The Medicines Company Reports First-Quarter 2018 Results

5 Apr 2018

ARSIPPANY, N.J.--(BUSINESS WIRE)--Apr. 25, 2018-- The Medicines Company (NASDAQ: MDCO) today reported its financial results for the rst quarter ended March 31, 2018.

During the first quarter of 2018, The Medicines Company continued to demonstrate strong clinical and operational execution, significantly dvancing the ORION development programs for our investigational agent, inclisiran, and delivering against all of our other 2018 objectives," aid Clive Meanwell, M.D., Ph.D., Chief Executive Officer of The Medicines Company.

irst quarter 2018 highlights included:

In January, the Company completed the sale of its infectious disease business unit to Melinta Therapeutics, Inc. ("Melinta"), significantly strengthening the Company's cash position and substantially reducing its cost structure.

In January, the Company achieved target enrollment in the ORION-11 Phase III clinical trial for inclisiran in patients with atherosclerotic cardiovascular disease (ASCVD) or cardiovascular risk-equivalents, randomizing more than 1,500 patients in only 11 weeks – 14 weeks ahead of schedule. ORION-11, together with the ORION-9 and ORION-10 clinical trials, comprise the pivotal trials with 18-month follow-up (collectively, the "ORION Pivotal Trials") designed to confirm inclisiran safety and efficacy, as well as provide data required for New Drug Application ("NDA") and Marketing Authorization Application ("MAA") submissions in the United States and Europe, respectively.

In January, the ORION Drug Safety Monitoring Board (the "DSMB") met to review data from the ORION Pivotal Trials and recommended that they continue without change or modification.

In January, the Company announced that it had achieved commercial scale manufacturing for inclisiran.

In January, the U.S. Food and Drug Administration (the "FDA") granted orphan drug designation to inclisiran for the treatment of homozygous familial hypercholesterolemia ("HoFH").

In February, the Company reached its enrollment target for the ORION-9 clinical trial in patients with heterozygous familial hypercholesterolemia ("HeFH"), enrolling 400 patients in only 10 weeks – 14 weeks ahead of schedule.

In March, the Company reached its enrollment target for the ORION-10 clinical trial in patients with ASCVD, randomizing more than 1,500 patients in only 12 weeks –10 weeks ahead of schedule, completing enrollment in the ORION Pivotal Trials.

In March, the ORION DSMB met for the second time to review data from the ORION Pivotal Trials and recommended that they continue without change or modification.

In March, the Company hosted a major scientific symposium at the American College of Cardiology 2018 Annual Meeting in Orlando, Florida. During the symposium, which was co-chaired by Eugene Braunwald, M.D., Distinguished Hersey Professor of Medicine at Harvard Medical School and founding Chairman of the Thrombolysis in Myocardial Infarction (TIMI) Study Group, and John J.P. Kastelein, M.D., Ph.D., Professor of Medicine and Chairman of the Department of Vascular Medicine at the Academic Medical Center of the University of

Amsterdam, the design of the Company's ORION-4 cardiovascular outcomes trial was presented and Dr. Braunwald presented the case for primordial prevention of coronary disease with one, annual 300 mg injection of inclisiran.

Recently, the Company successfully completed manufacturing of its first batch of pre-filled syringes – the same syringe that will be used for inclisiran launch, and which will now be used in a portion of the ORION Pivotal Trials.

Over 50% of patients in the ORION Pivotal Trials have now received the second dose of inclisiran at Day-90, increasing by tenfold the number of patients receiving two doses of inclisiran over the previously-completed ORION-1 Phase II trial.

To date, the Company has accumulated more than 1,000 patient years of safety data for inclisiran.

During the first quarter of 2018, the Company substantially completed the implementation of its previously-announced restructuring, with all remaining restructuring activities, primarily consisting of the divestiture or separation of the pre-clinical infectious disease business not acquired by Melinta and the full wind down of all legacy businesses and assets, expected to be completed by June 30, 2018, as anticipated.

Commenting further, Dr. Meanwell said, "We fully expect to continue our significant clinical and operational momentum throughout 2018 and into 2019, further demonstrating and enhancing inclisiran's unique and potentially game-changing attributes. Based on the accelerated pace of our development program, we expect clinical data readout for all four ORION Pivotal Trials, as well as NDA and MAA submissions, in the second half of 2019. We are also very satisfied with our progress in focusing the Company on inclisiran and – after one-time restructuring and other costs incurred during the first quarter of 2018, plus additional one-time costs anticipated in the second quarter, as previously announced recurring savings in our operating expenditures, which will become very clear by the second half of 2018. Our financial results for the first quarter of 2018 met or exceeded all of our goals, and we will continue to reduce expenses in all other areas of the Company to enable us to fund the optimal development of inclisiran and, thereby, create substantial shareholder value."

First-Quarter 2018 Financial Summary from Continuing Operations

On a GAAP basis, loss from continuing operations in the first quarter of 2018 was $84.8 million, or $1.14 per share, compared to $71.0 million, or $1.00 per share, in the first quarter of 2017. Included in loss from continuing operations for the first quarter of 2018 was a non-cash, mark-to-market change in fair value of approximately $30.0 million associated with the Company's common stock ownership in Melinta. On a non-GAAP basis, adjusted loss [(1)] from continuing operations in the first quarter of 2018 was $56.4 million, or $0.76[(1)] per share, compared to $53.3 million, or $0.75[(1)] per share, in the first quarter of 2017.

(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.

First-Quarter 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 ($215 million of guaranteed cash and Melinta common stock with a closing date value of approximately $55 million), 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.

Net income from discontinued operations in the first quarter of 2018 was $114.0 million compared to a net loss of $31.7 million in 2017. Net income from discontinued operations in the first quarter of 2018 includes a gain of approximately $169.0 million from the sale of the Company's infectious disease business to Melinta.

At March 31, 2018 the Company had $216.0 million in cash and cash equivalents, compared to $151.4 million at the end of 2017.

First-Quarter 2018 Conference Call and Webcast Information

The Company will host a conference call and webcast today, April 25, 2018, at 8:30 a.m., Eastern Daylight Time, to discuss its first-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

onference ID: 5683598

taped replay of the conference call will be available from 11:30 a.m., Eastern Daylight Time, today until 11:30 a.m., Eastern Daylight Time, on lay 2, 2018. The replay may be accessed as follows:

.S./Canada: (855) 859-2056

ıternational: (404) 537-3406

onference ID: 5683598

he webcast can be accessed in the “Investors” section of The Medicines Company website (http://cts.businesswire.com/ct/CT?l=smartlink&url=http%3A%2F%2Fwww.themedicinescompany.com%2Finvestors&esheet=51794855&newsitemid=20180425005692&lan=en-S&anchor=The+Medicines+Company+website&index=1&md5=db05035e5822b92b96bb712f0f6de834). A replay of the webcast will also be vailable.

bout Inclisiran

ıclisiran (formerly known as PCSK9si and ALN-PCSsc) is an investigational GalNAc-conjugated RNA interference therapeutic targeting CSK9 - a genetically validated protein regulator of LDL receptor metabolism - being developed for the treatment of hypercholesterolemia. In ontrast to anti-PCSK9 monoclonal antibodies (MAbs) that bind to PCSK9 in blood, inclisiran is a first-in-class investigational medicine that cts by turning off PCSK9 synthesis in the liver.

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 ledicines 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 ıe economics of healthcare. The Company’s goal is to create transformational solutions to address the most pressing healthcare needs ıcing 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 ıose expressed or implied by these forward-looking statements. Important factors that may cause or contribute to such differences include ıe 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; hether its regulatory submissions will receive approvals from regulatory agencies on a timely basis or at all; and such other factors as are set ɔrth in the risk factors detailed from time to time in the Company's periodic reports and registration statements filed with the Securities and xchange Commission, including, without limitation, the risk factors detailed in the Company's Annual Report on Form 10-K filed with the SEC n March 1, 2018, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-ɔoking statements.

ON-GAAP FINANCIAL PERFORMANCE MEASURES

ı 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 ıeasures 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, inventory djustments, restructuring charges, changes in contingent purchase price, legal settlements and non-cash interest expense. The Company elieves these non-GAAP financial measures help indicate underlying trends in the Company's business and are important in comparing urrent results with prior period results and understanding projected operating performance. Non-GAAP financial measures provide the ompany and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to e reflective of the Company's ongoing results. See the attached Reconciliations of GAAP to Adjusted Loss from Continuing Operations and djusted Loss per Share for explanations of the amounts excluded and included to arrive at adjusted net loss and adjusted loss per share mounts for the three-months ended March 31, 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 March 31,	
	2018	**2017**
let revenues	$ 7,771	$ 17,465
)perating expenses:		
ost of product revenues	2,737	9,978
esearch and development	40,366	26,444
elling, general and administrative	28,951	40,457
otal operating expenses	72,054	76,879
oss from operations	(64,283)	(59,414)
o-promotion and license income	228	757
oss on short-term investment	(29,989)	–
nterest expense	(12,077)	(12,422)
)ther income	2,369	111
oss from continuing operations before income taxes	(103,752)	(70,968)
enefit (provision) for income taxes	18,916	(28)
oss from continuing operations	(84,836)	(70,996)
ncome (loss) from discontinued operations, net of tax	113,985	(31,674)
let income (loss)	$ 29,149	$ (102,670)

Basic (loss) earnings per common share:		
Loss from continuing operations	$ (1.14)	$ (1.00)
Earnings (loss) from discontinued operations	1.54	(0.44)
Basic earnings (loss) per share	$ 0.40	$ (1.44)
Diluted (loss) earnings per common share:		
Loss from continuing operations	$ (1.14)	$ (1.00)
Earnings (loss) from discontinued operations	1.54	(0.44)
Diluted earnings (loss) per share	$ 0.40	$ (1.44)
Weighted average number of common shares outstanding:		
Basic	74,116	71,073
Diluted	74,116	71,073

THE MEDICINES COMPANY

BALANCE SHEET ITEMS

UNAUDITED

(In thousands)

	March 31, 2018	December 31, 2017
Cash and cash equivalents	$ 215,962	$ 151,359
Short-term investment	$ 24,521	$ –
Total assets	$ 861,174	$ 872,983
Convertible senior notes (due 2022 and 2023)	$ 655,943	$ 649,198
The Medicines Company stockholders' equity	$ 67,656	$ 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 March 31,

		2018	2017
oss from continuing operations		$ (84,836)	$ (70,996)
efore tax adjustments:			
ost of product revenues:			
hare-based compensation expense	(1)	(6)	171
mortization of acquired intangible assets	(2)	–	4,486
nventory adjustments	(3)	(416)	(411)
estructuring charges	(4)	443	(66)
esearch and development:			
hare-based compensation expense	(1)	984	592
estructuring charges	(4)	326	(108)
elling, general and administrative:			
hare-based compensation expense	(1)	3,449	5,431
estructuring charges	(4)	4,537	(51)
hanges in contingent purchase price	(5)	(264)	692
egal settlements	(6)	3,550	–
ther:			
lon-cash interest expense	(7)	6,745	6,973
hange in short-term investments	(8)	28,027	–
let loss tax adjustments	(9)	(18,916)	–
oss from continuing operations - Adjusted		$ (56,377)	$ (53,287)
oss per share - Adjusted			
asic		$ (0.76)	$ (0.75)
iluted		$ (0.76)	$ (0.75)
Veighted average number of common shares outstanding:			
asic		74,116	71,073
iluted		74,116	71,073

xplanation of Adjustments:

) Excludes share-based compensation of $4,427 and $6,194 for the three months ended March 31, 2018 and 2017 because these expenses re 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 ardiovascular products.

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

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

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

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

9) Excludes the estimated tax effect related to the sale of Melinta.

n addition to the financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that he Company believes provide investors and management with supplemental information relating to operating performance and trends that acilitate comparisons between periods and with respect to projected information. These adjusted measures should be considered in addition o, but not as a substitute for, the information prepared in accordance with U.S. GAAP. The Company strongly encourages investors to review its onsolidated financial statements and publicly filed reports in their entirety and cautions investors that the non-GAAP measures used by the ompany may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

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