



The Medicines Company Reports Fourth-Quarter and Full-Year 2015 Business and Financial Results

17 Feb 2016

- Recent data presentations highlight pipeline progress and potential
- New-product revenues increasing
- Strategy to deploy capital against highest value assets on track with the divestiture of hemostasis portfolio

PARSIPPANY, N.J.--(BUSINESS WIRE)--Feb. 17, 2016-- The Medicines Company (NASDAQ:MDCO) today announced its business and financial results for the fourth quarter and full year ended December 31, 2015.

During and since the fourth quarter of 2015, the Company has:

- **ALN-PCSsc:** Announced positive results from the Phase 1 study of ALN-PCSsc at the American Heart Association 2015 Scientific Sessions demonstrating the drug's durable effects on PCSK9 knockdown and LDL-cholesterol reduction. Launched patient enrollment in the Orion-1 Phase 2 clinical trial of ALN-PCSsc in patients with atherosclerotic cardiovascular disease;
- **MDCO-216:** Announced the publication of positive Phase 1 results for MDCO-216 and the enrollment of patients in the MILANO-PILOT study evaluating the drug's effects on atherosclerotic plaque burden;
- **ABP-700:** Presented the first clinical results addressing the safety and tolerability of ABP-700 at the ANESTHESIOLOGY 2015 and International Society of Anesthetic Pharmacologists annual meetings;
- **CARBAVANCE:** Advanced Phase 3 clinical trials towards our goal of completion in 2016 and NDA filing shortly after;
- **Angiomax®:** Received an order from the U.S. Court of Appeals for the Federal Circuit that granted the Company's request for rehearing of its appeal in its ANDA litigation with Hospira and overturned the Court's earlier decision that invalidated the Company's two Orange Book patents for Angiomax®.
- Revenues for our launch products (Kengreal, Cleviprex, Orbactiv, Minocin IV and Ionsys) increased 294% to \$10.7 million in the fourth quarter of 2015 over the same period in 2014;
- Sold the Company's hemostasis products (RECOTHROM®, PreveLeak™ and RAPLIXA™) to Mallinckrodt for an initial payment of \$174 million plus \$235 million in potential future milestone payments. The Company has accounted for this divestment as discontinued operations.

Clive Meanwell, MD, PhD, Chief Executive Officer, The Medicines Company, stated: "We had a transformational year in 2015 during which five products were approved in the United States and Europe, four potential blockbuster products have emerged from our pipeline, our lead product became an authorized generic and we launched a new corporate strategy to unlock shareholder value, generate non-dilutive capital and focus on our most promising development programs. In the year ahead, we look forward to reporting data from ongoing studies of our four leading product candidates - ALN-PCSSc, MDCO-216, ABP-700 and CARBAVANCE – and to continuing our efforts to divest non-core assets as we focus on our late-stage clinical programs."

Fourth-Quarter 2015 Financial Summary from Continuing Operations

Worldwide net revenue was \$67.2 million for the fourth quarter of 2015 compared to \$173.1 million in the fourth quarter of 2014. Worldwide Angiomax®/Angiox® (bivalirudin) net product sales were \$23.2 million in the fourth quarter of 2015 compared to \$165.9 million in the fourth quarter of 2014, with net product sales in the United States decreasing to \$18.7 million in the fourth quarter of 2015 from \$157.5 million in the fourth quarter of 2014 driven by the loss of Angiomax exclusivity. Included in total net revenue for the fourth quarter of 2015 is \$29.4 million of royalty revenues derived from the gross profit of authorized generic sales of Angiomax (bivalirudin) by Sandoz, Inc. Other products including Cleviprex, Argatroban for Injection, 50 mg per ml, Minocin for injection, Orbactiv, and Kengreal recorded sales of \$14.6 million during the fourth quarter of 2015 compared to \$7.1 million in the fourth quarter of 2014.

The net loss from continuing operations for the fourth quarter of 2015 was \$68.2 million, or (\$0.99) per share, compared to net income from continuing operations of \$5.7 million, or \$0.09 per share, for the fourth quarter of 2014. Adjusted net loss⁽¹⁾ from continuing operations for the fourth quarter of 2015 was \$60.8 million, or (\$0.88)⁽¹⁾ per share, compared to adjusted net income⁽¹⁾ from continuing operations of \$11.6 million, or \$0.18⁽¹⁾ per share, for the fourth quarter of 2014.

Fourth-Quarter 2015 Financial Summary from Discontinued Operations

In the fourth quarter of 2015, the Company sold its hemostasis products. The Company accounted for this divestment as discontinued operations and recorded an impairment charge of \$133.3 million. The net loss for the fourth quarter of 2015 from discontinued operations was \$137.8 million, or (\$2.00) per share, compared to net loss from discontinued operations for the fourth quarter of 2014 of \$11.1 million, or (\$0.17) per share.

Full-Year 2015 Financial Summary from Continuing Operations

Worldwide net revenue was \$309.0 million for the full year 2015 compared to \$659.7 million for the full year 2014. Worldwide Angiomax/Angiox net product sales were \$212.0 million for the full year 2015 compared to \$635.7 million for the full year 2014, with net product sales in the United States decreasing to \$193.2 million for the full year 2015 from \$599.5 million for the full year 2014. Included in total net revenue for 2015 is \$53.9 million of royalty revenues derived from the gross profit of authorized generic sales of Angiomax (bivalirudin) by Sandoz, Inc. Other products including Cleviprex, ready-to-use Argatroban, Minocin IV for injection, Orbactiv, and Kengreal recorded sales of \$43.2 million for the full year 2015, compared to \$24.0 million for 2014.

The net loss from continuing operations for the full year 2015 was \$221.9 million, or (\$3.32) per share, compared with net income from continuing operations of \$0.2 million for the full year 2014. Adjusted net loss⁽¹⁾ from continuing operations for the full year 2015 was \$161.6 million, or (\$2.42)⁽¹⁾ per share, compared to adjusted net income⁽¹⁾ from continuing operations of \$72.6 million, or \$1.10⁽¹⁾ per share for the full year 2014.

The following significant items are included in the Company's financial statements for 2015. Included in other income for 2015 is a \$22.7 million re-measurement gain on an equity investment, a \$19.8 million gain on the sale of an investment, \$8.2 million of license income related to our collaboration agreement with SciClone Pharmaceuticals and a gain of \$5.0 million from a legal settlement.

Full Year 2015 Financial Summary from Discontinued Operations

In the fourth quarter of 2015, the Company sold its hemostasis products. The Company accounted for this divestment as discontinued operations and recorded an impairment charge of \$133.3 million. The net loss for discontinued operations for 2015 was \$130.8 million, or (\$1.96) per share, compared to net loss from discontinued operations for 2014 of \$32.5 million, or (\$0.50) per share.

⁽¹⁾ Adjusted net income from continuing operations and adjusted earnings per share from continuing operations 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 and Adjusted Earnings Per Share 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 December 31, 2015, the Company had \$373 million in cash and investments compared to \$371 million at the end of 2014.

Conference Call Information

There will be a conference call with management today at 8:30 a.m. Eastern Time to discuss these financial results and operational developments and outlook for 2016.

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

Domestic dial-in: 877-359-9508

International dial-in: 224-357-2393

Passcode for both dial-in numbers: 41690207

Replay is available from 11:30 a.m. Eastern Time following the conference call through February 24th, 2016. To hear a replay of the call, dial 855-859-2056 (domestic) or 404-537-3406 (international). The passcode for both dial in numbers is 41690207.

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=51281161&newsitemid=20160217005778&lan=en-US&anchor=www.themedicinescompany.com&index=1&md5=7ba3ec46f59389827af29a2683e254b8>).

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 from continuing operations and adjusted earnings per share from continuing operations 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 from continuing operations excludes upfront collaboration payments, amortization of acquired intangible assets and other charges, deal related charges, restructuring charges, stock-based compensation expense, changes in contingent consideration, legal settlement, milestone payments, non-cash interest, impairment charges, inventory adjustments, gain on settlement, gain on sale of investment, gain on re-measurement of equity 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 month periods and year ended December 31, 2015 and December 31, 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 is able to raise additional capital on favorable terms or at all, 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 November 9, 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 OPERATIONS

UNAUDITED

(In thousands, except per share amounts)

	Three Months Ended December 31,	
	2015	2014
Net product revenues	\$ 37,811	\$ 173,052
Royalty revenues	29,356	–
Total net revenues	67,167	173,052
Operating expenses:		
Cost of product revenue	25,449	51,921
Research and development	40,186	48,759
Selling, general and administrative	76,959	98,233
Total operating expenses	142,594	198,913
Loss from operations	(75,427)	(25,861)
Legal settlement	–	25,736
Co-promotion and license income	121	8,026
Loss in equity investment	–	(527)

Interest expense	(9,590)	(3,700)
Other (loss) income	(204)	123
(Loss) income from continuing operations before income taxes	(85,100)	3,797
Benefit from income taxes	16,853	1,925
Net (loss) income from continuing operations	(68,247)	5,722
Loss from discontinued operations, net of tax	(137,825)	(11,104)
Net loss	(206,072)	(5,382)
Net loss attributable to non-controlling interest	6	59
Net loss attributable to The Medicines Company	\$ (206,066)	\$ (5,323)

Basic (loss) earnings per common share attributable to The Medicines Company:

(Loss) earnings from continuing operations	\$ (0.99)	\$ 0.09
Loss from discontinued operations	(2.00)	(0.17)
Basic loss per share	\$ (2.99)	\$ (0.08)

Diluted (loss) earnings per common share attributable to The Medicines Company:

(Loss) earnings from continuing operations	\$ (0.99)	\$ 0.09
Loss from discontinued operations	(2.00)	(0.17)
Diluted loss per share	\$ (2.99)	\$ (0.08)

Weighted average number of common shares outstanding:

Basic	68,976	64,800
Diluted	68,976	66,347

THE MEDICINES COMPANY
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,	
	2015	2014
Net product revenues	\$ 255,148	\$ 659,690
Royalty revenues	53,859	–
Total net revenues	309,007	659,690
Operating expenses:		
Cost of product revenue	119,931	233,330
Research and development	123,606	139,512
Selling, general and administrative	337,943	314,954
Total operating expenses	581,480	687,796
Loss from operations	(272,473)	(28,106)
Legal settlement	5,000	25,736
Co-promotion and license income	10,132	24,236
Gain on remeasurement of equity investment	22,741	–
Gain on sale of investment	19,773	–
Loss in equity investment	(144)	(1,711)
Interest expense	(37,092)	(15,701)
Investment impairment	–	(7,500)
Other income	400	918
Loss from continuing operations before income taxes	(251,663)	(2,128)
Benefit from income taxes	29,743	2,309
Net (loss) income from continuing operations	(221,920)	181
Loss from discontinued operations, net of tax	(130,826)	(32,529)
Net loss	(352,746)	(32,348)
Net (income) loss attributable to non-controlling interest	(10)	138

Net loss attributable to The Medicines Company	\$ (352,756)	\$ (32,210)
Basic (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	\$ (3.32)	\$ –
Loss from discontinued operations	(1.96)	(0.50)
Basic loss per share	\$ (5.28)	\$ (0.50)
Diluted (loss) earnings per common share attributable to The Medicines Company:		
(Loss) earnings from continuing operations	\$ (3.32)	\$ –
Loss from discontinued operations	(1.96)	(0.50)
Diluted loss per share	\$ (5.28)	\$ (0.50)

Weighted average number of common shares outstanding:

Basic	66,809	64,473
Diluted	66,809	66,668

**THE MEDICINES COMPANY
BALANCE SHEET ITEMS**

(In thousands)

	December 31,	
	2015	2014
Cash and cash equivalents	\$ 373,173	\$ 370,741
Total assets	\$ 1,806,951	\$ 1,885,705
Convertible senior notes (due 2017 and due 2022*)	\$ 579,015	\$ 246,676
The Medicines Company stockholders' equity	\$ 732,123	\$ 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 December 31,		Year ended December 31,	
	2015	2014	2015	2014
Net (loss) income from continuing operations attributable to The Medicines Company –GAAP	\$ (68,241)	\$ 5,781	\$ (221,930)	\$ 319
Before tax adjustments:				
Cost of revenue:				
Share-based compensation expense	(1) 398	103	987	454
Inventory adjustments	(2) –	–	32,400	–
Amortization of acquired intangible assets	(3) 6,267	8,391	17,281	26,560
Research and development:				
Share-based compensation expense	(1) 697	666	3,513	4,462
Milestone payments	(4) 1,007	10,000	6,359	18,429
Selling, general and administrative:				
Share-based compensation expense	(1) 5,380	7,304	25,677	26,248
Restructuring charges	(5) –	7,159	–	7,159
Amortization of acquired intangible assets	(3) –	1,414	164	5,657
Change in contingent purchase price	(6) 4,704	5,370	27,812	29,029
Expenses incurred for certain transactions	(7) –	–	–	566
Milestone payment	(4) –	–	–	2,500
Other:				
Non-cash interest expense	(8) 6,144	3,046	23,676	11,920

Investment impairment	(9)	–	–	–	7,500
Gain on sale of investment	(10)	–	–	(19,773)	–
Gain on remeasurement of equity investment	(11)	–	527	(22,597)	1,711
Settlement	(12)	–	(25,736)	(5,000)	(25,736)
Net income tax adjustments	(13)	(17,145)	(12,384)	(30,182)	(44,162)
Net (loss) income attributable to The Medicines Company - Adjusted					
		<u>\$ (60,789)</u>	<u>\$ 11,641</u>	<u>\$ (161,613)</u>	<u>\$ 72,616</u>

Net (loss) income per share attributable to The Medicines Company - Adjusted

Basic		\$ (0.88)	\$ 0.18	\$ (2.42)	\$ 1.13
Diluted	(14)	\$ (0.88)	\$ 0.18	\$ (2.42)	\$ 1.10

Weighted average number of common shares outstanding:

Basic		68,976	64,800	66,809	64,473
Diluted – Adjusted	(14)	68,976	66,347	66,809	66,284

Explanation of Adjustments:

1) Excludes share-based compensation of \$6,475 and \$8,073 for three months ended December 31, 2015 and December 31, 2014, respectively and \$30,177 and \$31,164 for the year ended December 31, 2015 and December 31, 2014, respectively.

2) Excludes inventory adjustments.

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

4) Excludes upfront and milestone payments for research and development collaboration arrangements and manufacturing scale up for MDCO-216.

5) Excludes restructuring charges relating to the reorganization of our European operations of \$7,159 in 2014.

6) Excludes changes in contingent purchase price due to shareholders of Targanta, Incline Therapeutics, Rempex and Annovation.

7) Excludes charges related to the acquisition of Tenaxis during 2014.

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

9) Excludes investment impairment.

- 10) Excludes gain on sale of investment.
- 11) Excludes gain on remeasurement of our equity investment in Annovation.
- 12) Excludes gain from legal settlement in 2015 and impact of a one-time income in connection with the settlement with the former equity holders of Incline in 2014.
- 13) Net income tax adjustments reflect the estimated tax effect of the above adjustments and the impact of certain other non-operating tax adjustments.
- 14) Reflects impact of note hedge transactions on outstanding diluted share amounts and net income per share 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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The Medicines Company

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