MEDICINES CO /DE
Form 8-K
January 16, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 16, 2007**

The Medicines Company

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-31191**	**04-3324394**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8 Campus Drive **Parsippany, New Jersey**	**07054**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code: **(973) 656-1616**

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On January 16, 2007, The Medicines Company (the Registrant) stated in a preliminary supplement (the Prospectus Supplement) to the prospectus included in the automatic shelf registration statement described in Item 7.01 below that it expected to report net revenues of approximately $60.3 million for the three months ended December 31, 2006 and net revenues of approximately $213.9 for the year ended December 31, 2006.

Item 7.01. Regulation FD Disclosure.

On January 16, 2007, the Registrant issued a press release announcing a proposed underwritten public offering of 6,000,000 shares of the Registrant s common stock, $0.001 par value per share, and up to an additional 900,000 shares issuable upon exercise of the underwriters over-allotment option, pursuant to an effective automatic shelf registration statement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Prospectus Supplement contains the following updated description of the Registrant s business.

Our Company

We are a pharmaceutical company committed to becoming a leading provider of innovative, cost effective acute care hospital products to the worldwide hospital marketplace. We have one marketed product, Angiomax® (bivalirudin), and two products in late-stage development, Cleviprex (clevidipine) and cangrelor, that we believe share common features valued by hospital practitioners, including a high level of pharmacological specificity, potency and predictability. We believe that Angiomax and our two product candidates possess favorable attributes that competitive products do not provide and can satisfy unmet medical needs in the acute care hospital product market and offer improved performance to hospital businesses.

Our first acute care hospital product, Angiomax, is an intravenous direct thrombin inhibitor approved for use as an anticoagulant in combination with aspirin in patients undergoing percutaneous coronary interventions, or PCI. PCI, which we also refer to as coronary angioplasty, is conducted to clear restricted blood flow in arteries around the heart. We are evaluating Angiomax for use in additional patient populations, including, in a Phase III trial, patients presenting with acute coronary syndromes, or ACS. Our revenues to date have been generated principally from sales of Angiomax in the United States. We reported net revenue of $153.5 million and net income of $9.5 million for the nine months ended September 30, 2006.

We are currently conducting Phase III clinical trials of Cleviprex and cangrelor as potential acute care hospital products. The first of these, Cleviprex, is an intravenous drug intended for the reduction and control of blood pressure in intensive care patients who require rapid and precise control of blood pressure. Our second product candidate, cangrelor, is an intravenous antiplatelet agent that is intended to prevent platelet activation and aggregation in the clotting process to reduce the risk of clot formation.

We currently focus our commercial and product development resources primarily on the U.S. acute care hospital market, which includes a concentration of hospitals that conduct a large percentage of acute care procedures in the United States. Our core strategy is to acquire, develop and commercialize products that we believe will help hospitals treat patients more efficiently by improving the effectiveness and safety of treatment while reducing cost. We believe that our ability to readily identify market needs and generate meaningful clinical data by investing aggressively in research and development enables us to successfully pursue this strategy. Our research and development investments are designed to provide clinical data that measure whether products:

- are effective, safe and predictable;
- enable shorter periods of treatment;
- are easier to use than current products;

- reduce the length of hospital stay; and
- lower hospital costs.

We believe that products with these attributes positively impact patient care and are attractive to the decision-makers who comprise our current and potential customers, including hospital management, physicians, hospital pharmacists, nurses and other care staff.

Angiomax

We exclusively licensed Angiomax from Biogen Idec Inc. in 1997 and we have exclusive license rights to develop, market and sell Angiomax worldwide. We received our first marketing approval from the U.S. Food and Drug Administration, or the FDA, in December 2000 for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA. In June 2005, the FDA approved new prescribing information for Angiomax to also include patients undergoing PCI, in addition to those undergoing PTCA. In November 2005, the FDA approved the expansion of the label to include PCI patients with or at risk of heparin-induced thrombocytopenia and thrombosis syndrome, a complication of heparin administration known as HIT/HITTS that can result in limb amputation, renal failure and death. In September 2004, we received authorization from the European Commission to market Angiomax under the name Angiox® (bivalirudin) in the member states of the European Union for use as an anticoagulant in combination with aspirin in patients undergoing PCI. Angiomax is also approved for sale in Australia, Canada, New Zealand and countries in Central America, South America and the Middle East for indications similar to those approved by the FDA.

We believe that Angiomax has the potential to replace heparin, an anticoagulant that historically has been used in the United States, in the treatment of arterial thrombosis, a condition involving the formation of blood clots in arteries. Arterial thrombosis is associated with life-threatening conditions, such as ischemic heart disease, peripheral vascular disease and stroke. There are three main areas of the hospital where heparin is used for acute treatment of arterial thrombosis: the cardiac catheterization laboratory, where coronary angioplasties are performed; the emergency department, where patients with ACS, including chest pain and heart attacks, are initially treated; and the operating room, where valve replacement surgery and coronary artery bypass graft surgery, or CABG surgery, a procedure in which surgeons bypass a blockage in the patient s artery by grafting a vein to the artery on both sides of the blockage to restore blood flow around the obstruction, are performed.

We have invested significantly in the development of clinical data on the clinical effects of Angiomax in the treatment of PCI and ACS patients. In almost all of our investigations to date, we have compared Angiomax to heparin or enoxaparin, a low-molecular weight heparin, which until relatively recently were the only injectable anticoagulants for use in coronary angioplasty, or combinations of drugs including heparin. In total, we have tested Angiomax against heparin or enoxaparin or combinations of drugs including heparin or enoxaparin in 12 comparative PCI and ACS trials. In the pivotal PCI and ACS trials, Angiomax use resulted in rates of complications, such as heart attack, also known as myocardial infarction, or MI, that were comparable to the comparator drugs in the trials while resulting in fewer bleeding events, including a reduction in the need for blood transfusion, as compared to the comparator drugs in the trials. In addition, in these trials, the therapeutic effects of Angiomax have been shown to be more predictable than heparin.

To date, we have concentrated our commercial efforts on replacing heparin in the cardiac catheterization laboratory, where the PCI procedures for which Angiomax is approved, are performed. In evaluating our operating performance in the United States, we focus on use of Angiomax by existing hospital customers and penetration into new hospitals, both of which are critical elements of our ability to

increase market share and revenue. We believe that Angiomax was used in approximately 30% of the coronary angioplasty procedures conducted in the United States in 2005.

We market Angiomax to interventional cardiology customers for its approved uses in PCI, including in patients with HIT/HITTS. We market and sell Angiomax in the United States with a sales force of approximately 140 representatives and managers experienced in selling to hospital customers. In the European Union and other foreign jurisdictions, we sell Angiomax to third party-distributors that market and distribute the product to hospitals.

We are seeking to expand the indications for which we may market Angiomax. In December 2005, we completed patient enrollment in a 13,819 patient Phase III trial, called ACUITY, studying Angiomax use in patients presenting to the emergency department with ACS. We were testing whether Angiomax use is safe and effective in ACS patients when it is first administered in the emergency department at a lower dose than that which is currently used in PCI patients. If an emergency department ACS patient subsequently underwent PCI, the dose was increased to provide the usual anticoagulation during the procedure. Outcomes were also measured among ACS patients not undergoing PCI, namely, those medically managed or those who underwent CABG surgery. All of these emergency department ACS patients were randomized into one of three arms: a control arm, Arm A, providing for the administration of heparin or enoxaparin with glycoprotein IIb/IIIa, or GP IIb/IIIa, inhibitors, a type of intravenous platelet inhibitor; a second arm, Arm B, providing for the administration of Angiomax with planned use of GP IIb/IIIa inhibitors; and a third arm, Arm C, providing for the administration of Angiomax alone and permitting use of GP IIb/IIIa inhibitors only in selected cases involving ischemic events during PCI.

The 30-day patient results, which were presented in March 2006 by the principal investigators, showed that Angiomax met all primary and secondary pre-specified 30-day objectives for the ACUITY study. Specifically, in Arm C, the Angiomax monotherapy arm, Angiomax was effective and reduced the risk of major bleeding by 47% compared to the control arm, Arm A. In the Angiomax combination arm, Arm B, the Angiomax and GP IIb/IIIa combination was as effective, with similar reductions in bleeding, as the control arm. These results were published in The New England Journal of Medicine in November 2006.

The investigators continued to conduct the ACUITY trial in 2006 as they collected 12-month patient follow-up results following the completion of enrollment in December 2005. We expect these results to be reported by the investigators in the first half of 2007. If these results are favorable, we expect to submit a supplemental New Drug Application, or sNDA, to the FDA in the second half of 2007 seeking an expansion of the Angiomax product label to include the trial results and information about ACUITY maintenance dosing regimen starting in the emergency department.

In December 2005, we submitted an application to the FDA for approval to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery. In October 2006, we received a non-approvable letter from the FDA in connection with this application. In the letter, the FDA stated that it did not consider the data that we submitted in support of the application adequate to support approval for this indication because it did not consider the evidence used to qualify patients for inclusion in the trials that formed the basis for our application as a persuasive indicator for the risk of HIT/HITTS. We plan to discuss this matter with the FDA and evaluate potential next steps following that discussion.

We are also preparing to study Angiomax in the pediatric setting and are supporting an investigator-initiated trial called HORIZONS to study Angiomax use in adult acute myocardial infarction, or AMI, patients. HORIZONS is designed to evaluate whether Angiomax with permitted use of GPIIb/IIIa inhibitors is as safe and effective as heparin or enoxaparin with planned use of GPIIb/IIIa inhibitors in AMI patients. We believe that additional studies provide an important service by helping us to provide contemporary clinical data about the use of Angiomax, to answer specific questions about the use of Angiomax posed by the marketplace and to give us direction for future clinical trials.

Cleviprex

We are developing Cleviprex, an intravenous drug intended for the short-term reduction and control of blood pressure in the acute care setting when oral therapy is not desirable or feasible. We exclusively licensed Cleviprex in March 2003 from AstraZeneca AB. Under the terms of our agreement with AstraZeneca, we have exclusive license rights to develop, market and sell Cleviprex worldwide.

Cleviprex belongs to a well-known class of drugs, called calcium channel blockers, which are used to control high blood pressure. Cleviprex acts by selectively relaxing the smooth muscle cells that line small arteries, resulting in widening of the artery and reduction of blood pressure. We believe that Cleviprex may address an unmet need for rapid, precise control of patient blood pressure based on attributes demonstrated in clinical trials to date, namely rapid, titratable onset of effect on blood pressure, simple preparation and administration, arterial selectivity and metabolism independent of organ function.

We are developing Cleviprex in a clinical trial program comprised of six Phase III clinical trials. We completed two Phase III efficacy clinical trials of Cleviprex, which we refer to as the ESCAPE trials. The ESCAPE trials were designed to evaluate the effectiveness of Cleviprex in controlling blood pressure before and after cardiac surgery compared to a placebo control. Results in both trials met the protocol-defined objective, as measured by rates of treatment success, which was defined as at least 15% reduction in blood pressure without the need to use an alternate drug. We have also completed three Phase III clinical trials, which we refer to as the ECLIPSE trials, to evaluate the safety of Cleviprex in approximately 1,600 patients in comparison to sodium nitroprusside, nicardipine and nitroglycerine, three leading blood pressure reducing agents, before, during and following cardiac surgery. Results in all three trials met the protocol-defined objectives, which included primary objectives measured by the incidences of death, stroke, myocardial infarction and renal dysfunction, and secondary objectives involving the evaluation of adverse experiences with Cleviprex and its blood pressure lowering effect. We expect to complete enrollment of patients in our sixth Phase III clinical trial of Cleviprex in January 2007. In this trial, which we refer to as the VELOCITY trial, we are evaluating Cleviprex in 100 patients with severe hypertension in an acute care setting. We plan to submit a New Drug Application, or NDA, to the FDA in the first half of 2007 for approval to market Cleviprex in patients receiving an intravenous antihypertensive in the acute care setting when oral therapy is not desirable or feasible. We expect to submit an application for marketing approval in the European Union within one year of submitting the NDA in the United States.

We plan to expand our U.S. sales force by between approximately 50 and 100 persons commencing three to six months before the potential launch of Cleviprex. We believe that an expanded sales force would enable us to sell Cleviprex efficiently to hospital customers, including to Angiomax customers, if Cleviprex is approved by the FDA for sale in the United States. We also intend in 2007, in preparation for the potential launch of Cleviprex, to continue manufacturing scale-up for Cleviprex and to conduct Phase IIIb trials of Cleviprex in neurology and cardiology and a health economics study.

Cangrelor

We are developing cangrelor, a short-acting injectable antiplatelet agent that is designed to prevent platelet activation and aggregation in the clotting process. Cangrelor is designed to bind directly to the P2Y12 receptor, a receptor that has been implicated in platelet aggregation. We exclusively licensed cangrelor in December 2003 from AstraZeneca. Under the terms of our agreement with AstraZeneca, we have exclusive license rights to develop, market and sell cangrelor worldwide, excluding Japan, China, Korea, Taiwan and Thailand.

We are developing cangrelor for potential use as an intravenous antiplatelet agent in the acute care settings of the cardiac catheterization laboratory. Based on input from our hospital customers in the cardiac catheterization laboratory, we believe that the acute care limitations of current oral therapy, such as clopidogrel, the leading oral P2Y12 receptor antiplatelet agent, which include delayed onset, prolonged

effect and unpredictable effect, have created a need for an intravenous platelet inhibitor that acts quickly, is cleared from the bloodstream rapidly and enables rapid recovery of platelet function. We believe that pre-clinical studies and clinical studies conducted in approximately 500 patients to date suggest that cangrelor has these attributes. These clinical studies consist of Phase II clinical trials of cangrelor conducted by AstraZeneca prior to licensing this product candidate to us, and a 40-person clinical trial that we conducted in healthy volunteers to identify a dosing strategy for use of cangrelor. Specifically, in these studies, cangrelor demonstrated:

- an immediate inhibitory effect on platelets;
- an inhibitory effect on platelet activation and aggregation that is proportional to the dose administered;
- inhibitory effects that are sustainable through the period of infusion;
- a plasma half-life of less than five minutes; and
- platelet function recovery in less than an hour.

We are currently evaluating cangrelor s effectiveness and safety in preventing ischemic events in patients who require PCI in two separate Phase III clinical trials. The larger trial, which we refer to as the CHAMPION-PCI trial and for which we commenced enrollment in March 2006, is an approximately 9,000-patient trial designed to evaluate whether use of intravenous cangrelor is superior to use of eight 75mg clopidrogrel tablets in patients undergoing PCI. This dose of multiple tablets is referred to as pre-loading. The primary composite endpoint of the CHAMPION-PCI trial will measure death, MI, or urgent revascularization at 48 hours after the procedure. Patients in this trial may be treated with other intravenous anticoagulants, such as Angiomax, heparin and GP IIb/IIIa inhibitors, at the investigator s discretion.

The second trial, which we refer to as the CHAMPION-PLATFORM trial and for which we commenced enrollment in October 2006, compares cangrelor plus usual care to placebo plus usual care in patients who require PCI. We currently expect to enroll between 4,400 and 6,000 patients in this trial. This trial will measure the composite endpoint of death, MI, or urgent revascularization at 48 hours after the procedure. The FDA has recommended that we use an alternative statistical design for this trial. We plan to discuss the statistical design with the FDA before we finalize the statistical design and before we complete the first interim analysis of this trial.

There were approximately 2,000 patients enrolled in CHAMPION-PCI and 150 patients enrolled in CHAMPION-PLATFORM at the end of 2006. We plan to enroll in excess of 8,000 patients in these trials in 2007 and expect to complete patient enrollment in both trials in 2008. If we complete these trials on a timely basis and the results of these trials are favorable, we anticipate making submissions for marketing approvals in the United States and the European Union in 2008.

Business Development

We anticipate expanding our portfolio of acute care hospital products. We believe we can acquire or license both early and late-stage products that we can develop and sell to hospital customers that satisfy their existing and evolving needs. We have assembled an experienced business development team that supports our efforts through intense data analysis designed to enable us to make efficient and informed decisions about pursuing business development opportunities. We believe our success in developing and marketing Angiomax provides us with a competitive advantage in identifying and securing future acquisition and licensing opportunities.

Financial Results Update

We expect to report net revenue of approximately $60.3 million for the three months ended December 31, 2006 and net revenue of approximately $213.9 for the year ended December 31, 2006.

In order to support the continued development of Angiomax, Cleviprex and cangrelor, we expect our research and development expense to increase in 2007 from 2006 anticipated levels. We expect our research and development expense to be between approximately $77 million and $81 million in 2007, with the increase being primarily attributable to costs associated with enrollment of our ongoing Phase III clinical trials for cangrelor, the 9,000 patient CHAMPION- PCI trial and the 4,400 to 6,000 patient CHAMPION-PLATFORM trial, and additional manufacturing development costs for Cleviprex and cangrelor. We expect sales, general and administrative expenses to increase in 2007 from 2006 anticipated levels to between approximately $88 million and $92 million primarily due to Cleviprex-related pre-launch expenditures, continued promotional spending on Angiomax marketing and increased sales force compensation. We also expect total stock-based compensation expense to increase in 2007 from 2006 anticipated levels to between approximately $16 million and $17 million in 2007 as a result of our higher stock price and anticipated stock option grants to new and current employees. We have not included stock-based compensation expense in the research and development and sales, general and administrative expense amounts discussed in this paragraph.

Special Note Regarding Forward-Looking Statements

Statements contained in this report about the Registrant, Angiomax®, Cleviprex , the Registrant s financial outlook for 2007, the timing of clinical trial results and product or indication launches, and all other statements that are not purely historical, may be deemed to be forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words believes, anticipates, plans, expects, intends, potential, estimates and similar expressions are intended identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that may cause the Registrant s actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by these forward-looking statements. Important factors that may cause or contribute to such differences include the extent of the commercial success of Angiomax®, the Registrant s dependence on wholesalers and international distribution partners for sales of Angiomax® and the fluctuation of revenues based on the buying patterns of these wholesalers and international distribution partners, the success of the arrangements with the Registrant s wholesalers, that these wholesaler arrangements are subject to termination on short notice, completion of accounting procedures with respect to the fourth quarter of 2006, acceptance by physicians, patients and other key decision-makers of Angiomax® clinical trial results, whether the Registrant will be able to obtain regulatory approval for additional indications of Angiomax®, whether the Registrant will receive approvals from regulatory agencies for Cleviprex and cangrelor, whether Angiomax®, Cleviprex and cangrelor will advance in the clinical trials process on a timely basis or at all, whether the clinical trial results will warrant submission of applications for regulatory approval, and such other factors as are set forth in the risk factors detailed from time to time in the

Registrant s periodic reports filed with the Securities and Exchange Commission including, without limitation, the risk factors detailed under Risk Factors in the Prospect Supplement. The Registrant specifically disclaims any obligation to update these forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

See Exhibit Index attached hereto.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THE MEDICINES COMPANY

Date: January 16, 2007	By:	/s/ Paul M. Antinori Paul M. Antinori Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	**Description**
99.1	Press Release dated January 16, 2007