

The Medicines Company Reports Third-Quarter and First Nine Months 2015 Business and Financial Results

3 Nov 2015

- **Four potential blockbuster development compounds progressing rapidly**
- **New hospital product launches progressing**
- **Chairman of the Board, Dr. Fred Eshelman, to provide an update on strategy**

PARSIPPANY, N.J.--(BUSINESS WIRE)--Nov. 3, 2015-- The Medicines Company (NASDAQ:MDCO) today announced its business and financial results for the third quarter and the nine months ended September 30, 2015.

The Company is developing four potentially class-leading investigational compounds through clinical trials:

1. A PCSK9 inhibitor (ALN-PCSsc) which is emerging as a potential best-in-class treatment for LDL-C reduction and which is entering phase 2 trials
2. A reverse cholesterol transport promoter (MDCO-216) which in prior trials showed evidence of rapid, significant reduction of coronary atheroma and which is entering into the proof of concept MILANO PILOT trial
3. A combination of meropenem and a novel beta-lactamase inhibitor (Carbavance®) for gram-negative infections associated with carbapenem-resistant Enterobacteriaceae which is currently in phase 3 trials
4. A novel intravenous anesthetic and sedation compound (ABP-700) which may improve the safety and efficiency of anesthesia and conscious sedation and which is anticipated to begin phase 2 trials in 2016

The Company has launched into the United States hospital market a series of hospital products including:

1. ORBACTIV® (oritavancin) for injection which is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSIs) caused or suspected to be caused by susceptible isolates of certain gram-positive microorganisms. <http://www.orbactiv.com/> (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.orbactiv.com%2F&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=http%3A%2F%2Fwww.orbactiv.com%2F&index=1&md5=6b2d54b5b64ec4b487154ab1d65abe22>),
2. MINOCIN® (minocycline) for injection which is indicated for the treatment of infections due to susceptible isolates of designated microorganisms, including Acinetobacter species bacteria. <http://www.minociniv.com/> (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.minociniv.com%2F&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=http%3A%2F%2Fwww.minociniv.com%2F&index=2&md5=3b56cd2486b559ba6f11d246f6949bc5>),
3. KENGREAL™ (cangrelor) for injection which is a P2Y₁₂ platelet inhibitor indicated 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. <http://www.kengreal.com/> (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.kengreal.com%2F&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=http%3A%2F%2Fwww.kengreal.com%2F&index=3&md5=0d6094d6c94c8d9caf7632ee4c864ebb>),

4. CLEVIPREX® (clevidipine) injectable emulsion, which is a dihydropyridine calcium channel blocker indicated for the reduction of blood pressure (BP) when oral therapy is not feasible or not desirable. <http://www.cleviprex.com/> (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.cleviprex.com%2F&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=http%3A%2F%2Fwww.cleviprex.com%2F&index=4&md5=95abfdb101346974ef9ba7ff2998b531>),

and

5. IONSYS® (fentanyl iontophoretic transdermal system) CII, which contains fentanyl, an opioid agonist, and is indicated for the short-term management of acute postoperative pain in adult patients requiring opioid analgesia in the hospital. <http://www.ionsys.com/> (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.ionsys.com%2F&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=http%3A%2F%2Fwww.ionsys.com%2F&index=5&md5=63be4c2397b3de9622af6538a5403623>),

Please see www.themedicinescompany.com (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.themedicinescompany.com&esheet=51215535&newsitemid=20151103005933&lan=en-US&anchor=www.themedicinescompany.com&index=6&md5=a1d4122defc83ee114bd1dbde4aa1b6c>), for complete indication and important safety information for these products.

Clive Meanwell, the Company's Chief Executive Officer, stated: "We have made significant progress recently with our four pipeline candidates and are now looking forward to several important clinical milestones, including the presentation of final results from the Phase 1 clinical trial of ALN-PCSsc in a late-breaker session at the American Heart Association scientific meeting in Orlando next week, the start of Phase 2 testing of ALN-PCSsc, the MILANO PILOT program for MDCO-216, the start of Phase 2 testing of ABP-700 and the completion of Phase 3 studies of Carbavance® (meropenem/RPX7009). These product candidates represent potentially important medical innovations to which we are dedicating substantial human and financial resources in order to maximize their clinical and commercial potential. In the meantime, we are pleased with the progress and growth potential of our new product launches – each of which is progressing through the process of formulary review and initial use in U.S. hospitals that we have decided to approach."

Third-Quarter 2015 Financial Summary

Worldwide net revenue was \$72.7 million for the third quarter of 2015 compared to \$172.4 million in the third quarter of 2014. Worldwide Angiomax®/Angiox® (bivalirudin) revenue was \$47.0 million in the third quarter of 2015 compared to \$151.0 million in the third quarter of 2014, with revenue in the United States decreasing to \$43.3 million in the third quarter of 2015 from \$143.5 million in the third quarter of 2014 driven by the loss of Angiomax exclusivity. Included in total net revenue for the third quarter of 2015 is \$24.5 million of royalty revenues derived from the gross profit of authorized generic sales of Angiomax (bivalirudin) by Sandoz, Inc. Recothrom®, Thrombin topical (Recombinant) sales were \$15.4 million in the third quarter of 2015 compared to \$16.8 million in the third quarter of 2014. Other products including Cleviprex, Argatroban for Injection, 50 mg per ml, Minocin for injection, Orbactiv, Kengreal, and PreveLeak™ Surgical Sealant recorded sales of \$10.3 million during the third quarter of 2015 compared to \$4.6 million in the third quarter of 2014.

The net loss for the third quarter of 2015 was \$105.1 million, or (\$1.57) per share, compared to a net loss of \$16.7 million, or (\$0.26) per share, for the third quarter of 2014. Adjusted net loss⁽¹⁾ for the third quarter of 2015 was \$55.1 million, or (\$0.82)⁽¹⁾ per share, compared to adjusted net income⁽¹⁾ of \$11.6 million, or \$0.18⁽¹⁾ per share for the third quarter of 2014.

The following significant items are included in the Company's financial statements for the third quarter of 2015. Included in cost of revenues for the third quarter of 2015 are a charge for potential inventory obsolescence of \$32.4 million and an impairment charge related to the product rights of PreveLeak of \$25.8 million. Included in other income for the third quarter of 2015 is a gain of \$5.0 million from a legal settlement.

First-Nine-Months 2015 Financial Summary

Worldwide net revenue was \$289.7 million for the first nine months of 2015 compared to \$533.4 million for the first nine months of 2014. Worldwide Angiomax/Angiox revenue was \$213.3 million for the first nine months of 2015 compared to \$469.8 million for the first nine months of 2014, with revenue in the United States decreasing to \$199.0 million for the first nine months of 2015 from \$442.0 million for the first nine months of 2014. Included in total net revenue for the first nine months of 2015 is \$24.5 million of royalty revenues derived from the gross profit of authorized generic sales of Angiomax (bivalirudin) by Sandoz, Inc. Recothrom sales were \$47.5 million for the first nine months of 2015, compared to \$46.5 million for the first nine months of 2014. Other products including Cleviprex, ready-to-use Argatroban, Minocin IV for injection, Orbactiv, Kengreal, and PreveLeak recorded sales of \$28.9 million for the first nine months of 2015, compared to \$17.1 million for the first nine months of 2014.

The net loss for the first nine months of 2015 was \$146.7 million, or (\$2.22) per share, compared with a net loss of \$26.9 million, or (\$0.42) per share for the first nine months of 2014. Adjusted net loss⁽¹⁾ for the first nine months of 2015 was \$92.2 million, or (\$1.39)⁽¹⁾ per share, compared to adjusted net income⁽¹⁾ of \$54.3 million, or \$0.82⁽¹⁾ per share for the first nine months of 2014.

The following significant items are included in the Company's financial statements for the first nine months of 2015. Included in cost of revenues for the first nine months of 2015 are a charge for potential inventory obsolescence of \$32.4 million and an impairment charge related to the product rights of PreveLeak of \$25.8 million. Included in other income for the first nine months of 2015 is a \$22.7 million remeasurement gain on an equity investment, a \$19.8 million gain on the sale of an investment, \$8.1 million of license income related to our collaboration agreement with SciClone Pharmaceuticals and a gain of \$5.0 million from a legal settlement. Included in other income for the first nine months of 2014 is a \$7.5 million investment impairment charge.

⁽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 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 September 30, 2015, the Company had \$509 million in cash and investments compared to \$371 million at the end of 2014.

A full business and product pipeline update will be provided on the earnings conference call. During the call, Dr Fred Eshelman, Chairman of the Board, will provide an overview of the Company's strategy over the short and medium term horizon.

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 the remainder of 2015.

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: 56448421

Replay is available from 11:30 a.m. Eastern Time following the conference call through November 10, 2015. 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 56448421.

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=51215535&newsitemid=20151103005933&lan=en-US&anchor=www.themedicinescompany.com&index=7&md5=d2cb41147f914a1634084f173ea5d0b9>).

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, inventory obsolescence 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 nine months ended September 30, 2015 and September 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 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 August 7, 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 data) | Three months ended September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|------------|
| | 2015 | 2014 | 2015 | 2014 |
| Net product revenues | \$ 48,175 | \$ 172,401 | \$ 265,163 | \$ 533,410 |
| Royalty revenues | 24,503 | – | 24,503 | – |
| Total net revenues | 72,678 | 172,401 | 289,666 | 533,410 |
| Operating expenses: | | | | |
| Cost of revenue | 86,970 | 69,076 | 157,706 | 221,630 |
| Research and development | 30,120 | 33,314 | 90,290 | 105,638 |
| Selling, general and administrative | 82,477 | 82,662 | 259,257 | 235,928 |
| Total operating expenses | 199,567 | 185,052 | 507,253 | 563,196 |
| Loss from operations | (126,889) | (12,651) | (217,587) | (29,786) |
| Co-promotion and license income | 985 | 2,864 | 10,011 | 16,210 |
| Gain on remeasurement of equity investment | – | – | 22,741 | – |
| Gain on sale of investment | – | – | 19,773 | – |
| Loss in equity investment | – | (1,184) | (144) | (1,184) |
| Legal settlement | 5,000 | – | 5,000 | – |

| | | | | |
|--|--------------|-------------|--------------|-------------|
| Interest expense | (9,547) | (3,958) | (27,502) | (11,710) |
| Investment impairment | – | (7,500) | – | (7,500) |
| Other (expense) income | (137) | (53) | 66 | (24) |
| Loss before income taxes | (130,588) | (22,482) | (187,642) | (33,994) |
| Benefit for income taxes | 25,447 | 5,693 | 40,968 | 7,026 |
| Net loss | (105,141) | (16,789) | (146,674) | (26,968) |
| Net (income) loss attributable to non-controlling interest | 9 | 53 | (16) | 79 |
| Net loss attributable to The Medicines Company | \$ (105,132) | \$ (16,736) | \$ (146,690) | \$ (26,889) |
| Loss per common share attributable to The Medicines Company: | | | | |
| Basic | \$ (1.57) | \$ (0.26) | \$ (2.22) | \$ (0.42) |
| Diluted | \$ (1.57) | \$ (0.26) | \$ (2.22) | \$ (0.42) |
| Weighted average number of common shares outstanding: | | | | |
| Basic | 67,137 | 64,534 | 66,079 | 64,363 |
| Diluted | 67,137 | 64,534 | 66,079 | 64,363 |

Balance Sheet Items

| (in thousands) | September 30, | | December 31, | |
|--|---------------|-----------|--------------|-----------|
| | 2015 | | 2014 | |
| | (unaudited) | | | |
| Cash and cash equivalents | \$ | 508,808 | \$ | 370,741 |
| Total assets | \$ | 2,073,091 | \$ | 1,885,705 |
| Convertible senior notes (due 2017 and due 2022) | \$ | 573,511 | \$ | 246,676 |
| The Medicines Company stockholders' equity | \$ | 922,771 | \$ | 920,565 |

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 September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|-------------|
| | 2015 | 2014 | 2015 | 2014 |
| Net loss attributable to The Medicines Company - GAAP | \$ (105,132) | \$ (16,736) | \$ (146,690) | \$ (26,889) |
| Before tax adjustments: | | | | |
| Cost of revenue: | | | | |
| Share-based compensation expense | (1) 267 | 149 | 690 | 351 |
| Amortization and other charges related to intangible assets | (2) 33,684 | 6,236 | 49,678 | 32,852 |
| Inventory adjustments | (3) 32,400 | | 32,400 | |
| Research and development: | | | | |
| Share-based compensation expense | (1) 888 | 1,629 | 2,952 | 4,442 |
| Development milestone payments | (4) – | – | 5,352 | 8,429 |
| Selling, general and administrative: | | | | |
| Share-based compensation expense | (1) 6,572 | 6,636 | 20,367 | 19,943 |
| Amortization of acquired intangible assets | (2) 41 | 1,414 | 164 | 4,243 |
| Development milestone payment | (4) – | 2,500 | – | 2,500 |
| Change in contingent purchase price | (5) 618 | 9,114 | 13,864 | 28,731 |
| Expenses incurred for certain transactions | (6) – | – | – | 566 |
| Other: | | | | |
| Non-cash interest expense | (7) 6,096 | 3,012 | 17,532 | 8,874 |
| Gain on sale of investment | (8) – | – | (19,773) | – |
| Gain on remeasurement of equity investment | (9) – | – | (22,741) | – |
| Investment impairment | (11) – | 7,500 | – | 7,500 |
| Loss in equity investment | (10) – | 1,184 | 144 | 1,184 |
| Legal settlement | (12) (5,000) | – | (5,000) | – |
| Net income tax adjustments | (13) (25,535) | (11,062) | (41,116) | (38,454) |
| Net (loss) income attributable to The Medicines Company – Adjusted | \$ (55,101) | \$ 11,576 | \$ (92,177) | \$ 54,272 |

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

– Adjusted

| | | | | | | | | | |
|---|------|----|--------|----|--------|----|--------|----|--------|
| Basic | | \$ | (0.82) | \$ | 0.18 | \$ | (1.39) | \$ | 0.84 |
| Diluted | (14) | \$ | (0.82) | \$ | 0.18 | \$ | (1.39) | \$ | 0.82 |
| Weighted average number of common shares outstanding: | | | | | | | | | |
| Basic | | | 67,137 | | 64,534 | | 66,079 | | 64,363 |
| Diluted – Adjusted | (14) | | 67,137 | | 66,067 | | 66,079 | | 66,262 |

Explanation of Adjustments:

(1) Excludes share-based compensation of \$7,727 and \$8,414 for the three months ended September 30, 2015 and September 30 2014, respectively, and \$24,009 and \$24,736 for the nine months ended September 30, 2015 and September 30, 2014, respectively.

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

(3) Inventory adjustments.

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

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

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

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

(8) Excludes gain on sale of investment.

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

(10) Excludes loss in equity investment.

(11) Excludes investment impairment.

(12) Excludes gain from legal settlement.

(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 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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The Medicines Company

Investor Relations:

Krishna Gorti, MD, +1 973-290-6122

Vice President, Investor Relations

Krishna.Gorti@themedco.com (<mailto:Krishna.Gorti@themedco.com>)

Or

Media:

Bob Laverty, +1 973-290-6162

Vice President, Communications

Robert.Laverty@themedco.com (<mailto:Robert.Laverty@themedco.com>)