$54.5 million due to the Company's license agreement with AstraZeneca related to cangrelor.

Given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Accordingly, these contingent payments have not been included in the table above as the timing of any future payment is not reasonable estimable.

In 2014, 2013 and 2012, the Company incurred aggregate royalties to Biogen and HRI of \$131.3 million, \$140.7 million and \$122.2 million, respectively, and royalties to AstraZeneca with respect to Cleviprex of \$0.8 million, \$1.0 million and \$1.0 million, and royalties to BMS with respect to Recothrom of \$7.5 million and \$7.4 million, respectively.

*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.

The Company is currently party to the other legal proceedings described in Part I, Item 3. *Legal Proceedings* of this Annual Report on Form 10-K, 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 on Form 10-K, 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 its consolidated results of operations in any one accounting period.

**18. 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, 2014, 2013 and 2012 of \$1.9 million, \$1.6 million and 1.2 million, respectively.

**19. 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Years Ended December 31,					
	2014		2013		2012	
	(In thousands)					
Net revenue:						
United States	\$ 687,830	95.0%	\$ 629,459	91.5%	\$ 512,044	91.7%
Europe	32,859	4.5%	50,419	7.3%	38,517	6.9%
Other	3,719	0.5%	7,986	1.2%	8,027	1.4%
Total net revenue	<u>\$ 724,408</u>		<u>\$ 687,864</u>		<u>\$ 558,588</u>	

	Years Ended December 31,					
	2014		2013			
	(In thousands)					
Long-lived assets:						
United States	\$ 1,218,370	99.3%	\$ 1,139,210	99.2%		
Europe	8,899	0.7%	9,035	0.8%		
Other	15	—%	22	—%		
Total long-lived assets	<u>\$ 1,227,284</u>		<u>\$ 1,148,267</u>			

20. Collaboration Agreements

*AstraZeneca LP*

In April 2012, the Company entered into an agreement with AstraZeneca LP pursuant to which the Company and AstraZeneca LP 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. Since inception, the Company has recognized \$41.0 million in co-promotion income. The agreement was terminated effective December 31, 2014.

*Alnylam Pharmaceuticals, Inc.*

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. Alnylam is responsible for the development costs of the products, subject to an agreed upon limit, until the completion of Phase 1 clinical studies. The Company is responsible for completing and funding the development costs of the products through commercialization, if successful. The Company paid Alnylam \$25 million in an initial license payment, which the Company recorded as research and development expense. The Company has also agreed to pay up to an aggregate of \$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 by the Company 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. In December 2014, under the terms of the license and collaboration agreement with Alnylam, Alnylam initiated a Phase 1 clinical trial of ALN-PCSsc in the UK. Upon initiation of the Phase I clinical trial, the Company incurred a \$10.0 million milestone.

*Boston Scientific Corporation*

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In December 2013, the Company entered into a co-promotion agreement with BSX for the Promus PREMIER Stent System, where the Company and BSX agreed to collaborate to provide promotional support for the Promus PREMIER Stent System in hospitals in the United States. Under the terms of the co-promotion agreement, the Company's sales force began collaborating with the BSX Interventional Cardiology sales force in January 2014. Since inception, the Company has recognized \$5.0 million in co-promotion income. The agreement was terminated effective December 31, 2014.

21. Accumulated Other Comprehensive Loss

The changes in accumulated other comprehensive losses are as follows:

	Foreign currency translation adjustment	Unrealized (gain) loss on available for sale securities	Total
	(in thousands)		
Balance at December 31, 2012	\$ (825)	\$ 59	\$ (766)
Other comprehensive (loss) income before reclassifications	(3,876)	(10)	(3,886)
Amounts reclassified from accumulated other comprehensive income*	—	—	—
Total other comprehensive (loss) income	(3,876)	(10)	(3,886)
Balance at December 31, 2013	\$ (4,701)	\$ 49	\$ (4,652)
Other comprehensive loss before reclassifications	7,180	—	7,180
Amounts reclassified from accumulated other comprehensive income*	—	—	—
Total other comprehensive loss	7,180	—	7,180
Balance at December 31, 2014	<u>\$ 2,479</u>	<u>\$ 49</u>	<u>\$ 2,528</u>

\* Amounts reclassified affect other income in the consolidated statements of income.

22. Subsequent Events

*Convertible Senior Notes Due 2022*

On January 13, 2015, the Company completed its private offering of \$400.0 million aggregate principal amount of its 2.50% convertible senior notes due 2022 (the 2022 notes) and entered into an indenture (the Indenture) with Wells Fargo Bank, National Association, a national banking association, as trustee (the Trustee), governing the 2022 notes. The aggregate principal amount of 2022 notes sold reflects the exercise in full by the initial purchasers of the 2022 notes of their option to purchase up to an additional \$50.0 million in aggregate principal amount of the 2022 notes. The net proceeds to the Company from the offering were \$387.1 million after deducting the initial purchasers' discounts and commissions and the offering expenses payable by the Company. The Company has not completed its accounting analysis, but expects to account for the 2022 notes as a liability and equity component where the carrying value of the liability component will be valued based on a similar instrument.

The 2022 notes will bear cash interest at a rate of 2.50% per year, payable semi-annually on January 15 and July 15 of each year, beginning on July 15, 2015. The 2022 notes will mature on January 15, 2022.

## THE MEDICINES COMPANY

Holders may convert their 2022 notes at their option at any time prior to the close of business on the business day immediately preceding October 15, 2021 only under the following circumstances: (1) during any calendar quarter commencing on or after March 31, 2015 (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 on each applicable trading day; (2) 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 governing the 2022 notes) per \$1,000 principal amount of 2022 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; (3) during any period after the Company has issued notice of redemption until the close of business on the scheduled trading day immediately preceding the relevant redemption date; or (4) upon the occurrence of specified corporate events. On or after October 15, 2021, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2022 notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay cash up to the aggregate principal amount of the 2022 notes to be converted and deliver shares of its common stock in respect of the remainder, if any, of its conversion obligation in excess of the aggregate principal amount of 2022 notes being converted, subject to a daily share cap.

The conversion rate for the 2022 notes will initially be 29.8806 shares of the Company's common stock per \$1,000 principal amount of the 2022 notes, which is equivalent to an initial conversion price of approximately \$33.47 per share of the Company's common stock. The initial conversion price of the 2022 notes represents a premium of approximately 35.0% to the last reported sale price per share of the Company's common stock of \$24.79 per share on January 7, 2015, the date that the Company priced the private offering of the 2022 notes.

The Company may not redeem the 2022 notes prior to January 15, 2019. The Company may redeem for cash all or any portion of the 2022 notes, at its option, on or after January 15, 2019 if the last reported sale price of its common stock has been at least 130% of the conversion price then in effect on the last trading day of, and for at least 19 other trading days (whether or not consecutive) during, any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the 2022 notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2022 notes, which means that the Company is not required to redeem or retire the 2022 notes periodically.

If the Company undergoes a fundamental change (as defined in the Indenture governing the 2022 notes), subject to certain conditions, holders of the 2022 notes may require the Company to repurchase for cash all or part of their 2022 notes at a repurchase price equal to 100% of the principal amount of the 2022 notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2022 notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the 2022 notes; equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

The Indenture governing the 2022 notes contains customary events of default with respect to the 2022 notes, including that upon certain events of default (including the Company's failure to make any payment of principal or interest on the 2022 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 2022 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) shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2022 notes to be due and payable. In case of 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 2022 notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

*Annovation.* On February 2, 2015, the Company completed the acquisition of Annovation BioPharma, Inc. (Annovation), and Annovation became the Company's wholly owned subsidiary. As a result of the acquisition of Annovation, the Company acquired ABP-700, a novel intravenous anesthetic. Under the terms of the terms of the acquisition agreement, the Company paid to the holders of Annovation's capital stock and the holders of options to purchase shares of Annovation's capital stock, which the Company refers to collectively as the Annovation equityholders, an aggregate of approximately \$28.4 million in cash. In addition, the Company may be obligated to pay Annovation's equityholders up to an additional \$26.3 million in milestone payments subsequent to the closing if the Company achieves certain development and regulatory approval milestones at the times and on the conditions set forth in the acquisition agreement. The Company has also agreed to pay Annovation equityholders a low single

## THE MEDICINES COMPANY

digit percentage of worldwide net sales, if any, of certain Annovation products, including ABP-700, during a specified earnout period. In addition, as a result of the Company's acquisition of Annovation, it, through its subsidiary Annovation, is a party to a license agreement with The General Hospital Corporation. Under the agreement, the Company will be obligated to pay General Hospital Corporation up to an aggregate of \$6.5 million upon achievement of specified development, regulatory and sales milestones. The Company will also be obligated to pay General Hospital Corporation low single-digit percentage royalties on a product-by-product and country-by-country basis based on net sales of ABP-700 products until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell ABP-700 products in a country and the date ten years from the Company first commercial sale of ABP-700 products in such country.

*Recothrom.* On February 6, 2015, the Company completed the acquisition of Recothrom assets from BMS. In February 2013, pursuant to a master transaction agreement with BMS, the Company acquired the right to sell, distribute and market Recothrom on a global basis for a two-year period, which is referred 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 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. Pursuant to the agreement, the Company exercised the option and on February 6, 2015 completed the acquisition of the remaining assets held by BMS which are exclusively related to Recothrom.

Under the master transaction agreement, in February 2013 the Company paid to BMS a one-time collaboration fee equal to \$105.0 million and a one-time option fee equal to \$10.0 million. Upon closing the exercise of the option in February 2015, the Company paid BMS approximately \$127.7 million in the aggregate, including approximately \$39.3 million for inventory. In addition, the Company has agreed to pay BMS up to an additional \$4.9 million upon the delivery of certain additional inventory following the closing, subject to specified terms and conditions. The Company did 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 any significant tangible assets related to the Recothrom business, other than inventory. Under the master transaction agreement, the Company paid BMS quarterly tiered royalty payments during the two-year collaboration term equal to a percentage of worldwide net sales of Recothrom.

### 23. Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the years ended December 31, 2014 and 2013.

	Three Months Ended							
	Mar. 31, 2014	June 30, 2014	Sept. 30, 2014	Dec. 31, 2014	Mar. 31, 2013	June 30, 2013	Sept. 30, 2013	Dec. 31, 2013
	(4)		(3)	(4)	(1)			(2)
(In thousands, except per share data)								
Net revenue	\$ 177,235	\$ 183,774	\$ 172,401	\$ 190,998	\$ 155,753	\$ 172,826	\$ 174,282	\$ 185,003
Cost of revenue	66,867	85,687	69,076	66,000	56,714	63,938	65,794	76,339
Total operating expenses	162,484	215,660	185,052	225,779	178,392	143,907	151,509	200,865
Net income (loss) attributable to The Medicines Company	(4,996)	(5,157)	(16,736)	(5,323)	(11,573)	18,094	7,793	1,198
Basic net income per common share attributable to The Medicines Company	\$ (0.08)	\$ (0.08)	\$ (0.26)	\$ (0.08)	\$ (0.21)	\$ 0.33	\$ 0.13	\$ 0.02
Diluted net income per common share attributable to The Medicines Company	\$ (0.08)	\$ (0.08)	\$ (0.26)	\$ (0.08)	\$ (0.21)	\$ 0.30	\$ 0.12	\$ 0.02

- (1) Net loss for the first quarter of 2013 includes licensing costs of \$25.0 million for a transaction with Alnylam on the PCSK9 RNAi hypercholesterolemia program.
- (2) Net income for the fourth quarter of 2013 includes a \$10.9 million increase related to the progression in development work for IONSYS related to the Company's Incline acquisition and a tax benefit of \$13.6 million from reducing the Company's deferred tax liabilities associated with the Incline acquisition.
- (3) In December 2014, the Company entered into a settlement and amendment to the merger agreement with Incline Therapeutics, Inc., which resulted in revisions to certain milestone triggers, a reduction in total milestone payments and the release of the escrow funds to the Company. As a result, net loss for the fourth quarter of 2014 includes \$25.7 million in one-time income in connection with the settlement with the former equityholders of Incline related to the representations and warranties included in the merger agreement.
- (4) Net loss for the second and fourth quarters of 2014 includes impairment charges on product licenses in the amount of \$15.1 million and \$6.4 million, respectively to cost of sales, as a result of reductions in estimated future cash flows expected to be generated by the acute care generic products as determined by an updated discounted cash flow analysis (Level 3).

### INDEX TO EXHIBITS

Number	Description
2.1	Agreement and Plan of Merger among the registrant, Boxford Subsidiary Corporation, and Targanta Therapeutics Corporation, dated as of January 12, 2009 (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed on January 14, 2009).
2.2#†	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 (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed January 10, 2013).
2.3†	Settlement and Amendment to Agreement and Plan of Merger, dated as of December 8, 2014, by and between the registrant and Fortis Advisors LLC. (filed herewith)
2.4#†	Master Transaction Agreement, dated December 11, 2012, by and between the registrant and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed February 8, 2013).
2.5#†	Share Purchase Agreement, dated June 4, 2013, by and among the registrant, ProFibrix B.V., the equityholders of ProFibrix, certain members of the management team of ProFibrix in their capacities as warrantors of certain information in the Share Purchase Agreement, the holders of options to acquire equity interests in ProFibrix and the representative (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed August 7, 2013).
2.6#†	Agreement and Plan of Merger, dated December 3, 2013, by and among the registrant, Rempex Pharmaceuticals, Inc., Ravioli Acquisition Corp. and Fortis Advisors LLC (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K filed December 6, 2013).
2.7#†	Agreement and Plan of Merger, dated April 21, 2014, by and among the Company, Tenaxis, Napa Acquisition Corp. and Fortis Advisors LLC (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K filed May 7, 2014).
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).
4.2	Indenture (including Form of Notes), dated as of January 13, 2015, 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 January 13, 2015).
10.1†	License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant (incorporated by reference to Exhibit 10.6 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)).
10.2†	License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc. (incorporated by reference to Exhibit 10.7 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)).
10.3†	License Agreement effective as of March 28, 2003 by and between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.17 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2003).
10.4†	Amendment No. 1 to License Agreement dated April 25, 2006 by and between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2006).
10.5	Amendment No. 2 to License Agreement, dated October 22, 2008 by and between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.38 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.6†	License Agreement dated as of December 18, 2003 by and between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.18 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2003).
10.7†	Amendment to License Agreement dated July 6, 2007 between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2007).

Number	Description
10.8	Second Amendment to License Agreement dated as of June 1, 2010 between AstraZeneca AB and the registrant (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2010).
10.9†	Second Amended and Restated Distribution Agreement effective as of October 1, 2010 between the registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.54 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010).
10.10†	First Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.11†	Second Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.6 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.12†	Third Amendment to Second Amended and Restated Distribution Agreement, dated April 23, 2012, between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2012).
10.13†	Fourth Amendment to Second Amended and Restated Distribution Agreement, dated April 29, 2013, by and between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2013).
10.14	Fifth Amendment to Second Amended and Restated Distribution Agreement, dated September 12, 2013, by and between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2013).
10.15†	Sixth Amendment to Second Amended and Restated Distribution Agreement, effective as of March 1, 2014, by and between registrant and Integrated Commercialization Solutions, Inc. (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2014).
10.16	License Agreement, dated December 23, 2005 by and between Targanta Therapeutics Corporation (as successor to InterMune, Inc.) and Eli Lilly and Company (incorporated by reference to 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).
10.17†	License Agreement dated as of December 18, 2009 between the registrant and Pfizer Inc. (incorporated by reference to Exhibit 10.41 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009).
10.18†	License Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.19†	Contract Manufacturing Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.20†	License and Supply Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.21†	AG Supply Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.22†	License Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.23†	Supply Agreement, dated September 30, 2011, between registrant and Plantex USA Inc. (incorporated by reference to Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.24†	Amendment 1 to the Supply Agreement, dated February 13, 2012, between registrant and Teva API, Inc. (formerly known as Plantex USA Inc.) (incorporated by reference to Exhibit 10.6 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.25†	License and Asset Transfer Agreement, dated June 21, 2010, between ALZA Corporation and Incline Therapeutics Inc. (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2013).
10.26†	License and Collaboration Agreement, dated February 3, 2013, between Alnylam Pharmaceuticals, Inc. and the registrant (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the registrant's quarterly report on Form 10-Q/A for the quarter ended March 31, 2013).

Number	Description
10.27†	Patent Licensing Agreement, dated October 25, 2004, by and between Quadrant Drug Delivery Limited and ProFibrix B.V., as amended by Amendment Deed No. 1, dated February 14, 2007, Amendment Deed No. 2, dated June 12, 2007, and Amendment Deed No. 3, dated July 2, 2012. (incorporated by reference to Exhibit 10.1 of the registrant's quarterly report on Form 10-Q for the period ended September 30, 2013).
10.28†	Chemilog Development and Supply Agreement, dated as of December 20, 1999, by and between the registrant and UCB Bioproducts S.A. (incorporated by reference to Exhibit 10.5 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)).
10.29†	Manufacturing Services Agreement, dated March 30, 2011, between registrant and Patheon International A.G. (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.30†	Agreement dated January 15, 2014 with effect from February 4, 2014 between Rempex Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2014).
10.31*	Consulting Agreement, dated July 6, 2012, by and between the registrant and Strategic Imagery, LLC (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2012).
10.32*	Amendment to Consulting Agreement, dated December 3, 2012, by and between the registrant and Strategic Imagery, LLC (incorporated by reference to Exhibit 10.66 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2012).
10.33*	Second Amendment to Consulting Agreement, dated July 6, 2013, by and between the registrant and Strategic Imagery, LLC. (filed herewith)
10.34*	Third Amendment to Consulting Agreement, dated July 7, 2014, by and between the registrant and Strategic Imagery, LLC. (filed herewith)
10.35	Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (incorporated by reference to Exhibit 10.32 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.36	Amendment to Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (incorporated by reference to Exhibit 10.40 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.37†	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 (incorporated by reference to Exhibit 10.42 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009).
10.38†	Settlement Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011).
10.39†	Settlement Agreement, dated January 22, 2012, between registrant and APP Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2012).
10.40*	Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell (incorporated by reference to Exhibit 10.12 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)).
10.41*	Letter Agreement dated March 2, 2006 by and between the registrant and Glenn P. Sblendorio, (incorporated by reference to Exhibit 10.23 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2005).
10.42*	Restricted stock agreement of Clive Meanwell under the registrant's Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.53 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010).
10.43*	Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Clive Meanwell and Glenn Sblendorio (incorporated by reference to Exhibit 10.24 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).

Number	Description
10.44*	Form of Amended and Restated Management Severance Agreement by and between the registrant and William O'Connor (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.45*	Director Compensation Summary. (incorporated by reference to Exhibit 10.10 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013).
10.46*	Summary of Performance Measures under the registrant's Annual Cash Bonus Plan (incorporated by reference to Item 5.02 of the registrant's current report on Form 8-K, filed on February 27, 2012).
10.47*	1998 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)).
10.48*	2000 Outside Director Stock Option Plan, as amended (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003).
10.49*	2001 Non-Officer, Non-Director Employee Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the registration statement on Form S-8 filed December 5, 2001 (registration no. 333-74612)).
10.50*	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).
10.51*	Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the registrant's registration statement on Form S-8, dated June 30, 2010).
10.52*	Form of stock option agreement under 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.22 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2004).
10.53*	Form of restricted stock agreement under 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006).
10.54*	Form of restricted stock agreement under the registrant's Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010).
10.55*	2007 Equity Inducement Plan (incorporated by reference to Exhibit 10.1 to the registration statement on Form S-8 filed January 11, 2008 (registration no. 333-148602)).
10.56*	Form of stock option agreement under 2007 Equity Inducement Plan (incorporated by reference to Exhibit 10.34 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.57*	Form of restricted stock agreement under 2007 Equity Inducement Plan (incorporated by reference to Exhibit 10.35 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.58*	2009 Equity Inducement Plan (incorporated by reference to Exhibit 10.1 to the registration statement on Form S-8 filed February 24, 2009 (registration number 333-157499)).
10.59*	Form of stock option agreement under 2009 Equity Inducement Plan (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009).
10.60*	Form of stock option agreement for employees in Italy under 2009 Equity Inducement Plan (incorporated by reference to Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009).
10.61*	Form of restricted stock agreement under 2009 Equity Inducement Plan (incorporated by reference to Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009).
10.62*	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).
10.63*	The Medicines Company 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2013).

Number	Description
10.64*	Amendment No. 1 to The Medicines Company 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2014).
10.65*	Form of employee stock option agreement under the registrant's 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2013).
10.66*	Form of non-employee director stock option agreement under the registrant's 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2013).
10.67*	Form of employee restricted stock option agreement under the registrant's 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2013).
10.68*	Form of non-employee director restricted stock option agreement under the registrant's 2013 Stock Incentive Plan (incorporated by reference as Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2013).
10.69	Contingent Payment Rights Agreement dated February 25, 2009 between the registrant and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 99.1 of the registrant's current report on Form 8-K, filed on March 2, 2009).
21	Subsidiaries of the registrant. (filed herewith)
23	Consent of Ernst & Young LLP, Independent Registered Accounting Firm. (filed herewith)
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. (filed herewith)
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. (filed herewith)
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. (furnished herewith)
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. (furnished herewith)
101.INS	The following materials from The Medicines Company Annual Report on Form 10-K for the year ended December 31, 2014, 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
#	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.





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