The Medicines Company Reports Second-Quarter and First-Half 2015 Financial Results

29 Jul 2015

- **Commercial resources focused on new product launches**
- **R&D investment in potential blockbusters continues**
- **Company contracts with Sandoz for launch of authorized generic bivalirudin (Angiomax)**
- **Company exploring strategic-partnering options to accelerate business development and unlock value**

PARSIPPANY, N.J.--(BUSINESS WIRE)--Jul. 29, 2015-- The Medicines Company (NASDAQ:MDCO) today announced its financial results for the second quarter and first half of 2015.

Clive Meanwell, the company's Chairman and Chief Executive Officer, stated: "As anticipated, revenue in the second quarter of 2015 fell further as purchasers continued to hold out for the potential arrival of generic Angiomax. Now, with resolution of that uncertainty we have moved on. We have contracted with Sandoz to launch an authorized generic of Angiomax; we are winding down our R&D and promotional expenditures on that product; we have reduced our workforce by 13% since the beginning of the year; focused our commercial resources on recently approved products Kengreal, Ionsys, Orbactiv, the new formulation of Minocin for Injection and Raplixa; and continued R&D investments in our potential blockbuster investigational products ALN-PCSsc (PCSK9), MDCO-216 (ApoA1-Milano), Carbavance and ABP-700. We have also been exploring a range of strategic-partnering options to accelerate our business and unlock shareholder value - and we continue to do so assiduously. As we progress in the coming quarters, we anticipate continued growth of products other than Angiomax, expect news flow from ongoing R&D projects and aim to secure strategic partnerships."

Second-Quarter 2015 Financial Summary

Worldwide net revenue was $90.5 million for the second quarter of 2015 compared to $183.8 million in the second quarter of 2014. Worldwide Angiomax®/Angiox® (bivalirudin) revenue was $65.6 million in the second quarter of 2015 compared to $163.1 million in the second quarter of 2014, with revenue in the United States decreasing to $60.5 million in the second quarter of 2015 from $152.2 million in the second quarter of 2014. Recothrom®, Thrombin topical (Recombinant) sales were $15.9 million compared to $16.3 million in the second quarter of 2014. Other products including Cleviprex® (clevidipine), Argatroban for Injection, 50 mg per mL, Minocin® (minocycline) for injection, Orbactiv® (oritavancin) and PreveLeak™ Surgical Sealant recorded sales of $9.0 million during second quarter of 2015 compared to $4.4 million in the second quarter of 2014. Excluding Angiomax, the company recorded 20% higher net revenue during the second quarter of 2015 compared to the second quarter of 2014.

The net loss for the second quarter of 2015 was $46.6 million, or ($0.71) per share, compared to a net loss of $5.2 million, or ($0.08) per share, for the second quarter of 2014. Adjusted net loss[(1)] for the second quarter of 2015 was $42.8 million, or ($0.65)[(1)] per share, compared to adjusted net income[(1)] of $20.6 million, or $0.31[(1)] per share for the second quarter of 2014.

Included in other income for the second quarter of 2015 is a $19.8 million gain on the sale of an investment.

First-Half 2015 Financial Summary

Worldwide net revenue was $217.0 million for the first half of 2015 compared to $361.0 million for the first half of 2014. Worldwide Angiomax/Angiox revenue was $166.3 million for the first half of 2015 compared to $318.8 million for the first half of 2014, with revenue in the United States decreasing to $155.6 million for the first half of 2015 from $298.4 million for the first half of 2014. Recothrom sales were $32.1 million in the United States for the first half of 2015, compared to $29.8 million for the first half of 2014. Other products including Cleviprex, Argatroban, Minocin, Orbactiv and PreveLeak recorded sales of $18.6 million for the first half of 2015, compared to $12.4 million for the first half of 2014. Excluding Angiomax, the company recorded 20% higher net revenue during the first half of 2015 compared to the first half of 2014.

The net loss for the first half of 2015 was $41.6 million, or ($0.63) per share, compared with a net loss of $10.2 million, or ($0.16) per share for the first half of 2014. Adjusted net loss[(1)] for the first half of 2015 was $37.1 million, or ($0.57)[(1)] per share, compared to adjusted net income[(1)] of $42.7 million, or $0.64[(1)] per share for the first half of 2014.

Included in other income for the first half of 2015 is a $22.7 million remeasurement gain on an equity investment, a $19.8 million gain on the sale of an investment, and $8.0 million of license income related to our collaboration agreement with SciClone Pharmaceuticals.

[(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 Reconciliation 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.

As of June 30, 2015, the company had $463 million in cash and investments compared to $371 million at the end of 2014.

Approved Product Update:

- Kengreal™ (cangrelor) – In June, the U.S. Food and Drug Administration (FDA) approved Kengreal, the first and only intravenous, reversible P2Y12 platelet inhibitor, as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a P2Y12 platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor. The Kengreal U.S. launch team includes 85 field sales professionals who are introducing this product to the same cardiac catheterization laboratories in which they promoted Angiomax.
- Orbactiv® (oritavancin)- Formulary adoption programs continue on track, hospitals and infusion centers continue to revise care pathways to enable patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible designated Gram-positive pathogens to be treated using a single infusion. In addition, reimbursement processes are adapting to this single dose treatment approach to ABSSSI patient management.
- Minocin® (minocycline) for Injection - On April 17, 2015, the FDA approved the sNDA for RPX-602 - a new formulation of Minocin for Injection, which allows for a lower dilution volume range to treat infections due to the susceptible strains of designated organisms, including those caused by Acinetobacter spp. In addition, the FDA designated RPX-602 as a qualified infectious disease product (QIDP) under the GAIN Act.
- Ionsys® (fentanyl iontophoretic transdermal system) - On April 30, 2015, the FDA approved Ionsys, the first needle-free, patient-controlled, pre-programmed fentanyl delivery system, for the short-term management of acute post-operative pain in adult patients requiring opioid analgesia in the hospital. Ionsys became available to the US market as anticipated in mid-July. The dedicated Ionsys U.S. launch team initially includes 65 dedicated field sales professionals. The Ionsys Risk Evaluation and Mitigation Strategy (REMS) Program to mitigate the risks of respiratory depression resulting from accidental exposure to persons for whom Ionsys is not prescribed is underway as required by the FDA.
- Raplixa™ (fibrin sealant (human)) - On April 30, 2015, the FDA approved Raplixa and the RaplixaSpray (RAPLIXA Delivery Device) as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature and cautery) is ineffective or impractical. As stated previously, we are scaling manufacturing of Raplixa in preparation for launch.

Please see www.themedicinescompany.com (http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.themedicinescompany.com&esheet=51151634&newsitemid=20150729005792&lan=en-US&anchor=www.themedicinescompany.com&index=1&md5=26b4d19d7f573cf518e80cb17483918a) for complete indication and important safety information for these products.

Investigational Product Candidates Update:

- ALN-PCSsc (PCSK9) – The Phase 1 clinical study of the investigational agent ALN-PCSsc in subjects with elevated low-density-lipoprotein cholesterol (LDL-C) is fully enrolled. The study is examining the effects of single or multiple subcutaneous doses of ALN-PCSsc on safety, pharmacokinetics, serum levels of LDL-C and plasma levels. Data from this study will be presented at the European Society of Cardiology Congress on August 30th in London.
- MDCO-216 (ApoA-I Milano) – In May, the company presented new data from a Phase 1 clinical study which showed significant remodeling effects on HDL-cholesterol particles which may result in reduced plaque burden in patients with atherosclerotic disease. A clinical study to affirm cholesterol efflux and efflux saturation and to assess ultrasound-measured plaque regression is underway with results anticipated by the first quarter of 2016.
- ABP-700 – Data presented at the 2015 Annual Dutch Society of Anesthesiology Conference during the second quarter showed the compound's anesthetic effect and potentially advantageous onset and offset attributes as well as promising characteristics related to respiration, blood pressure and heart rate. We expect additional clinical data will be presented at the American Society of Anesthesiologists annual meeting, October 24-28, 2015, in San Diego.
- Carbavance (meropenem/RPX7009) – Patient enrollment is continuing in the two ongoing Phase 3 TANGO clinical studies to assess the efficacy and safety of this anti-infective combination therapy in patients with complicated urinary tract infections including acute pyelonephritis and in patients with carbapenem-resistant enterobacteriaceae (CRE) infections. We expect data from multiple studies from the infectious disease portfolio will be presented at the American Society for Microbiology's ICAAC 2015 conference in September in San Diego.

Conference Call Information

There will be a conference call with management today at 8:30 a.m. Eastern Time to discuss second quarter and first half 2015 financial results, operational developments and outlook for 2015.

The conference call will be available via phone and webcast. The dial-in information is listed below:

Domestic Dial In: + 1 (877) 359-9508
International Dial In: + 1 (224) 357-2393
Passcode for both dial-in numbers: 80816169

Replay is available from 11:30 a.m. Eastern Time following the conference call through August 5, 2015. To hear a replay of the call, dial +1 (855) 859-2056 (domestic) and +1 (404) 537-3406 (international). Passcode for both dial in numbers is 80816169.

This call is being webcast and can be accessed via The Medicines Company website at www.themedicinescompany.com (http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.themedicinescompany.com&esheet=51151634&newsitemid=20150729005792&lan=en-US&anchor=www.themedicinescompany.com&index=2&md5=a6d7e3cb286118cab0b0896b18788c34)

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 3,000 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.

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 and other charges, deal related charges, restructuring charges, share-based compensation expense, changes in contingent consideration, arbitration award, milestone payments, non-cash interest, impairment charges, gain on settlement, loss on equity investment, gain on remeasurement of equity investment, gain on sale of investment 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 and six months ended June 30, 2015 and June 30, 2014.

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.

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 financial results, are intended to identify forward-looking statements. These forward-looking statements involve important 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 our products, the Company's ability to develop its global operations and penetrate foreign markets, whether the Company's product candidates 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 the Company's ongoing and planned commercial launches will be successful, whether physicians, patients and other key decision makers will accept clinical trial results, whether the Company can protect its intellectual property 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 Quarterly Report on Form 10-Q filed on May 5, 2015, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

The Medicines Company

Consolidated Statements of Income

(Unaudited)

(in thousands, except per share data)	Three months ended June 30,		Six months ended June 30,	
	2015	**2014**	**2015**	**2014**
Net revenue	$ 90,472	$ 183,774	$ 216,988	$ 361,009
Operating expenses:				
Cost of revenue	36,999	85,687	70,736	152,554
Research and development	36,221	41,228	60,170	72,324
Selling, general and administrative	96,246	88,745	176,780	153,266
Total operating expenses	169,466	215,660	307,686	378,144
Loss from operations	(78,994)	(31,886)	(90,698)	(17,135)
Co-promotion and license income	638	7,326	9,026	13,346

Gain on remeasurement of equity investment	–	–	22,741	–
Gain on sale of investment	19,773	–	19,773	–
Loss in equity investment	–	–	(144)	–
Interest expense	(9,348)	(3,892)	(17,955)	(7,752)
Other (expense) income	94	(150)	203	29
Loss before income taxes	(67,837)	(28,602)	(57,054)	(11,512)
Benefit for income taxes	21,298	23,428	15,521	1,333
Net loss	(46,539)	(5,174)	(41,533)	(10,179)
Net loss (income) attributable to non-controlling interest	(53)	17	(25)	26
Net loss attributable to The Medicines Company	$ (46,592)	$ (5,157)	$ (41,558)	$ (10,153)
Loss per common share attributable to The Medicines Company:				
Basic	$ (0.71)	$ (0.08)	$ (0.63)	$ (0.16)
Diluted	$ (0.71)	$ (0.08)	$ (0.63)	$ (0.16)
Weighted average number of common shares outstanding:				
Basic	65,903	64,400	65,541	64,277
Diluted	65,903	64,400	65,541	64,277

Balance Sheet Items

(in thousands)	**June 30, 2015**	**December 31, 2014**
	(unaudited)	
Cash and cash equivalents	$ 462,743	$ 370,741
Total assets	$ 2,066,631	$ 1,885,705
Convertible senior notes (due 2017 and due 2022*)	$ 568,044	$ 246,676
The Medicines Company stockholders' equity	$ 972,241	$ 920,565

** Convertible senior notes due 2022 issued on January 13, 2015*

The Medicines Company

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

(unaudited)

(in thousands, except per share amounts)		Three months ended June 30,		Six months ended June 30,	
		2015	**2014**	**2015**	**2014**
Net loss attributable to The Medicines Company - GAAP		$ (46,592)	$ (5,157)	$ (41,558)	$ (10,153)
Before tax adjustments:					
Cost of revenue:					
Share-based compensation expense	(1)	227	120	423	202
Amortization of acquired intangible assets	(2)	9,584	21,526	15,994	26,616
Research and development:					
Share-based compensation expense	(1)	1,133	1,480	2,064	2,813
Development milestone payments	(3)	5,352	8,429	5,352	8,429
Selling, general and administrative:					
Share-based compensation expense	(1)	7,304	7,350	13,795	13,307
Amortization of acquired intangible assets	(2)	61	1,282	123	2,829
Change in contingent purchase price	(4)	11,826	17,353	13,246	19,617
Expenses incurred for certain transactions	(5)	–	566	–	566
Other:					
Non-cash interest expense	(6)	5,920	2,948	11,436	5,862
Gain on sale of investment	(7)	(19,773)	–	(19,773)	–
Gain on remeasurement of equity investment	(8)	–	–	(22,741)	–
Loss in equity investment	(9)	–	–	144	–
Net income tax adjustments	(10)	(17,794)	(35,310)	(15,581)	(27,392)
Net (loss) income attributable to The Medicines Company - Adjusted		$ (42,752)	$ 20,587	$ (37,076)	$ 42,696
Net (loss) income per share attributable to The Medicines Company - Adjusted					

Basic	$ (0.65)	$ 0.32	$ (0.57)	$ 0.66
Diluted [11]	$ (0.65)	$ 0.31	$ (0.57)	$ 0.64
Weighted average number of common shares outstanding:				
Basic	65,903	64,400	65,541	64,277
Diluted - Adjusted [11]	65,903	66,061	65,541	66,358

Explanation of Adjustments:

(1) Excludes share-based compensation of $8,664 and $8,950 for the three months ended June 30, 2015 and June 2014, respectively, and $16,282 and $16,322 for the six months ended June 30, 2015 and June 30, 2014, respectively.

(2) Excludes amortization of intangible assets and other charges resulting from transactions with Nycomed, CSL, APP, Teva, Targanta, BMS, Rempex and Tenaxis.

(3) Excludes development milestone payments for manufacturing scale up for MDCO-216.

(4) Excludes changes in contingent purchase price due to shareholders of Targanta, Incline Therapeutics, ProFibrix, Rempex, Tenaxis and Annovation.

(5) Excludes charges related to the acquisition of Tenaxis.

(6) Excludes non-cash interest expense related to convertible senior notes.

(7) Excludes gain on sale of investment.

(8) Excludes gain on remeasurement of our equity investment in Annovation.

(9) Excludes loss in equity investment.

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

(11) Reflects impact of note hedge transactions on outstanding diluted share amounts and net income per share associated with 2017 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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