The Medicines Company Reports Second-Quarter 2018 Results

Aug 2018

PARSIPPANY, N.J.--(BUSINESS WIRE)--Aug. 1, 2018-- The Medicines Company (NASDAQ:MDCO) today reported its financial results for the second quarter ended June 30, 2018.

"During the second quarter of 2018, we continued to advance inclisiran's development programs, including the accumulation of further promising safety data from 3,660 patients in Phase III trials," said Clive Meanwell, M.D., Ph.D., Chief Executive Officer of The Medicines Company. "We were also able to present consistent phase II subset efficacy data in various demographic and disease populations for LDL-C and other atherogenic lipoproteins. We look forward to further progress in 2018 and Phase III data read-outs in 2019."

Second quarter 2018 highlights included the following:

In April, the Company presented new data and analyses from multiple studies in the ORION development program for inclisiran at the National Lipid Association 2018 Scientific Sessions. The data demonstrated that inclisiran likely has a "one-size-fits-all" dosing regimen, without the necessity of dose adjustments, across a wide range of dyslipidemia patient populations, including those hard-to-treat patients with homozygous familial hypercholesterolemia (HoFH) and other sub-groups, such as patients with renal impairment and diabetes. The data showed that inclisiran lowered low-density lipoproteins cholesterol (LDL-C) by more than 50% for a wide range of dyslipidemia patient populations and sub-groups, and by up to 44% in HoFH patients.

In May, the Company presented the results of a pre-specified analysis of secondary endpoints from the ORION-1 Phase II trial at the 86thEuropean Atherosclerosis Society Congress. The results, which were published in *Circulation*, the journal of the American Heart Association, showed that, beyond its powerful effect on LDL-C, inclisiran also reduced atherogenic lipoproteins in a profound and sustained manner. Atherogenic lipoproteins – non-HDL-C, ApoB, VLDL-C and Lp(a) – have been associated with an increased risk of heart attacks and strokes, particularly in high-risk patients. The reductions, which were generally dose-dependent, were achieved most clearly with a 300 mg dose of inclisiran given on Day-1 and Day-90, and were sustained to the pre-specified time of assessment (180 days) and beyond (at least 210 days). This is the same starting dose of inclisiran being utilized in the Phase III trials (the Phase III dose of inclisiran is 300 mg given on Day-1 and Day-90, and then every six months thereafter).

In June, the Company presented new data from a pre-specified, subgroup analysis of dosing, efficacy and safety of inclisiran in patients with diabetes from the ORION-1 Phase II trial at the American Diabetes Association 78th Scientific Sessions®. The data demonstrated that a subcutaneous injection of 300 mg of inclisiran given at Day-1 and Day-90 lowered LDL-C at Day-180 by more than 50% in patients with atherosclerotic cardiovascular disease (ASCVD) and those considered ASCVD-risk equivalents, regardless of whether those patients had diabetes. Importantly, the data showed that patients with and without diabetes experienced similar adverse event profiles, including no effects on control of blood glucose levels over six months.

In June, the Independent Data Monitoring Committee (IDMC) for the ongoing inclisiran Phase III clinical trials conducted its third, planned review of safety and efficacy data from the trials and recommended that they continue without modification. At the time of the review, substantially all patients in trials had received two doses of inclisiran or placebo, and more than 1,550 patient-years of safety data for inclisiran had been accumulated – with an additional 5 patient-years of safety data continuing to accumulate every day.

During the second quarter, the Company substantially completed the implementation of its previously-announced restructuring, as anticipated.

Commenting further, Dr. Meanwell said, “We continued to deliver against our 2018 objectives during the second quarter, demonstrating strong execution on all fronts. We remain sharply focused on tightening expense management and advancing the inclisiran development program efficiently.”

Second-Quarter 2018 Financial Summary from Continuing Operations

On a GAAP basis, loss from continuing operations in the second quarter of 2018 was $54.5 million, or $0.74 per share, compared to a loss of $370.1 million, or $5.15 per share, in the second quarter of 2017. Included in loss from continuing operations for the second quarter of 2018 were restructuring charges of $6.1 million. On a non-GAAP basis, adjusted loss[(1)] from continuing operations in the second quarter of 2018 was $46.3 million, or $0.63[(1)] per share, compared to a loss of $52.0 million, or $0.72[(1)] per share, in the second quarter of 2017.

First Half 2018 Financial Summary from Continuing Operations

On a GAAP basis, loss from continuing operations in the first half of 2018 was $139.3 million, or $1.89 per share, compared to a loss of $441.1 million, or $6.17 per share, in the first half of 2017. Included in loss from continuing operations for the first half of 2018 was a non-cash, mark-to-market change in fair value of approximately $31.1 million associated with the Company's common stock ownership in Melinta, guaranteed repayments and restructuring charges of $11.4 million. On a non-GAAP basis, adjusted loss[(1)] from continuing operations in the first half of 2018 was $102.6 million, or $1.40[(1)] per share, compared to a loss of $105.3 million, or $1.47[(1)] per share, in the first half of 2017.

First Half 2018 Financial Summary from Discontinued Operations

In the first quarter of 2018, the Company completed the sale of its infectious disease business, consisting of the products Vabomere™, Orbactiv® and Minocin® IV, as well as line extensions of those products, for $270 million in upfront consideration and guaranteed payments, tiered royalty payments of between 5% to 25% on worldwide net sales of Vabomere, Orbactiv and Minocin IV, and the assumption by Melinta of all royalty, milestone and other payment obligations relating to those products.

(1) Adjusted net loss and adjusted loss per share from continuing operations are non-GAAP financial performance measures with no standardized definitions under U.S. GAAP. For further information and a detailed reconciliation, refer to the “Non-GAAP Financial Performance Measures” and “Reconciliations of GAAP to Adjusted Loss From Continuing Operations and Adjusted Loss per Share” sections of this press release.

Net income from discontinued operations in the first half of 2018 was $114.2 million, compared to a net loss of $58.9 million in 2017. Net income from discontinued operations in the first half of 2018 included a pre-tax gain of approximately $169.0 million from the sale of the Company's infectious disease business to Melinta.

At June 30, 2018, the Company had $162.5 million in cash and cash equivalents, compared to $151.4 million at the end of 2017.

Second-Quarter 2018 Conference Call and Webcast Information

The Company will host a conference call and webcast today, August 1, 2018, at 8:30 a.m., Eastern Daylight Time, to discuss its second-quarter 2018 financial results and provide clinical and operational updates. The dial-in information to access the call is as follows:

U.S./Canada:	(877) 359-9508
International:	(224) 357-2393
Conference ID:	5847059

A taped replay of the conference call will be available from 11:30 a.m., Eastern Daylight Time, today until 11:30 p.m., Eastern Daylight Time, on August 8, 2018. The replay may be accessed as follows:

U.S./Canada:	(855) 859-2056
International:	(404) 537-3406
Conference ID:	5847059

he webcast can be accessed in the "Investors" section of The Medicines Company website (http://cts.businesswire.com/ct/CT?d=smartlink&url=http%3A%2F%2Fwww.themedicinescompany.com%2Finvestors&esheet=51846243&newsitemid=20180801005289&lan=en-US&anchor=The+Medicines+Company+website&index=1&md5=370bcf2d1c57d2ea185d5401a866e07b). A replay of the webcast will also be vailable.

bout Inclisiran

nclisiran is an investigational GalNAc-conjugated RNA interference therapeutic, which inhibits the synthesis of PCSK9 protein in liver cells, hereby reducing liver cell LDL receptor turnover, and lowering plasma LDL-C.

he Medicines Company and Alnylam Pharmaceuticals, Inc. are collaborating in the advancement of inclisiran pursuant to their 2013 greement. Under the terms of the agreement, Alnylam completed certain pre-clinical studies and the Phase I clinical study, with The Medicines Company leading and funding the development of inclisiran from Phase II forward, as well as potential commercialization.

bout The Medicines Company

he Medicines Company is a biopharmaceutical company driven by an overriding purpose – to save lives, alleviate suffering and contribute to he economics of healthcare. The Company's goal is to create transformational solutions to address the most pressing healthcare needs acing patients, physicians and providers in cardiovascular care. The Company is headquartered in Parsippany, New Jersey.

orward-Looking Statements

tatements contained in this press release about The Medicines Company that are not purely historical, and all other statements that are not urely historical, may be deemed to be forward-looking statements for purposes of the safe harbor provisions under The Private Securities itigation Reform Act of 1995. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and "potential' and similar xpressions, are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and ncertainties that may cause the Company's actual results, levels of activity, performance or achievements to be materially different from hose expressed or implied by these forward-looking statements. Important factors that may cause or contribute to such differences include he ability of the Company to effectively develop inclisiran; whether inclisiran will advance in the clinical trials process on a timely basis or at all, r succeed in achieving its specified endpoints; whether the Company will make regulatory submissions for inclisiran on a timely basis; whether its regulatory submissions will receive approvals from regulatory agencies on a timely basis or at all; the extent of the commercial uccess of inclisiran, if approved; and such other factors as are set forth in the risk factors detailed from time to time in the Company's eriodic reports and registration statements filed with the Securities and Exchange Commission (SEC), including, without limitation, the risk actors detailed in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2018, which are incorporated herein by eference. The Company specifically disclaims any obligation to update these forward-looking statements.

ION-GAAP FINANCIAL PERFORMANCE MEASURES

n addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted loss from continuing perations and adjusted loss per share from continuing operations attributable to The Medicines Company. The Company believes these neasures provide investors and management with supplemental information relating to operating performance and trends that facilitate omparisons between periods and with respect to projected information.

djusted loss from continuing operations excludes share-based compensation expense, amortization of acquired intangible assets, asset npairment charges, inventory adjustments, restructuring charges, charges associated with product discontinuance, changes in contingent urchase price, legal settlements, changes in short-term investments and non-cash interest expense. The Company believes these non-GAAP nancial measures help indicate underlying trends in the Company's business and are important in comparing current results with prior period esults and understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an ndication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ngoing results. See the attached Reconciliations of GAAP to Adjusted Loss from Continuing Operations and Adjusted Loss per Share for xplanations of the amounts excluded and included to arrive at adjusted net loss and adjusted loss per share amounts for the three- and six nonths ended June 30, 2018 and 2017.

hese adjusted measures are non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in ccordance with U.S. GAAP. The Company strongly encourages investors to review its consolidated financial statements and publicly-filed eports in their entirety and cautions investors that the non-GAAP measures used by the Company may differ from similar measures used by ther companies, even when similar terms are used to identify such measures.

THE MEDICINES COMPANY
CONSOLIDATED STATEMENTS OF OPERATIONS
UNAUDITED
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	$ 1,667	$ 10,861	$ 9,438	$ 28,326
Operating expenses:				
Cost of revenues	2,931	12,490	5,668	22,468
Asset impairment charges	–	329,097	–	329,097
Research and development	30,294	23,249	70,660	49,693
Selling, general and administrative	21,013	28,359	49,964	68,816
Total operating expenses	54,238	393,195	126,292	470,074
Loss from operations	(52,571)	(382,334)	(116,854)	(441,748)
Co-promotion and license income	254	757	482	1,514
Loss on short-term investment	(3,474)	–	(33,463)	–
Interest expense	(12,108)	(12,521)	(24,185)	(24,943)
Other income	1,053	1,033	3,422	1,144
Loss from continuing operations before income taxes	(66,846)	(393,065)	(170,598)	(464,033)
Benefit (provision) for income taxes	12,393	23,000	31,309	22,972
Loss from continuing operations	(54,453)	(370,065)	(139,289)	(441,061)
Income (loss) from discontinued operations, net of tax	256	(27,203)	114,241	(58,877)
Net Loss	$ (54,197)	$ (397,268)	$ (25,048)	$ (499,938)
Basic (loss) earnings per common share:				
Loss from continuing operations	$ (0.74)	$ (5.15)	$ (1.89)	$ (6.17)
Earnings (loss) from discontinued operations	–	(0.38)	1.55	(0.82)
Basic loss per share	$ (0.74)	$ (5.53)	$ (0.34)	$ (6.99)
Diluted (loss) earnings per common share:				
Loss from continuing operations	$ (0.74)	$ (5.15)	$ (1.89)	$ (6.17)
Earnings (loss) from discontinued operations	–	(0.38)	1.55	(0.82)

Diluted loss per share	$ (0.74)	$ (5.53)	$ (0.34)	$ (6.99)
Weighted average number of common shares outstanding:				
Basic	73,349	71,918	73,574	71,498
Diluted	73,349	71,918	73,574	71,498

THE MEDICINES COMPANY
BALANCE SHEET ITEMS
UNAUDITED
(In thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 162,530	$ 151,359
Short-term investment	$ 21,042	$ –
Total assets	$ 795,837	$ 872,983
Convertible senior notes (due 2022 and 2023)	$ 662,729	$ 649,198
The Medicines Company stockholders' equity	$ 21,229	$ 24,914

THE MEDICINES COMPANY
RECONCILIATIONS OF GAAP TO ADJUSTED LOSS FROM CONTINUING OPERATIONS AND ADJUSTED LOSS PER SHARE
UNAUDITED
(In thousands, except per share amounts)

		Three Months Ended June 30,		Six Months Ended June 30,	
		2018	2017	2018	2017
Loss from continuing operations		$ (54,453)	$ (370,065)	$ (139,289)	$ (441,061)
Before tax adjustments:					
Cost of product revenues:					
Share-based compensation expense	(1)	75	236	69	407
Amortization of acquired intangible assets	(2)	–	–	–	4,486
Inventory adjustments	(3)	9	(2,554)	(407)	(2,965)

Restructuring charges	(4)	318	–	761	(66)
Market withdrawal of Ionsys	(5)	–	8,458	–	8,458
Asset impairment charges					
Market withdrawal of Ionsys	(5)	–	264,097	–	264,097
Discontinuance of MDCO 700	(6)	–	65,000	–	65,000
Research and development:					
Share-based compensation expense	(1)	1,195	934	2,179	1,526
Restructuring charges	(4)	3,322	504	3,648	396
Market withdrawal of Ionsys	(5)	–	1,032	–	1,032
Selling, general and administrative:					
Share-based compensation expense	(1)	3,377	7,786	6,826	13,217
Restructuring charges	(4)	2,458	(53)	6,995	(104)
Changes in contingent purchase price	(7)	6	–	(258)	692
Legal settlements	(8)	–	–	3,550	–
Market withdrawal of Ionsys	(5)	–	3,434	–	3,434
Discontinuance of MDCO 700	(6)	–	(14,701)	–	(14,701)
Other:					
Non-cash interest expense	(9)	6,786	6,849	13,531	13,822
Change in short-term investments	(10)	3,074	–	31,101	–
Net loss tax adjustments	(11)	(12,426)	(22,988)	(31,342)	(22,989)
Loss from continuing operations - Adjusted		$ (46,259)	$ (52,031)	$ (102,636)	$ (105,319)
Loss per share - Adjusted					
Basic		$ (0.63)	$ (0.72)	$ (1.40)	$ (1.47)
Diluted		$ (0.63)	$ (0.72)	$ (1.40)	$ (1.47)
Weighted average number of common shares outstanding:					
Basic		73,349	71,918	73,574	71,498
Diluted		73,349	71,918	73,574	71,498

Explanation of Adjustments:

1) Excludes share-based compensation of $4,647 and $8,956 for the three months ended June 30, 2018 and 2017 and $9,074 and $15,150 for the six months ended June 30, 2018 and 2017 because these expenses are substantially dependent on changes in the market price of the Company's common stock.

2) Excludes amortization of intangible assets resulting from the Incline Therapeutics transaction.

3) Excludes all non-cash inventory adjustments.

4) Excludes restructuring charges related to workforce reorganization initiated in the first quarter 2018 and the sale of the non-core cardiovascular products.

5) Excludes charges associated with the voluntary discontinuation and withdrawal of Ionsys from the market in the United States and cessation of related commercial activities in 2017.

6) Excludes costs associated with the decision to discontinue the MDCO-700 program.

7) Excludes changes in fair value of the contingent price related to the acquisitions of Rempex that were not included in the sale to Melinta.

8) Excludes net loss from one-time legal settlements in 2018.

9) Excludes non-cash interest expense which is in excess of the actual interest expense paid on the Convertible Senior Notes.

10) Excludes changes in fair value with our investment in Melinta and guaranteed payments associated with the sale of our infectious disease business.

11) Excludes the estimated tax effect related to the sale of Melinta in 2018 and the decision to discontinue the MDCO-700 program in 2017.

In addition to the financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that the Company believes 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. The Company strongly encourages investors to review its consolidated financial statements and publicly filed reports in their entirety and cautions investors that the non-GAAP measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

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