The Medicines Company Reports Third Quarter 2013 Financial Results

23 Oct 2013

27% Increase in Third Quarter 2013 Net Revenue to $174.3 Million; 26% Increase YTD September 2013 Net Revenue to $502.9 Million; Net Income in Third Quarter 2013 Totals $7.8 Million or $0.12 per Share; 100% Increase in Third Quarter 2013 Adjusted Net Income(1) to $29.3 Million

PARSIPPANY, NJ -- (Marketwired) -- 10/23/13 -- The Medicines Company (NASDAQ: MDCO), a global biopharmaceutical company focused on saving lives, alleviating suffering, and improving the economic efficiency of the world's leading hospitals, today announced third quarter financial results for 2013.

"The third quarter was yet another financial growth period and we made significant progress with our acute/intensive care portfolio," said Glenn Sblendorio, President and Chief Financial Officer of The Medicines Company. "We continue to make progress on our late stage development programs with four product launches anticipated in the next 12 to 24 months. We are serving a concentrated, yet growing worldwide hospital market while leveraging and building our organization efficiently, consistent with our purpose to save lives, alleviate suffering, and contribute to the economics of healthcare by focusing on leading hospitals worldwide."

Financial Highlights for the Third Quarter 2013

Net revenue: Net revenue increased by 27% to $174.3 million for the third quarter of 2013, up from $136.8 million in the third quarter of 2012. Angiomax® (bivalirudin) US sales increased by 12% to $138.5 million in the third quarter of 2013 compared to $123.8 million in the third quarter of 2012. Recothrom® Thrombin, topical (recombinant) US sales were $17.0 million for the third quarter of 2013. Angiomax/Angiox® (bivalirudin) international net revenue increased by 52% to $15.1 million in the third quarter of 2013 compared with $10.0 million in the third quarter of 2012. Net sales of Ready-to-Use (RTU) Argatroban, Cleviprex® (clevidipine) and our generic portfolio increased by 22% to $3.7 million in the third quarter of 2013 compared with $3 million in the third quarter of 2012.

Net income: Net income for the third quarter of 2013 was $7.8 million, or $0.12 per share, compared with net income of $9.3 million, or $0.17 per share for the third quarter of 2012.

Adjusted net income[1] for the third quarter of 2013 increased 100% to $29.3 million, or $0.47 per share[1], compared to adjusted net income of $14.7 million, or $0.27 per share[1] for the third quarter 2012.

Financial Highlights for the First Nine Months Ended September 2013

Net revenue: Net revenue increased by 26% to $502.9 million for the nine months ended September 2013, up from $399.1 million in the nine months ended September 2012. Angiomax US sales increased by 13% to $407.8 million in the first nine months of 2013 compared to $360.5 million in the first nine months of 2012. Recothrom revenue for The Medicines Company was $43.5 million for the first nine months of 2013. Angiomax/Angiox international net revenue in the first nine months of 2013 increased by 23% to $39.9 million compared with $32.5 million in the first nine months of 2012. Net sales of RTU Argatroban, Cleviprex and our generic portfolio increased by 91% to $11.7 million in the first nine months of 2013 compared with $6.1 million in the first nine months of 2012.

Net income: Net income for the first nine months of 2013 was $14.3 million, or $0.24 per share, compared with net income of $30.6 million, or $0.55 per share for the first nine months of 2012. The first nine months of 2013 includes one-time costs in the amount of $43.5 million including licensing costs of $25 million for a transaction with Alnylam on the PCSK9 RNAi hypercholesterolemia program, a restructuring charge of $6.4 million, $7.1 million of deal costs, and an arbitration payment in the amount of $5.0 million.

Adjusted net income[1] for the first nine months of 2013 increased 76% to $76.5 million, or $1.29 per share[1], compared to adjusted net income[1] of $43.4 million, or $0.78 per share[1], for the first nine months of 2012.

Cash position and debt: As of September 30 2013, the Company had cash and cash equivalents of $462.4 million and convertible senior notes of $233.5 million due June, 2017. These notes have a face value of $275 million.

Shares outstanding: For the three months ended September 30, 2013, our fully diluted and basic weighted average shares outstanding totaled 63.2 million and 59.2 million, respectively. Both figures reflect our mid-August 2013 sale of 6.7 million common shares which raised net proceeds of $189.6 million.

Recent Operational Highlights

Acute Cardiovascular Care Area

Angiomax® (bivalirudin) is an injectable direct thrombin inhibitor. On October 9, the Company announced enrollment of the first patient in its 3,900 patient Phase III ENDOMAX trial (ENDOvascular interventions with AngioMAX (bivalirudin)), which is the first randomized, double blind, clinical trial to study pharmacology in patients undergoing Peripheral Endovascular Intervention (PEI). PEI is performed in approximately 500,000 patients in the United States each year. Angiomax is currently approved for use in patients undergoing angioplasty, also called percutaneous coronary intervention (PCI). The Medicines Company intends to pursue labeling expansion in the PEI setting.

Cangrelor is an investigational intravenous, direct-acting, $P2Y_{12}$ receptor antagonist in development for prevention of platelet activation and aggregation that leads to thrombosis in the acute care setting including in patients undergoing PCI. A pre-specified, pooled analysis of patient-level data from CHAMPION-PCI, CHAMPION-PLATFORM, and CHAMPION-PHOENIX was presented at the European Society of Cardiology in September and concurrently published in *The Lancet*. On October 9, The Medicines Company also announced completion of two pharmacodynamic trials evaluating the transition of its investigational acute intravenous antiplatelet agent, cangrelor, to chronic oral therapy with ticagrelor (Brilinta®) or prasugrel (Effient®) in patients with coronary artery disease (CAD). These data are also expected to be published in peer review journals. On July 1, The Medicines Company announced that the U.S. Food and Drug Administration (FDA) accepted the filing of the New Drug Application (NDA) for cangrelor. The Medicines Company anticipates submission of a European Market Authorization Application (MAA) in the fourth quarter of 2013.

Cleviprex® (clevidipine) is an intravenous calcium channel blocker, approved in the US for blood pressure reduction when oral therapy is not feasible or not desirable. In 2013, The Medicines Company received regulatory approval for Cleviprex in 11 countries (Germany, France, Spain, UK, Austria, the Netherlands, Belgium, Luxembourg, Switzerland, Canada, and Australia) with an indication for blood pressure control in perioperative settings.

MDCO-216 (ApoA-I Milano), an investigational product, is a naturally occurring variant of a protein found in high-density lipoprotein (HDL) formulated with lipids to emulate an HDL particle. It has the potential to modify atheromatous disease by promoting reverse cholesterol transport and may, in the future, be tested in trials to measure reductions in the risk of adverse atherothrombotic events. On October 9, The Medicines Company reported progress with manufacturing development. The Medicines Company expects a Phase I trial to be completed by the end of 2013.

ALN-PCS02 and ALN-PCSsc (ALN-PCS program) are PCSK9 synthesis inhibitors under investigation as agents that may reduce intracellular and extracellular levels of PCSK9 with a view to lowering plasma levels of low-density lipoprotein (LDL) cholesterol. On October 9, The Medicines Company and partner Alnylam announced a lead development candidate that will be tested as a subcutaneously administered RNAi therapeutic (ALN-PCSsc) targeting PCSK9. New data from non-human primate studies were presented at the Oligonucleotide Therapeutics Society (OTS) meeting in October.

Surgery and Perioperative Care Area

Fibrocaps™ is an investigational agent that is a dry powder topical fibrinogen thrombin hemostat in development for a range of surgeries. In August, The Medicines Company completed the acquisition of ProFibrix B.V. and reported results from the Phase III FINISH-3 trial, which studied a total of 719 patients. The trial met primary and secondary hemostasis efficacy endpoints in four surgical indications of spinal surgery, hepatic resection, soft tissue dissection and vascular surgery. The Medicines Company anticipates submission of a European MAA in the fourth quarter of 2013.

Recothrom® Thrombin, topical (recombinant) is a recombinant human thrombin approved in the US for use as an aid to hemostasis whenever control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age. In December 2012, The Medicines Company and Bristol-Myers Squibb Company signed a global license and two year collaboration for Recothrom, which is marketed in the United States and Canada.

IONSYS™ is under investigation in a pre-registration stage as a patient-controlled analgesia system for the management of acute postoperative pain. The Medicines Company anticipates submitting a supplemental NDA in the US in early 2014.

Infectious Disease Care Area

Oritavancin is an investigational agent under development for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Phase III data from two oritavancin (SOLO) trials in patients with ABSSSI caused by susceptible gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA) were presented at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) conference in Denver in September. The Medicines Company anticipates submission of a NDA in the fourth quarter of 2013.

Anticipated Upcoming Events

- Angiox® (bivalirudin): Presentation of EUROMAX (a Prospective, Randomized Trial of Ambulance Initiation of Bivalirudin vs. Heparin ± Glycoprotein IIb/IIIa Inhibitors in Patients with STEMI Undergoing Primary PCI), as a late breaking trial on October 30th at the Transcatheter Cardiovascular Therapeutics (TCT) 2013 scientific symposium in San Francisco
- Cangrelor: submission of a European MAA in the fourth quarter of 2013
- Oritavancin: submission of a NDA in the fourth quarter 2013
- Fibrocaps: submission of a European MAA in the fourth quarter 2013
- MDCO-216: completion of Phase I clinical trial in the fourth quarter 2013 and data report in the first quarter 2014
- IONSYS: submission of a supplemental NDA in the US in early 2014

Conference Call Information

There will be a conference call with management today at 8:30 a.m. Eastern Time to discuss first three quarters 2013 financial results, operational developments, and outlook. The conference call will be available via phone and webcast. The webcast can be accessed at www.themedicinescompany.com (http://www.themedicinescompany.com/).

Domestic Dial In: +1 (866) 825 3209
International Dial In: +1 (617) 213 8061
Passcode for both dial in numbers: 71562508

Replay is available from 10:30 a.m. Eastern Time following the conference call through November 6, 2013. To hear a replay of the call dial +1 888 286 8010 (domestic) and +1 617 801 6888 (international). Passcode for both dial in numbers is 20051387.

NON-GAAP FINANCIAL PERFORMANCE MEASURES

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted net income and adjusted earnings per share measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. Adjusted net income excludes upfront collaboration payments, amortization of acquired intangible assets, deal related charges, restructuring charges, stock-based compensation expense, arbitration award, changes in contingent consideration, non-cash interest and net income tax adjustments. See the attached Reconciliations of GAAP to Adjusted Net Income and Adjusted Earnings Per Share for explanations of the amounts excluded and included to arrive at adjusted net income and adjusted earnings per share amounts for the three month periods and nine month period ended September 30, 2013 and September 30, 2012.

These adjusted measures are non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways.

About The Medicines Company

The Medicines Company's purpose is to save lives, alleviate suffering, and contribute to the economics of healthcare by focusing on 3000 leading acute/intensive care hospitals worldwide. Its vision is to be a leading provider of solutions in three areas: acute cardiovascular care, surgery and perioperative care, and serious infectious disease care. The company operates in the Americas, Europe and the Middle East, and Asia Pacific regions with global centers today in Parsippany, NJ, USA and Zurich, Switzerland.

Forward Looking Statements

Statements contained in this press release about The Medicines Company that are not purely historical, 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" and "expects" and similar expressions, including the Company's preliminary revenue results, are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that may cause the Company'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 Company's ability to develop its global operations and penetrate foreign markets, whether the Company's products will advance in the clinical trials process on a timely basis or at all, whether the Company will make regulatory submissions for product candidates on a timely basis, whether its regulatory submissions will receive approvals from regulatory agencies on a timely basis or at all, whether physicians, patients and other key decision makers will accept clinical trial results, and such other factors as are set forth in the risk factors detailed from time to time in the Company's periodic reports and registration statements filed with the Securities and Exchange Commission including, without limitation, the risk factors detailed in the Company's Registration Statement on Form S-3 filed on August 12, 2013, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

About Angiomax (bivalirudin) for Injection

In the United States, Angiomax is indicated in patients undergoing PCI with provisional use of glycoprotein IIb/IIIa inhibitor (GPI), and in patients with, or at risk of, heparin-induced thrombocytopenia and thrombosis syndrome (HIT/HITTS) undergoing PCI. In addition, Angiomax is indicated for use as an anticoagulant in patients with unstable angina (UA) undergoing percutaneous transluminal coronary angioplasty (PTCA). Angiomax is intended for use with aspirin. Angiomax is not approved for use in patients with acute coronary syndromes (ACS) not undergoing PCI or PTCA. In clinical trials comparing Angiomax and heparin, the most common adverse reaction for Angiomax was bleeding (28%). Other common adverse reactions were headache, thrombocytopenia and fever. An unexplained fall in blood pressure or hematocrit, or any unexplained symptom, should lead to serious consideration of a hemorrhagic event and cessation of Angiomax administration. Angiomax should be used with caution in patients with disease states associated with an increased risk of bleeding. In gamma brachytherapy, an increased risk of thrombus formation, including fatal outcomes, has been associated with the use of Angiomax. Angiomax is contraindicated in patients with active major bleeding or hypersensitivity to Angiomax or its components.

Please see full prescribing information for Angiomax available at http://www.angiomax.com (http://www.angiomax.com/).

About Cleviprex (clevidipine) Injectable Emulsion

In the United States, Cleviprex is indicated for the reduction of blood pressure reduction when oral therapy is not feasible or not desirable. Cleviprex is contraindicated in patients with allergies to soybeans, soy products, eggs, or egg products; defective lipid metabolism seen in conditions such as pathologic hyperlipemia, lipoid nephrosis, or acute pancreatitis if it is accompanied by hyperlipidemia; and severe aortic stenosis. Cleviprex is intended for intravenous use. Use aseptic technique and discard any unused product within 12 hours of stopper puncture. Hypotension and reflex tachycardia are potential consequences of rapid upward titration of Cleviprex. Dihydropyridine calcium channel blockers can produce negative inotropic effects and exacerbate heart failure. Monitor heart failure patients carefully. Cleviprex gives no protection against the effects of abrupt beta-blocker withdrawal. Patients who receive prolonged Cleviprex infusions and are not transitioned to other antihypertensive therapies should be monitored for the possibility of rebound hypertension for at least 8 hours after the infusion is stopped. Most common adverse reactions are (greater than 2%) are headache, nausea, and vomiting.

Please see full prescribing information for Cleviprex available at http://www.cleviprex.com (http://www.cleviprex.com/).

About Recothrom Thrombin, topical (recombinant)

Recothrom is indicated as an aid to hemostasis whenever control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age. Recothrom should not be injected directly into the circulatory system or used for the treatment of massive or brisk arterial bleeding. Recothrom should not be administered to patients with a history of hypersensitivity to Recothrom, any of its components, or hamster proteins. Recothrom may cause thrombosis if it enters the circulatory system. Apply Recothrom topically. DO NOT INJECT. Hypersensitivity reactions, including anaphylaxis, may occur with the use of Recothrom. The most common adverse reaction (incidence 6%) was thromboembolic events. Antibody formation to Recothrom occurred in < 1% of patients. None of the antibodies detected neutralized native human thrombin.

Please see full prescribing information for Recothrom available at http://www.recothrom.com (http://www.recothrom.com/).

[1] Adjusted net income and adjusted earnings per share are non-GAAP financial performance measures with no standardized definitions under US GAAP. For further information and a detailed reconciliation, refer to the Non-GAAP Financial Performance Measures and Reconciliations of GAAP to Adjusted Net income sections of this release for explanations of the amounts excluded and included to arrive at adjusted net income and adjusted earnings per share amounts.

The Medicines Company

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except per share data)	*Three months ended September 30,*	
	2013	*2012*
Net revenue	$ 174,282	$ 136,786
Operating expenses:		
Cost of revenue	65,794	43,767
Research and development	23,187	34,536
Selling, general and administrative	62,528	43,396
Total operating expenses	151,509	121,699
Income from operations	22,773	15,087
Co-promotion income	4,423	3,750
Interest expense	(3,765)	(3,605)
Other income	383	204
Income before income taxes	23,814	15,436
Provision for income taxes	(16,068)	(6,172)
Net income	7,746	9,264
Net loss attributable to non-controlling interest	47	1
Net income attributable to The Medicines Company	$ 7,793	$ 9,265
Basic earnings per common share attributable to The Medicines Company	$ 0.13	$ 0.18
Shares used in computing basic earnings per common share	59,231	52,896
Diluted earnings per common share attributable to The Medicines Company	$ 0.12	$ 0.17
Shares used in computing diluted earnings per common	63,173	55,145

share

The Medicines Company

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except per share data)	*Year to Date September 30, 2013*	
	2013	*2012*
Net revenue	$ 502,861	$ 399,098
Operating expenses:		
Cost of revenue	186,446	125,111
Research and development	108,408	100,276
Selling, general and administrative	178,954	127,049
Total operating expenses	473,808	352,436
Income from operations	29,053	46,662
Co-promotion income	12,241	6,250
Interest expense	(11,143)	(4,389)
Other income	1,186	963
Income before income taxes	31,337	49,486
Provision for income taxes	(17,163)	(18,897)
Net income	14,174	30,589
Net loss attributable to non-controlling interest	140	2
Net income attributable to The Medicines Company	$ 14,314	$ 30,591
Basic earnings per common share attributable to The Medicines Company	$ 0.25	$ 0.57
Shares used in computing basic earnings per common share	56,296	53,653

Diluted earnings per common share attributable to The Medicines Company	$ 0.24	$ 0.55
Shares used in computing diluted earnings per common share	60,510	55,455

Balance Sheet Items	*September 30,*	*December 31,*
(in thousands)	*2013*	*2012*
	(unaudited)	
Cash and cash equivalents	$ 462,360	$ 570,321
Total assets	$ 1,545,564	$ 972,182
Convertible senior notes (due 2017)	$ 233,544	$ 226,109
The Medicines Company stockholders' equity	$ 868,888	$ 586,222

The Medicines Company

Reconciliation of GAAP to Adjusted Net Income and Adjusted Earnings Per Share

(unaudited)

(in thousands)

	Three months ended September 30,		*Nine months ended September 30,*	
	2013	*2012*	*2013*	*2012*
Net income attributable to The Medicines Company - GAAP	$ 7,793	$ 9,265	$ 14,314	$ 30,591
Before tax adjustments:				
Cost of revenue: (excluding amortization of acquired intangible assets)				

Stock based compensation expense	*(1)*	43	54	147	127
Restructuring charges	*(2)*	-		581	
Research and development:					
Stock based compensation expense	*(1)*	924	700	2,630	1,726
Restructuring charges	*(2)*	-		1,252	
Upfront collaboration payments	*(3)*	-		25,000	
Selling, general and administrative: (excluding amortization of acquired intangible assets)					
Stock based compensation expense	*(1)*	4,492	3,083	12,850	9,279
Restructuring charges	*(2)*	-		4,525	
Expenses incurred for certain transactions	*(4)*	2,907	112	7,076	112
Arbitration award	*(5)*			5,000	
Amortization of acquired intangible assets	*(6)*	6,212	1,132	17,302	3,304
Change in contingent value rights	*(7)*	5,480	1,065	(168)	2,202
Other:					
Non-cash interest expense	*(8)*	2,820	2,656	8,307	3,233
Net income tax adjustments	*(9)*	(1,381)	(3,410)	(22,319)	(7,162)
Net income attributable to The Medicines Company - Adjusted		$ 29,290	$ 14,657	$ 76,497	$ 43,412
Net income per share attributable to The					

Medicines Company - Adjusted								
Basic		$	0.49	$	0.28	$	1.36	$	0.81
Diluted	*(10)*	$	0.47	$	0.27	$	1.29	$	0.78

Note: Amounts may not sum due to rounding

Explanation of Adjustments:

(1) Exclude share based compensation of $5,459 and $3,837 for three months ended September 30, 2013 and September 30, 2012 and $15,627 and $11,132 for the nine months ended September 30, 2013 and September 30, 2012.

(2) Exclude restructuring charges relating to headcount reduction of $6,358 for nine months, September 30, 2013.

(3) Exclude upfront payments for research and development collaboration arrangements.

(4) Exclude charges related to the acquisition of Incline, ProFibrix and license of Recothrom.

(5) Exclude one time arbitration award to Eagle.

(6) Exclude amortization of intangible assets resulting from transactions with Nycomed, CSL, APP, Teva, and BMS.

(7) Exclude changes in contingent value rights due to shareholders of Targanta Therapeutics, Incline Therapeutics and ProFibrix.

(8) Exclude non-cash interest expense related to convertible senior notes.

(9) Net income tax adjustments reflect the estimated tax effect of the above adjustments and the impact of certain other non-operating tax adjustments.

(10) Reflects impact of note hedge transactions on outstanding diluted share amounts associated with convertible senior notes.

In addition to the financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do

not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways.

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