

MEDICINES CO /DE
Form 10-K/A
June 05, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 1)

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2011

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 000-31191

THE MEDICINES COMPANY

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

(Exact name of registrant as specified in its charter)

Delaware

04-3324394

(State or other jurisdiction of
incorporation or organization)

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

8 Sylvan Way

Parsippany, New Jersey

07054

(Address of principal executive offices)

(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.

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

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

DOCUMENTS INCORPORATED BY REFERENCE

On April 27, 2012, the registrant filed a proxy statement pursuant to Regulation 14A. Portions of the proxy statement are incorporated by reference into the following parts of the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2011:

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 Accountant Fees and Services.

Explanatory Note

This Amendment No. 1 to The Medicines Company's (the "Company") Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which was filed with the Securities and Exchange Commission (the "SEC") on February 29, 2012 (the "Original 10-K"), is being filed solely for the purpose of correcting certain clerical errors contained in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"), of the Original 10-K. Specifically, the last sentence of the Contractual Obligations subsection of MD&A, found on page 28 of this Amendment No. 1, which states the royalty payments made to Biogen, Inc. and Health Research, Inc. in 2011 and 2010 and to AstraZeneca in 2011 and 2010 has been revised to reflect the correct amounts paid in conformity with the Company's audited consolidated financial statements included with the Original 10-K. In addition, certain disclosure in MD&A, found on pages 18 and 34 of this Amendment No. 1, has been revised to reflect the value of the Company's deferred tax assets at December 31, 2011 of \$110.4 million rather than \$112.5 million as stated in the Original 10-K. The cover page of this Amendment No. 1 has been updated to reflect the filing on April 27, 2012 of the Company's definitive proxy statement pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with its 2012 Annual Meeting of Stockholders, portions of which proxy statement are incorporated by reference herein. This Amendment No. 1 does not reflect the restatement of any previously reported financial statements or change any other disclosures.

This Amendment No. 1 continues to speak as of the date of the Original 10-K and the Company has not updated or amended the disclosures contained herein to reflect events that have occurred since the filing of the Original 10-K, or modified or updated those disclosures in any way other than as described in the preceding paragraph. Accordingly, this Amendment No. 1 should be read in conjunction with the Company's filings made with the SEC subsequent to the filing of the Original 10-K.

As a result of this Amendment No. 1, as required by Rule 12b-15 under the Exchange Act the Company is filing new certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by its principal executive officer and principal financial officer as exhibits to this Amendment No. 1 under Item 15 of Part IV hereof.

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

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

Overview

Our Business

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have three marketed products, Angiomax®(bivalirudin), Cleviprex® (clevidipine butyrate) injectable emulsion and our ready-to-use formulation of Argatroban. We have not sold our ready-to-use formulation of Argatroban since its voluntary recall in December 2011. We also have a pipeline of acute and intensive care hospital products in development, including three late-stage development product candidates, cangrelor, oritavancin and MDCO-157, and two early stage development product candidates, MDCO-2010 and MDCO-216. In addition, in January 2012 we acquired from APP Pharmaceuticals, LLC, or APP, non-exclusive rights to market in the United States a portfolio of ten generic drugs, which we refer to as our acute care generic products.

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

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

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

Angiomax Patent Litigation

The principal U.S. patents covering Angiomax include the 404 patent, the 727 patent and the 343 patent. The 404 patent, was set to expire in March 2010, but was extended on an interim basis to August 13, 2012 under the Hatch-Waxman Act following our litigation against the U.S. Patent and Trademark Office, or PTO, the Food and Drug Administration, or FDA, and

the U.S. Department of Health and Human Services, or HHS. On January 31, 2012, the PTO issued a notice of final determination finding the 404 patent eligible for patent term extension under the Hatch-Waxman Act and concluding that the term of extension ends on December 15, 2014. On February 3, 2012, we accepted the extension of the term of the 404 patent. The PTO has not yet issued a certificate of extension, but we expect to receive it shortly. As a result of our study of Angiomax in the pediatric setting, we are entitled to a six-month period of pediatric exclusivity following expiration of the 404 patent. If the term of the 404 patent is extended to December 15, 2014, we believe that this pediatric exclusivity would extend until June 15, 2015.

On January 22, 2012, we entered into a legal settlement with APP in which APP agreed to dismiss its appeal of the federal district court's August 3, 2010 order that the PTO consider our patent term extension application timely filed. Upon dismissal of APP's appeal, all pending litigation regarding the 404 patent was resolved.

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

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

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

Cleviprex Resupply, Re-launch and Formulation

In December 2009 and March 2010, we conducted voluntary recalls of manufactured lots of Cleviprex due to the presence of visible particulate matter at the bottom of some vials. As a result, we were not able to supply the market with Cleviprex and sell Cleviprex from the first quarter of 2010 through the first quarter of 2011. We cooperated with the FDA and our contract manufacturer to remedy the problem at the manufacturing site that resulted in the recalls. We began to resupply existing customers with Cleviprex in April 2011. In June 2011, the FDA approved our supplemental New Drug Application, or sNDA, for an improved formulation of Cleviprex. The new formulation triples the maximum allowable infusion time per vial, commonly referred to in hospitals as hang time, to 12 hours compared to the original 4-hour hang time vial approved by the FDA in 2008. We re-launched Cleviprex in October 2011 with the new formulation, targeting neurocritical care patients, including intracranial bleeding and acute ischemic stroke patients requiring blood pressure control, and cardiac surgery patients, including patients undergoing coronary artery bypass graft surgery, heart valve replacement or repair, and surgery for the repair of aortic dissection.

Distribution and Sales

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

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

Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on our customers historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and other specified conditions.

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

In Europe, we market and sell Angiox with a sales force that, as of February 15, 2012, consisted of 41 engagement partners and engagement managers experienced in selling to hospital customers. Our European sales force targets hospitals with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. In October 2011,

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

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

Workforce Reductions

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

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

Business Development Activity

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

quarter of 2012. We also agreed to pay contingent milestone payments of up to an additional 25.0 million if we

proceed with further clinical development of MDCO-2010 and achieve a commercial milestone and to pay royalties based on net sales.

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

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

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

- Upon approval from the European Medicines Agency of a Marketing Authorization Application for oritavancin for the treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI (which were formerly referred to as complicated skin and skin structure infections) on or before December 31, 2013, approximately \$10.5 million.
- Upon final approval from the FDA of a NDA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$10.5 million.
- Upon final approval from the FDA of an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion on or before December 31, 2013, approximately \$14.7 million. This payment may become payable simultaneously with the payment described in the previous bullet above.
- If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million.

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

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

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

GeNO, LLC. In December 2011, we made a \$7.5 million non-controlling equity investment in GeNO, LLC, or GeNO, an advanced, development-stage privately held technology company that has created unique nitric oxide generation and delivery technology. In addition to acquiring the equity stake, we also acquired an exclusive option to license GeNO technologies in the acute and intensive care hospital setting in certain geographies. GeNO's product candidate is currently in clinical trials. Nitric oxide therapy is approved for the treatment of term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension and its use avoids more invasive and costly therapies for these infants.

U.S. Health Care Reform

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

Results of Operations

Years Ended December 31, 2011 and 2010

Net Revenue:

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

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

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

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

Cleviprex/Argatroban. Cleviprex net sales increased by \$0.1 million in 2011 compared to 2010 as the 2010 period reflected an offset of \$0.7 million due to returns related to the Cleviprex recall. We began to resupply existing customers with Cleviprex in April 2011 and re-launched Cleviprex in October 2011 with a new formulation. Ready-to-use Argatroban net sales in 2011 were completely offset by returns related to the Argatroban recall in December 2011. We did not recognize any revenue from sales of ready-to-use Argatroban in 2010 as it was not approved until July 2011.

Cost of Revenue:

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

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

Cost of Revenue

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

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

Research and Development Expenses:

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

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

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

Research and Development Spending

| | Year Ended December 31, | | % of Total R&D | Year Ended December 31, | | % of Total R&D |
|------------------------------------|-------------------------|-------------------|-------------------|-------------------------|-------------------|-------------------|
| | 2011 (In thousands) | % of Total R&D | | 2010 (In thousands) | % of Total R&D | |
| Angiomax | | | | | | |
| Clinical trials | \$ 6,606 | 6% | \$ 6,439 | 7% | | |
| Manufacturing development | 288 | % | 4,466 | 5% | | |
| Administrative and headcount costs | 2,574 | 3% | 2,381 | 3% | | |
| Total Angiomax | 9,468 | 9% | 13,286 | 15% | | |
| Cleviprex | | | | | | |
| Clinical trials | 1,492 | 1% | 1,545 | 2% | | |
| Manufacturing development | 295 | % | 1,777 | 2% | | |
| Administrative and headcount costs | 1,557 | 2% | 1,835 | 2% | | |
| Total Cleviprex | 3,344 | 3% | 5,157 | 6% | | |
| Cangrelor | | | | | | |
| Clinical trials | 26,823 | 24% | 9,232 | 11% | | |
| Manufacturing development | 955 | 1% | 1,998 | 2% | | |
| Administrative and headcount costs | 6,671 | 6% | 7,328 | 9% | | |
| Total Cangrelor | 34,449 | 31% | 18,558 | 22% | | |
| Oritavancin | | | | | | |
| Clinical trials | 21,944 | 20% | 6,196 | 7% | | |
| Manufacturing development | 3,454 | 3% | 8,199 | 10% | | |
| Administrative and headcount costs | 5,221 | 5% | 7,609 | 9% | | |
| Total Oritavancin | 30,619 | 28% | 22,004 | 26% | | |
| MDCO-157 | | | | | | |

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

| | | | | |
|--------------------------------------|-------------------|-------------|------------------|-------------|
| Administrative and headcount costs | 1,072 | 1% | | % |
| Acquisition license fee | 1,750 | 2% | | % |
| Total MDCO-157 | 2,822 | 3% | | % |
| MDCO-2010 | | | | |
| Clinical trials | 713 | 1% | 2,056 | 2% |
| Manufacturing development | 416 | % | 1,475 | 2% |
| Administrative and headcount costs | 4,637 | 4% | 4,288 | 5% |
| Clinical milestone | 5,275 | 5% | 4,329 | 5% |
| Government subsidy | (222) | % | (1,403) | (1)% |
| Total MDCO-2010 | 10,819 | 10% | 10,745 | 13% |
| MDCO-216 | | | | |
| Clinical trials | 692 | 1% | 689 | 1% |
| Manufacturing development | 2,364 | 2% | 2,716 | 3% |
| Administrative and headcount costs | 1,373 | 1% | 608 | 1% |
| Total MDCO-216 | 4,429 | 4% | 4,013 | 5% |
| Ready-to-Use Argatroban | | | | |
| Manufacturing development | | % | 316 | % |
| Administrative and headcount costs | 491 | % | 629 | 1% |
| Total Ready-to-Use Argatroban | 491 | % | 945 | 1% |
| Other | 13,739 | 12% | 10,533 | 12% |
| Total | \$ 110,180 | 100% | \$ 85,241 | 100% |

Angiomax

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

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

Cleviprex

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

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

Cangrelor

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

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

Oritavancin

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

We expect to incur increased research and development expenses relating to oritavancin in 2012 as compared to 2011 due to the SOLO I and SOLO II clinical trials. We plan to enroll a total of approximately 2,000 patients in the SOLO I and SOLO II clinical trials and to test the use of a simplified dosing regimen involving a single dose of oritavancin as compared to multiple doses of vancomycin for the treatment of ABSSSI. We currently have enrolled approximately 700 patients in the SOLO I and SOLO II clinical trials. We have decided to focus on accelerating enrollment in the SOLO I trial and expect to complete enrollment in such trial in the third quarter of 2012. If the SOLO I trial results are positive, we plan to accelerate enrollment in the SOLO II trial. Under the accelerated timeline, if the results of the trials warrant it, we would expect to file an NDA in the first half of 2013.

MDCO-157

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

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

MDCO-2010

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

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

MDCO-216

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

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

Ready-to-Use Argatroban

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

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

Other Research and Development Expense

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

Our success in further developing Angiomax and obtaining marketing approvals for Angiomax in additional countries and for additional patient populations, developing and obtaining marketing approvals for Cleviprex outside the United States, and developing and obtaining marketing approvals for our products in development, is highly uncertain. We cannot predict expenses associated with ongoing data analysis or regulatory submissions, if any. Nor can we reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to continue the development of Angiomax, Cleviprex and our products in development, or the period in which material net cash inflows are expected to commence from further developing Angiomax and Cleviprex, obtaining marketing approvals for Angiomax in additional countries and additional patient populations and for Cleviprex outside the United States or developing and obtaining marketing approvals for our products in development, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

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

Selling, General and Administrative Expenses:

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

shareholders and \$5.3 million of lower general and administrative spending resulting from a reduction in personnel costs due to the first quarter 2010 reduction in force and the closure of our Indianapolis site.

Legal settlement:

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

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

Other income (expense):

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

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

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

Benefit from Income Tax:

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

On a periodic basis, we evaluate our ability to realize our deferred tax assets net of deferred tax liabilities and adjust such amounts in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, any regulatory or legislative actions by relevant authorities with respect to the Angiomax patents, and the status of litigation with respect to those patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation

allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods. During 2011, based on review of the following positive and negative evidence, we reduced our valuation allowance against our deferred tax assets by \$66.5 million and recorded a corresponding tax benefit.

Positive:

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

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

- on September 30, 2011, we entered into a settlement agreement and a license agreement with Teva, with respect to our patent infringement suits against Teva, which includes our suit against Pliva Hrvatska d.o.o., et al. As part of the settlement agreement, Teva admitted that the 727 patent and 343 patent are valid and enforceable and that they would be infringed by the manufacture and sale of Teva's generic bivalirudin for injection products. Under the license agreement, we granted Teva a non-exclusive license under the 727 patent and 343 patent to sell a generic bivalirudin for injection product under a Teva ANDA in the United States beginning June 30, 2019 or earlier under certain conditions;

- on January 22, 2012, we entered into a settlement agreement and a license agreement with APP with respect to APP's appeal (as described in the first bullet above) and the patent infringement suits. Under the settlement agreement, APP admitted that the 727 patent and 343 patent are valid and enforceable and that they would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDAs. In connection with the settlement, we entered into a license agreement with APP under which we granted APP a non-exclusive license under the 727 patent and 343 patent to sell a generic bivalirudin for injection product in the United States beginning on May 1, 2019. In certain

limited circumstances, this license to APP could become effective prior to May 1, 2019 and could include an authorized generic bivalirudin product supplied by us; and

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

Negative:

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

In 2011, we recorded a \$66.5 million income tax benefit by reducing our valuation allowance to \$4.2 million against \$110.4 million of deferred tax assets compared to a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets at December 31, 2010. Any changes to the valuation allowance or deferred tax assets in the future would impact our income taxes.

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

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

Years Ended December 31, 2010 and 2009

Net Revenue:

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

Net Revenue

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

Net revenue during 2010 increased by \$33.4 million compared to 2009 primarily due to an increase in sales of Angiox in Europe and an increase in sales of Angiomax in the United States. The net revenue increase was comprised of net volume increases of \$39.8 million, price decreases of \$5.5 million and the unfavorable impact from foreign exchange of \$0.9 million. Net sales in the United States in both 2011 and 2010 reflect chargebacks related to the 340B Drug Pricing Program under the Public Health Services Act and rebates related to the PPACA. Under this program, we offer qualifying entities a discount off the commercial price of Angiomax for patients undergoing PCI on an outpatient basis. These chargebacks were higher in 2010 than 2009, reflecting increased sales of Angiomax under the program. U.S. sales also include net revenue of \$0.8 million from sales of Cleviprex in 2010 compared to \$3.0 million in 2009, as we did not sell any Cleviprex during 2010 after the first quarter as a

result of the recalls and related supply issues. The \$0.8 million in sales of Cleviprex in 2010 reflects an offset of \$0.7 million due to returns related to the 2010 Cleviprex recall.

International net revenue increased by \$6.3 million during 2010 compared to 2009 primarily as a result of increased demand for Angiox in France, Italy, Sweden and the United Kingdom, which increased demand was partially offset by decreased sales of Angiomax in Canada.

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

Cost of Revenue:

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

Cost of Revenue

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

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

Research and Development Expenses:

Research and development expenses decreased by 28% to \$85.2 million for 2010, compared to \$117.6 million for 2009. The decrease primarily reflects reduced clinical activity for cangrelor as we discontinued enrollment in the CHAMPION clinical trial program for cangrelor in

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

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

Research and Development Spending

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

Angiomax

Research and development spending related to Angiomax during 2010 decreased by approximately \$8.9 million compared to 2009, primarily due to a decrease of \$8.0 million in manufacturing development expenses related to product lifecycle management activities. Administrative costs in 2010 decreased by \$2.0 million primarily reflecting the increased costs incurred in 2009 in connection with the regulatory filing filed with the FDA in the second quarter of 2009 related to the report of the clinical study conducted to obtain the pediatric extension. These decreases were partially offset by an increase of \$1.1 million in clinical trial costs, primarily due to increased expenditures in connection with our Phase 4 EUROMAX and EUROVISION clinical trials. We commenced enrollment in our Phase 4 EUROMAX clinical trial in March 2010. In October 2010 we completed enrollment in our EUROVISION trial with 2,022 patients at 70 sites in six European countries.

Cleviprex

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

Cangrelor

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

Oritavancin

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

MDCO-2010

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

MDCO-216

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

Ready-to-Use Argatroban

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

Other

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

Selling, General and Administrative Expenses:

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

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

Other (Expense):

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

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

Benefit from (Provision for) Income Tax:

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

We recorded a \$40.5 million net benefit from income taxes for 2010 based on income before taxes of \$64.1 million and a \$48.1 million provision for income taxes for 2009 based on losses before income taxes of \$28.2 million. Our effective income tax rates for 2010 and 2009 were approximately 63.1% and 170.6%, respectively. The net benefit from income taxes in 2010 was driven mainly by our decision to reduce the valuation allowance against our deferred tax assets by \$45.2 million as it is more likely than not that we will realize the future benefit of these assets. The 2009 provision for income taxes was driven mainly by our decision to increase the valuation allowance against our deferred tax assets by \$47.7 million to \$171.4 million (100%) as we determined at that time that it was more likely than not that we would not realize the future benefit of any of these assets.

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

Positive:

- our deferred tax assets primarily relate to U.S. net operating losses and tax credits, the oldest of which will not expire until 2028;
- for the most recent three fiscal years, our reported cumulative U.S. income before income taxes totaled approximately \$95 million and we utilized approximately \$137 million of net operating loss carryforwards in our U.S. income tax returns;
- in 2010, our operating income exceeded \$64 million and we expect to be profitable in 2011;

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

- in August 2010, the U.S. District Court for the Eastern District of Virginia ordered the PTO to consider our patent extension application for the 404 patent that covers Angiomax timely filed;
- in August 2010, the PTO granted a one-year interim extension of the term of the 404 patent that covers Angiomax;
- the PTO and FDA thereafter initiated the regulatory process to reach a final determination of the extension of the term of the 404 patent, which is proceeding as set forth in the regulations;
- in October 2010, the period for the U.S. government to appeal the federal district court's August 2010 decision expired and the U.S. government did not appeal;
- additional U.S. patents that cover Angiomax exist through July 2028;
- in February 2011, we entered into a settlement agreement with one of our law firms resolving our potential claims related to the 404 patent. Terms of the settlement include \$18 million in expense reimbursement paid upfront and up to an additional \$214 million available for damages in the event of launch of a generic version of Angiomax in the United States before June 15, 2015 as a result of the extension of the 404 patent being held invalid on the basis that the application for the extension was not timely filed; and
- our second product, Cleviprex, was approved for sale in the United States; we expect it to generate revenue well past the term of the 404 patent.

Negative:

- since inception, except for 2004, 2006 and 2010, we have incurred net losses on an annual basis, as of December 31, 2010, we had an accumulated deficit of approximately \$239.5 million;
- our primary revenue generating product, Angiomax, could face generic competition before June 15, 2015 if the extension of the 404 patent is held invalid and we are not successful in defending the additional Angiomax patents that expire in July 2028; and
- we are currently involved in patent infringement litigation relating to the additional U.S. Angiomax patents with a number of companies that, if unfavorably resolved, would adversely affect future operations and profit levels.

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

Liquidity and Capital Resources

Sources of Liquidity

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

Cash Flows

As of December 31, 2011, we had \$315.4 million in cash and cash equivalents, as compared to \$126.4 million as of December 31, 2010. Our primary sources of cash during 2011 included \$96.4 million of net cash provided by operating activities, which includes the impact of the approximately \$18.0 million received from the legal settlement with WilmerHale, \$78.4 million in net cash provided by investing activities and \$16.1 million in net cash provided by financing activities.

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

The cash provided by operating activities in 2010 reflected a net income of \$104.6 million, offset by non-cash items of \$24.8 million consisting primarily of a deferred tax benefit of \$43.6 million, stock-based compensation expense of \$8.3 million and depreciation and amortization of \$6.1 million. Cash provided by operating activities in 2010 also included a decrease of \$12.4 million due to changes in working capital items. These changes in working capital items reflect an increase in accounts receivable of \$16.6 million due to increased volume of our sales of Angiomax.

During 2011, \$78.4 million in net cash was provided by investing activities, which reflected \$126.7 million in proceeds from the maturity and sale of available for sale securities and a \$1.0 million decrease in restricted cash resulting from a reduction of our outstanding letter of credit associated with the lease of our principal executive offices, offset by \$33.6 million used to purchase available for sale securities, \$7.0 million used to acquire intangible assets, \$7.5 million used for a non-controlling equity investment in GeNO, LLC and \$1.3 million used to purchase fixed assets.

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

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

Funding Requirements

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

- the extent to which Angiomax is commercially successful globally;

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

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

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

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

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

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

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

If our existing cash resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements due to slower than anticipated sales of Angiomax and Cleviprex or higher than anticipated costs globally, we may need to sell equity or debt securities or seek additional financing through other arrangements.

Any sale of additional equity or debt securities may result in dilution to our stockholders. Debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all.

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

Certain Contingencies

We may be, from time to time, a party to various disputes and claims arising from normal business activities. We accrue for loss contingencies when information available indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. We believe that the ultimate resolution of these matters will not have a material adverse effect on our financial condition or liquidity. However, adjustments, if any, to our estimates could be material to operating results for the periods in which adjustments to the liability are recorded.

Currently, we are party to the legal proceedings described in Part I, Item 3 of this annual report, We have assessed such legal proceedings and do not believe that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. As a result, we have not recorded a loss contingency related to these legal proceedings.

Contractual Obligations

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

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

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

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

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

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

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

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

In addition to the amounts shown in the above table, we are contractually obligated to make potential future success-based development, regulatory and commercial milestone payments and royalty payments in conjunction with collaborative agreements or acquisitions we have entered into with third-parties. The amount of these contingent payments could be significant. These contingent payments include royalty payments with respect to Angiomax under our license agreements with Biogen Idec and HRI, royalty and milestone payments with respect to Cleviprex, contingent cash payments of up to approximately \$85.1 million that would be owed to former Targanta shareholders under our merger agreement with Targanta and contingent payments with respect to cangrelor, MDCO-157, MDCO-2010, MDCO-216 and ready-to-use Argatroban. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. For these reason, these contingent payments have not been included in the table above. Further, the timing of any future payment is not reasonably estimable. In 2011 and 2010, the Company paid aggregate royalties to Biogen Idec and HRI of \$108.2 million and \$85.5 million and royalties to AstraZeneca with respect to Cleviprex of \$0.9 million and \$0.7 million.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS*, or ASU 2011-04, that clarifies the application of existing guidance and disclosure requirements, changes certain fair value measurement principles and requires additional disclosures about fair value measurements. ASU 2011-04 will be effective for interim and annual periods beginning on or after December 15, 2011 and therefore is effective for us in our first quarter of fiscal 2012 and will be applied prospectively. We do not expect our adoption of ASU 2011-04 to have a material impact on our financial statements.

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

and interim periods within those years, beginning after December 15, 2011 and therefore will be effective for us in our first quarter of fiscal 2012. Early adoption of ASU 2011-05 is permitted; however, we do not expect that we will do so. We believe the adoption of ASU 2011-05 will change the order in

which certain financial statements are presented and provide additional detail on those financial statements when applicable, but will not have any other impact on our financial statements.

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

Application of Critical Accounting Estimates

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

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

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

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

Revenue Recognition

Product Sales. We distribute Angiomax, Cleviprex and, prior to the December 2011 recall of ready-to-use Argatroban, distributed ready-to-use Argatroban, in the United States through a sole source distribution model with ICS. Under this model, we currently sell Angiomax and Cleviprex

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

and, when and if available for sale, expect to sell ready-to-use Argatroban to our sole source distributor, ICS and record revenue upon shipment of Angiomax to ICS. ICS then sells Angiomax and Cleviprex, and, when and if available for sale, would sell, ready-to-use Argatroban to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. We expect that we will also sell the acute care generic products that we acquired the non-exclusive rights to sell and distribute from APP through the same sole source distribution model. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax, Cleviprex and ready-to-use Argatroban in the United States. Under the terms of this fee-for-service agreement, ICS places orders with us for sufficient quantities of Angiomax, Cleviprex and ready-to-use Argatroban to maintain an appropriate level of inventory based on our customers' historical purchase volumes. ICS assumes all credit and inventory risks, is subject to our standard return policy and has sole responsibility for determining

the prices at which it sells Angiomax, Cleviprex and ready-to-use Argatroban, subject to specified limitations in the agreement. The agreement terminates on September 30, 2013, but will automatically renew for additional one-year periods unless either party gives notice at least 90 days prior to the automatic extension. Either party may terminate the agreement at any time and for any reason upon 180 days prior written notice to the other party. In addition, either party may terminate the agreement upon an uncured default of a material obligation by the other party and other specified conditions.

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

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

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

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

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

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

In estimating the likelihood of product being returned, we rely on information from ICS and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. We also

consider the past buying patterns of ICS and wholesalers, the estimated remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

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

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

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

Based on these agreements, most of our hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, we typically provide a credit to ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, we typically pay the rebate directly to the hospitals.

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

We base our estimates on industry data, hospital purchases and the historic chargeback data we receive from ICS, most of which ICS receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds.

Our allowance for chargebacks was \$15.6 million and \$13.9 million at December 31, 2011 and December 31, 2010, respectively. A 10% change in our allowance for chargebacks would have had an approximate \$1.6 million effect on our reported net revenue for the year ended December 31, 2011. Our accrual for rebates was \$1.2 million at December 31, 2011. We did not have any significant allowance for rebates at December 31, 2010 or 2009.

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

We have adjusted our allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past based on actual sales experience, and we will likely be required to make adjustments to these allowances and accruals in the

future. We continually monitor our allowances and accruals and make adjustments when we believe actual experience may differ from our estimates.

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

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

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

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

Inventory

We record inventory upon the transfer of title from our vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw materials and its costs are determined using acquisition costs from our contract manufacturers. We record work-in-progress costs of filling, finishing and packaging against specific product batches. We obtain all of our Angiomax bulk drug substance from Lonza Braine, S.A. and Teva API. Under the terms of our agreement with Lonza Braine, we provide forecasts of our annual needs for Angiomax bulk substance 18 months in advance. We also have a separate agreements with Ben Venue Laboratories, Inc., Patheon Italia S.p.A and APP for the fill-finish of Angiomax drug product.

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

Stock-Based Compensation

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

We account for stock-based compensation in accordance with FASB Accounting Standards Codification, or ASC, 718-10, and recognize expense using the accelerated expense attribution method. ASC 718-10 requires companies to recognize compensation expense in an amount equal to the fair value of all stock-based awards granted to employees.

We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, and prevailing interest rates. ASC 718-10 also requires us to estimate forfeitures in calculating the expense relating to stock-based compensation as opposed to only recognizing forfeitures and the corresponding reduction in expense as they occur.

We have based our assumptions on the following:

| Assumption | Method of Estimating |
|--|--|
| <ul style="list-style-type: none"> Estimated expected term of options | <ul style="list-style-type: none"> Employees' historical exercise experience and, at times, estimates of future exercises of unexercised options based on the midpoint between the vesting date and end of the contractual term |
| <ul style="list-style-type: none"> Expected volatility | <ul style="list-style-type: none"> Historical price of our common stock and the implied volatility of the stock of our peer group |
| <ul style="list-style-type: none"> Risk-free interest rate | <ul style="list-style-type: none"> Yields of U.S. Treasury securities corresponding with the expected life of option grants |
| <ul style="list-style-type: none"> Forfeiture rates | <ul style="list-style-type: none"> Historical forfeiture data |

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

Income Taxes

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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

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

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

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

In 2011, we recorded a \$66.5 million income tax benefit by reducing our valuation allowance to \$4.2 million against \$110.4 million of deferred tax assets at December 31, 2011 compared to a \$104.3 million valuation allowance against \$150.1 million of deferred tax assets at December 31, 2010. Any changes to the valuation allowance or deferred tax assets in the future would impact our income taxes.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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 June 5, 2012.

THE MEDICINES COMPANY

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

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

INDEX TO EXHIBITS

| Number | Description |
|---------------|---|
| 2.1 | Sale and Purchase Agreement, dated August 4, 2008, between The Medicines Company (Leipzig) GmbH and Curacyte AG (filed as Exhibit 2.1 of the registrant's current report on Form 8-K/A, filed on November 10, 2008) |
| 2.2 | Agreement and Plan of Merger among the registrant, Boxford Subsidiary Corporation, and Targanta Therapeutics Corporation, dated as of January 12, 2009 (filed as Exhibit 2.1 of the registrant's current report on Form 8-K, filed on January 14, 2009) |
| 2.3 | Amendment to Sale and Purchase Agreement dated December 14, 2009 between The Medicines Company (Leipzig) GmbH and Curacyte AG (filed as Exhibit 2.3 to the registrant's annual report on Form 10-K for the year ended December 31, 2009) |
| 3.1 | Third Amended and Restated Certificate of Incorporation of the registrant, as amended (filed as Exhibit 4.1 to the Amendment No. 1 to the registrant's registration statement on Form 8-A/A, filed July 14, 2005) |
| 3.2 | Amended and Restated By-laws of the registrant, as amended (filed as Exhibit 3.2 to the registrant's annual report on Form 10-K for the year ended December 31, 2007) |
| 10.1 | Amended and Restated Registration Rights Agreement, dated as of August 12, 1998, as amended, by and among the registrant and the other parties thereto (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2002) |
| 10.2 | Lease for 8 Campus Drive dated September 30, 2002 by and between Sylvan/Campus Realty L.L.C. and the registrant, as amended by the First Amendment and Second Amendment, (filed as Exhibit 10.15 to the registrant's annual report on Form 10-K for the year ended December 31, 2003) |
| 10.3 | Third Amendment to Lease for 8 Campus Drive dated December 30, 2004 by and between Sylvan/Campus Realty L.L.C. and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2004) |
| 10.4 | Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.32 to the registrant's annual report on Form 10-K for the year ended December 31, 2007) |
| 10.5 | Amendment to Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.40 to the registrant's annual report on Form 10-K for the year ended December 31, 2008) |
| 10.6* | Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell (filed as Exhibit 10.12 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)) |
| 10.7* | Letter Agreement dated March 2, 2006 by and between the registrant and Glenn P. Sblendorio, (filed as Exhibit 10.23 to the registrant's annual report on Form 10-K for the year ended December 31, 2005) |
| 10.8* | Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Clive Meanwell and Glenn Sblendorio (filed as Exhibit 10.24 to the registrant's annual report on Form 10-K for the year ended December 31, 2008) |
| 10.9* | Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Paul Antinori, William O Connor and Leslie Rohrbacker (filed as Exhibit 10.25 to the registrant's annual report on Form 10-K for the year ended December 31, 2008) |
| 10.10* | Form of Lock-Up Agreement dated as of December 23, 2005 by and between the registrant and each of its executive officers and directors (filed as Exhibit 10.27 to the registrant's annual report on Form 10-K for the year ended December 31, 2005) |
| 10.11* | 1998 Stock Incentive Plan, as amended (filed as Exhibit 10.1 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)) |

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

- 10.12* Form of stock option agreement under 1998 Stock Incentive Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004)
- 10.13* 2000 Employee Stock Purchase Plan, as amended (filed as Exhibit 10.1 of the registrant's registration statement on Form S-8, filed on September 1, 2009)
- 10.14* 2000 Outside Director Stock Option Plan, as amended (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003)

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

| Number | Description |
|--------|--|
| 10.15* | 2001 Non-Officer, Non-Director Employee Stock Incentive Plan (filed as Exhibit 99.1 to the registration statement on Form S-8 filed December 5, 2001 (registration no. 333-74612)) |
| 10.16* | Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 99.1 to the registrant's registration statement on Form S-8, dated July 3, 2008) |
| 10.17* | Form of stock option agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.22 to the registrant's annual report on Form 10-K for the year ended December 31, 2004) |
| 10.18* | Form of restricted stock agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006) |
| 10.19* | 2007 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed January 11, 2008 (registration no. 333-148602)) |
| 10.20* | Form of stock option agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.34 to the registrant's annual report on Form 10-K for the year ended December 31, 2007) |
| 10.21* | Form of restricted stock agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.35 to the registrant's annual report on Form 10-K for the year ended December 31, 2007) |
| 10.22* | 2009 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed February 24, 2009 (registration number 333-157499)) |
| 10.23* | Form of stock option agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009) |
| 10.24* | Form of stock option agreement for employees in Italy under 2009 Equity Inducement Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009) |
| 10.25* | Form of restricted stock agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009) |
| 10.26* | Summary of Annual Cash Bonus Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008) |
| 10.27* | Summary of Performance Measures under the registrant's Annual Cash Bonus Plan (filed in Item 5.02 of the registrant's current report on Form 8-K, filed on February 27, 2012) |
| 10.28 | License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant (filed as Exhibit 10.6 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)) |
| 10.29 | License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc. (filed as Exhibit 10.7 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404)) |
| 10.30 | License Agreement effective as of March 28, 2003 by and between AstraZeneca AB and the registrant |
| 10.31 | Amendment No. 1 to License Agreement dated April 25, 2006 by and between AstraZeneca AB |
| 10.32 | Amendment No. 2 to License Agreement, dated October 22, 2008 by and between the registrant and AstraZeneca AB (filed as Exhibit 10.38 to the registrant's annual report on Form 10-K for the year ended December 31, 2008) |
| 10.33 | License Agreement dated as of December 18, 2003 by and between AstraZeneca AB and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2003) |
| 10.34 | Amendment to License Agreement dated July 6, 2007 between AstraZeneca AB and the registrant (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2007) |

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

- 10.35 License Agreement, dated December 23, 2005 by and between Targanta Therapeutics Corporation (as successor to InterMune, Inc.) and Eli Lilly and Company (filed as Exhibit 10.11 to Targanta's registration statement on Form S-1 (registration no. 333-142842), as amended, originally filed with the SEC on May 11, 2007)
- 10.36 Contingent Payment Rights Agreement dated February 25, 2009 between the registrant and American Stock Transfer & Trust Company (filed as Exhibit 99.1 of the registrant's current report on Form 8-K, filed on March 2, 2009)
- 10.37 License Agreement dated as of December 18, 2009 between the registrant and Pfizer Inc. (filed as Exhibit 10.41 to the registrant's annual report on Form 10-K for the year ended December 31, 2009)
- 10.38 Consent and Release Agreement dated as of December 18, 2009 between the registrant and Washington Cardiovascular Associates, LLC, HDLT LLC, H. Bryan Brewer, Silvia Santamarina-Fojo and Michael Matin (filed as Exhibit 10.42 to the registrant's annual report on Form 10-K for the year ended December 31, 2009)

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

| Number | Description |
|--------|---|
| 10.40 | Second Amendment to License Agreement dated as of June 1, 2010 between AstraZeneca AB and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2010) |
| 10.41* | The Medicines Company's 2010 Employee Stock Purchase Plan (incorporated by reference to Appendix I to the registrant's definitive proxy statement, dated and filed with the Securities and Exchange Commission on April 30, 2010, for the registrant's 2010 Annual Meeting of Stockholders) |
| 10.42* | The Medicines Company's 2004 Amended and Restated Stock Incentive Plan, as amended (incorporated by reference to Appendix II to the registrant's definitive proxy statement, dated and filed with the Securities and Exchange Commission on April 30, 2010, for the registrant's 2010 Annual Meeting of Stockholders) |
| 10.43 | First Amendment to lease for 400 Fifth Avenue, Waltham, MA, dated as of June 30, 2010 by and between ATC Realty Sixteen Inc. and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010) |
| 10.44* | Form of restricted stock agreement under the registrant's Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010) |
| 10.45* | Restricted stock agreement of Clive Meanwell under the registrant's Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 10.53 to the registrant's annual report on Form 10-K for the year ended December 31, 2010) |
| 10.46 | Second Amended and Restated Distribution Agreement effective as of October 1, 2010 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.54 to the registrant's annual report on Form 10-K for the year ended December 31, 2010) |
| 10.47 | Settlement Agreement and Release, dated February 14, 2011, between registrant and Wilmer Cutler Pickering Hale and Dorr LLP (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2011) |
| 10.48 | Fourth Amendment to Lease, dated June 30, 2011, between registrant and Sylvan/Campus Realty L.L.C. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2011) |
| 10.49 | Manufacturing Services Agreement, dated March 30, 2011, between registrant and Patheon International A.G. (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 10.50 | Settlement Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 10.51 | License Agreement, dated September 30, 2011, between registrant and Teva Pharmaceuticals USA, Inc. (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 10.52 | Supply Agreement, dated September 30, 2011, between registrant and Plantex USA Inc. (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 10.53 | First Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc. (filed as Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 10.54 | Second Amendment to the Second Amended and Restated Distribution Agreement, dated July 1, 2011, between registrant and Integrated Commercial Solutions, Inc. (filed as Exhibit 10.6 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2011) |
| 21 | Subsidiaries of the registrant (filed as Exhibit 21 to the registrant's annual report on Form 10-K for the year ended December 31, 2011) |
| 23 | Consent of Ernst & Young LLP, Independent Registered Accounting Firm (filed as Exhibit 23 to the registrant's annual report on Form 10-K for the year ended December 31, 2011) |

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

- 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 as Exhibit 31.1 to the registrant's annual report on Form 10-K for the year ended December 31, 2011)
- 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 as Exhibit 31.2 to the registrant's annual report on Form 10-K for the year ended December 31, 2011)
- 31.3 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

Edgar Filing: MEDICINES CO /DE - Form 10-K/A

| Number | Description |
|---------|---|
| 31.4 | Chief Financial Officer Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Chief Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed as Exhibit 32.1 to the registrant's annual report on Form 10-K for the year ended December 31, 2011) |
| 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 (filed as Exhibit 32.2 to the registrant's annual report on Form 10-K for the year ended December 31, 2011) |
| 101.INS | The following materials from The Medicines Company Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statement of Operations, (iii) the Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements (filed as Exhibits to the registrant's annual report on Form 10-K for the year ended December 31, 2011) |

* Management contract or compensatory plan or arrangement filed as an exhibit to this form pursuant to Items 15(a) and 15(c) of Form 10-K

Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission Unless otherwise indicated, the exhibits incorporated herein by reference were filed under Commission file number 000-31191.

+ In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this annual report on Form 10-K shall be deemed to be furnished and not filed.