The Medicines Company

edicines Company Reports Third-Quarter 2017 Business and Financial s

Y, N.J.--(BUSINESS WIRE)--Oct. 25, 2017-- The Medicines Company (NASDAQ: MDCO) today reported its financial results for the third ed September 30, 2017, and provided an update on its clinical and operational activities.

ignificant clinical and strategic progress during the third quarter," said Clive Meanwell, M.D., Ph.D., Chief Executive Officer of The Medicines We aggressively advanced start-up work for the inclisiran Phase III clinical program, preparing investigational sites–which began screening eptember–and manufacturing double-blind-packaged drug supply, and are pleased to announce that dosing of patients in the Phase III LDL- rogram will commence next week. We remain confident that all trials comprising the inclisiran LDL-C lowering program will commence before urning to our process to monetize our Infectious Disease Business (ID Business), we continue to expect to announce a transaction to divest s before the end of the year. In the meantime, independent of that transaction, we are finalizing plans to significantly restructure the f The Medicines Company. We anticipate that the restructuring, which we intend to substantially implement within the next 45 days, will lcount to less than 60 people at The Medicines Company (excluding the ID Business), significantly reducing go-forward annual operating s indicated in our strategic plans previously disclosed, we believe that the restructuring, when taken together with the anticipated disposition siness, will provide the Company with a strong financial position from which to aggressively advance the inclisiran development program to eadout of final data from the Phase III LDL-C lowering trials in the second half of 2019. We expect to provide further information regarding uring plan and its implementation in our third quarter Form 10-Q."

er 2017 Highlights

CSK9 synthesis inhibitor)

ust 28, 2017, new, one-year data from the ORION-1 Phase II study of inclisiran was presented in the "Hot Line – Late-Breaking Clinical Trials ion at the European Society of Cardiology (ESC) Congress 2017. Efficacy data presented reaffirmed inclisiran's significant LDL-C lowering following a starting dose of 300 mg given on Day-1 and Day-90, after which the mean LDL-C reduction was 56% at Day-150 and 51% at Day- the subsequent six-month period – from Day-90 to Day-270 – the time-averaged LDL-C reduction was 51%, with minimum intra-patient ty over time (all comparisons to placebo P <0.0001). These robust data underscore the selection of a six-monthly maintenance dose of 300 ıe inclisiran Phase III clinical program. With completion of one-year follow-up, safety data for inclisiran from the Phase II ORION-1 study now 370 subject-years of observation, including at least 300 subject-years of inclisiran effects. As in prior analyses, no material safety issues bserved on inclisiran, which continued to demonstrate an adverse event profile similar to placebo. There were no deaths or serious adverse during the extended observation period. In particular, in spite of the prolonged LDL-C lowering effects of inclisiran, there were no ational drug-related elevations of liver enzymes and no neuropathy, change in renal function, thrombocytopenia or anti-drug antibodies during ed follow-up, or at any earlier time periods in the ORION-1 study.

™

ust 29, 2017, the U.S. Food and Drug Administration (FDA) approved VABOMERE (meropenem-vaborbactam) for injection for the treatment of ıtients with complicated urinary tract infections (cUTI), including pyelonephritis, caused by designated susceptible Enterobacteriaceae – *chia coli, Klebsiella pneumoniae* and *Enterobacter cloacae species* complex.

eek 2017 in October, the Company presented new data on VABOMERE, including results from the landmark TANGO II study of VABOMERE 'best available therapy" (BAT) in the treatment of suspected or documented infections due to carbapenem-resistant Enterobacteriaceae Highlights from the posters on the TANGO II study included:

- VABOMERE was associated with a higher clinical cure versus BAT in patients with a baseline organism that was CRE (mCRE-MITT population) at both end-of-therapy (EOT) (VABOMERE 64.3% vs. BAT 33.3%; p=0.04) and test-of-cure (TOC) (VABOMERE 57.1% vs. BAT 26.7%; p=0.04). In immunocompromised patients, VABOMERE was also associated with a higher clinical cure versus BAT at EOT (VABOMERE 60% vs. BAT 12.5%; p<0.01), and a relative mortality benefit of 46.7%.
- In further exploratory analyses, VABOMERE was associated with a relative mortality benefit of 84% (p = 0.03) compared to BAT when excluding patients with previous antibiotic failures.

Analysis of Clinical Cure at TOC and All-Cause Mortality at Day 28 Across All ypes (mCRE-MITT) Excluding Prior Antibiotic Failure

	M-V N=19 n (%)	BAT N=15 n (%)	Absolute Difference (95% CI)	*P* value	Relative Difference
n All Infection Types					
e at TOC	13 (68.4)	4 (26.7)	41.8 (11.1 to 72.4)	0.008	156.2
cause Mortality	1 (5.3)	5 (33.3)	-28.1 (-54.0 to -2.2)	0.03	-84.1

ERE was associated with decreased nephrotoxicity and significantly fewer treatment-related adverse events versus BAT.

ysis using the composite endpoints of clinical failure or nephrotoxicity demonstrated a risk-benefit profile favoring VABOMERE versus BAT MERE 32.1% vs BAT 80.0% (95% CI: −74.5 to −21.2; *P*< 0.001)).

2017, the Company announced randomization in the TANGO II trial was stopped early following a recommendation by the TANGO II ndent Data and Safety Monitoring Board (DSMB) based on an analysis of 72 patients, including 43 patients with microbiologically evaluable ections of blood, lung, urinary tract and abdominal organs. The DSMB concluded that a risk-benefit analysis of available data no longer ed randomization of additional patients to the best available therapy comparator arm.

ERE is now available for pharmacies to order through wholesalers and usual distribution channels.

er 2017 Financial Summary from Continuing Operations
et revenue was $16.9 million in the third quarter of 2017 compared to $37.6 million in the third quarter of 2016. Included in total net revenue quarter of 2017 and 2016 was $7.9 million and $28.9 million, respectively, of total Angiomax revenue, including both royalty revenues derived ss profit on authorized generic sales of Angiomax® (bivalirudin) by Sandoz, Inc. and worldwide Angiomax®/Angiox® (bivalirudin) net product products recorded aggregate sales of $9.0 million in the third quarter of 2017 compared to $6.7 million in the third quarter of 2016. Among products, Minocin® (minocycline) for Injection and Orbactiv® (oritavancin) recorded sales of $9.0 million in the third quarter of 2017 $6.5 million in the third quarter of 2016, an increase of 38%, predominantly driven by an increase in Orbactiv (oritavancin) revenue of 57%, illion in the third quarter of 2016 to $6.8 million in the third quarter of 2017. The third quarter of 2016 also included $2.0 million of sales e divested non-core cardiovascular products.

basis, net loss from continuing operations in the third quarter of 2017 was $30.2 million, or $0.42 per share, compared to $86.4 million, or are, in the third quarter of 2016. On a non-GAAP basis, adjusted net loss [(1)] from continuing operations in the third quarter of 2017 was $86.3 .19[(1)] per share, compared to $44.8 million, or $0.64[(1)] per share, in the third quarter of 2016.

er 2016 Financial Summary from Discontinued Operations
uarter of 2016, the Company completed the divestiture of its hemostasis products for an upfront payment of $174.1 million, and potential ayments of up to an additional $235.0 million, in the aggregate, following the achievement of certain specified net sales milestones. Net ı discontinued operations in the third quarter of 2016 was $0.1 million.

lonths 2017 Financial Summary from Continuing Operations
et revenue was $59.8 million in the first nine months of 2017 compared to $142.6 million in the first nine months of 2016. Included in total net the first nine months of 2017 and 2016 was $35.9 million and $104.9 million, respectively, of total Angiomax revenue, including both royalty rived from the gross profit on authorized generic sales of Angiomax (bivalirudin) by Sandoz, Inc. and worldwide Angiomax/Angiox (bivalirudin) sales. Other products, including Minocin (minocycline) for Injection and Orbactiv (oritavancin), recorded aggregate sales of $23.9 million in months of 2017 compared to $17.4 million in the first nine months of 2016. The first nine months of 2016 also included $20.3 million of sales e divested non-core cardiovascular products.

basis, net loss from continuing operations in the first nine months of 2017 was $530.1 million, or $7.39 per share, compared to net income uing operations of $5.1 million, or $0.07 per share, in the first nine months of 2016. Included in net loss from continuing operations for the first of 2017 were net charges of approximately $277.0 million associated with the discontinuation and market withdrawal of Ionsys (fentanyl c transdermal system) in the U.S. market, and $27.3 million associated with the discontinuation of the clinical development program for our investigational anesthetic agent. On a non-GAAP basis, adjusted net loss [(1)] from continuing operations in the first nine months of 2017 million, or $3.27[(1)] per share, compared to $164.2 million, or $2.35[(1)] per share, in the first nine months of 2016.

lonths 2016 Financial Summary from Discontinued Operations
n discontinued operations in the first nine months of 2016 was $1.4 million, or $0.02 per share.

net loss and adjusted loss per share from continuing operations are non-GAAP financial performance measures with no standardized nder U.S. GAAP. For further information and a detailed reconciliation, refer to the “Non-GAAP Financial Performance Measures” and ions of GAAP to Adjusted Net Loss and Adjusted Loss per Share” sections of this press release.

er 30, 2017, the Company had a total of $208.9 million in cash and cash equivalents and available for sale securities.

er 2017 Conference Call and Webcast Information
ny will host a conference call and webcast today, October 25, 2017, at 8:30 a.m., Eastern Daylight Time, to discuss its third-quarter 2017 ults and provide clinical and operational updates. The dial-in information to access the call is as follows:

: (877) 359-9508
l: (224) 357-2393
ID: 9194649

ay 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 November 1, play may be accessed as follows:

: (855) 859-2056
l: (404) 537-3406
ID: 9194649

t can be accessed in the Investors section of The Medicines Company (http://cts.businesswire.com/ct/CT?&url=http%3A%2F%2Fwww.themedicinescompany.com%2Finvestors%2Fevents&esheet=51704844&newsitemid=20171025005540&lan=en-=The+Medicines+Company&index=1&md5=23a3d06fb3239d303d032bc1a4beda1f) website. A replay of the webcast will also be available.

OMERE™
™ (meropenem and vaborbactam) is indicated for the treatment of patients 18 years of age and older with complicated urinary tract UTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cies* complex.

e development of drug-resistant bacteria and maintain the effectiveness of VABOMERE and other antibacterial drugs, VABOMERE should to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

ormation on VABOMERE, including its important safety information and package insert, please see www.vabomere.com usinesswire.com/ct/CT?&url=http%3A%2F%2Fwww.vabomere.com%2F&esheet=51704844&newsitemid=20171025005540&lan=en-=www.vabomere.com&index=2&md5=dbe90316670832 98db32d172b00b3cf7).

ıiran

rmerly known as PCSK9si and ALN-PCSsc) is an investigational GalNAc-conjugated RNAi therapeutic targeting PCSK9 – a genetically otein regulator of LDL receptor metabolism – being developed for the treatment of hypercholesterolemia. In contrast to anti-PCSK9 antibodies (MAbs) that bind to PCSK9 in blood, inclisiran is a first-in-class investigational medicine that acts by turning off PCSK9 synthesis

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

Medicines Company

es Company is a biopharmaceutical company driven by an overriding purpose – to save lives, alleviate suffering and contribute to the of healthcare. The Company's mission is to create transformational solutions to address the most pressing healthcare needs facing patients, nd providers in serious infectious disease care and cardiovascular care. The Company is headquartered in Parsippany, New Jersey, with a ation center in California.

oking Statements

contained in this press release that are not purely historical may be deemed to be forward-looking statements for purposes of the safe sions under The Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words "believes," "anticipates," "plans," nd similar expressions, including the Company's preliminary financial results, are intended to identify forward-looking statements. These king statements involve known and unknown risks and uncertainties that may cause the Company's actual results, levels of activity, e or achievements to be materially different from those expressed or implied by these forward-looking statements. Important factors that may ntribute to such differences include whether the Company's product candidates will advance in the clinical trials process on a timely basis or ceed in achieving their specified endpoints; whether the Company will make regulatory submissions for product candidates on a timely basis; egulatory submissions will receive approvals from regulatory agencies on a timely basis or at all; whether the Company's ongoing and nmercial launches will be successful; the extent of the commercial success of our products; the Company's ability to penetrate foreign ether physicians, patients and other key decision makers will accept clinical trial results; whether the Company can protect its intellectual ıether the Company will be able to raise additional capital on favorable terms or at all when needed; and such other factors as are set forth in ors detailed from time to time in the Company's periodic reports and registration statements filed with the Securities and Exchange , including, without limitation, the risk factors detailed in the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017, corporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

FINANCIAL PERFORMANCE MEASURES

o financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted net loss and adjusted loss per share uing operations attributable to The Medicines Company. The Company believes these measures provide investors and management with al information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected

t loss from continuing operations excludes share-based compensation expense, amortization of acquired intangible assets, asset impairment entory adjustments, restructuring charges, charges associated with product discontinuance, milestone payments, changes in contingent ice, expenses incurred for certain transactions, non-cash interest expense, gain on sale of assets, loss on repurchase of debt and net loss ents. The Company believes these non-GAAP financial measures help indicate underlying trends in the Company's business and are comparing current results with prior period results and understanding projected operating performance. Non-GAAP financial measures Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not ive of the Company's ongoing results. See the attached Reconciliations of GAAP to Adjusted Net Loss and Adjusted Loss per Share for s of the amounts excluded and included to arrive at adjusted net loss and adjusted loss per share amounts for the three- and nine-month ed September 30, 2017 and 2016.

ted measures are non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in accordance with The Company strongly encourages investors to review its consolidated financial statements and publicly-filed reports in their entirety and estors that the non-GAAP measures used by the Company may differ from similar measures used by other companies, even when similar sed to identify such measures.

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2017	2016	2017	2016
revenues	$ 10,935	$ 18,843	$ 38,135	$ 80,542
enues	5,936	18,756	21,694	62,094
venues	16,871	37,599	59,829	142,636
xpenses:				
duct revenues	9,601	20,777	39,436	54,804
rment charges	–		329,097	–
nd development	45,838	23,537	117,337	94,595
eral and administrative	47,198	69,022	159,980	242,478
ing expenses	102,637	113,336	645,850	391,877
perations	(85,766)	(75,737)	(586,021)	(249,241)
on and license income	769	757	2,283	3,073
e of assets	–	–	–	288,301
nguishment of debt	–	–	–	(5,380)
ense	(11,886)	(12,089)	(36,898)	(32,198)
income	71	865	916	741
ne from continuing operations before income taxes	(96,812)	(86,204)	(619,720)	5,296
vision) for income taxes	66,637	(163)	89,607	(220)
come from continuing operations	(30,175)	(86,367)	(530,113)	5,076
s) from discontinued operations, net of tax	–	96	–	(1,390)
come	(30,175)	(86,271)	(530,113)	3,686
ributable to non-controlling interest	–	13	–	50
come attributable to The Medicines Company	$ (30,175)	$ (86,258)	$ (530,113)	$ 3,736
ributable to The Medicines Company:				
come from continuing operations	$ (30,175)	$ (86,354)	$ (530,113)	$ 5,126
s) from discontinued operations, net of tax	–	96	–	(1,390)
come attributable to The Medicines Company	$ (30,175)	$ (86,258)	$ (530,113)	$ 3,736
earnings per common share attributable to The Medicines Company:				
ngs from continuing operations	$ (0.42)	$ (1.23)	$ (7.39)	$ 0.07
iscontinued operations	–	–	–	(0.02)

earnings per share	$ (0.42)	$ (1.23)	$ (7.39)	$ 0.05
) earnings per common share attributable to The Medicines Company:				
ngs from continuing operations	$ (0.42)	$ (1.23)	$ (7.39)	$ 0.07
iscontinued operations	–	–	–	(0.02)
) earnings per share	$ (0.42)	$ (1.23)	$ (7.39)	$ 0.05
erage number of common shares outstanding:				
	72,286	70,194	71,763	69,711
	72,286	70,194	71,763	72,920

THE MEDICINES COMPANY
BALANCE SHEET ITEMS
UNAUDITED
(In thousands)

	September 30, 2017	December 31, 2016
ash equivalents	$ 166,734	$ 541,835
sale securities	$ 42,168	$ –
	$ 1,006,980	$ 1,705,211
senior notes (due 2022 and 2023)	$ 642,655	$ 677,333
es Company stockholders' equity	$ 188,055	$ 652,501

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
come from continuing operations attributable to The Company - GAAP	$ (30,175)	$ (86,354)	$ (530,113)	$ 5,126
djustments:				

duct revenues:					
d compensation expense	(1)	205	195	613	691
n of acquired intangible assets	(2)	3,105	6,469	11,557	19,319
ljustments	(3)	(348)	6,460	(3,531)	1,248
ıg charges	(4)	18	108	(48)	383
drawal of Ionsys	(5)	–	–	8,458	–
rment charges					
drawal of Ionsys	(5)	–	–	264,097	–
nce of MDCO 700	(6)	–	–	65,000	–
nd development:					
d compensation expense	(1)	1,332	916	3,888	2,923
ıg charges	(4)	(36)	91	359	1,451
ayments	(7)	–	–	–	11,000
drawal of Ionsys	(5)	–	–	1,032	–
eral and administrative:					
d compensation expense	(1)	6,341	6,849	19,579	20,555
ıg charges	(4)	1,110	1,447	1,007	14,445
contingent purchase price	(8)	(7,673)	12,393	4,234	14,346
drawal of Ionsys	(5)	–	–	3,434	–
nce of MDCO 700	(6)	–	–	(14,701)	–
ıcurred for certain transactions	(9)	–	–	–	7,887
terest expense	(10)	6,504	6,622	20,326	19,392
e of assets	(11)	–	–	–	(288,301)
nguishment of debt	(12)	–	–	–	5,380
adjustments	(13)	(66,713)	1	(89,702)	–
ributable to The Medicines Company - Adjusted		$ (86,330)	$ (44,803)	$ (234,511)	$ (164,155)
share attributable to The Medicines Company - Adjusted					
		$ (1.19)	$ (0.64)	$ (3.27)	$ (2.35)
		$ (1.19)	$ (0.64)	$ (3.27)	$ (2.35)
verage number of common shares outstanding:					
		72,286	70,194	71,763	69,711
		72,286	70,194	71,763	69,711

of Adjustments:

share-based compensation of $7,878 and $7,960 for the three months ended September 30, 2017 and 2016 and $24,080 and $24,169 for nths ended September 30, 2017 and 2016 because these expenses are substantially dependent on changes in the market price of the common stock.
s amortization of intangible assets resulting from transactions with Targanta, Incline Therapeutics and Rempex.
s all non-cash inventory adjustments. Prior year balances revised to reflect all non-cash inventory adjustments for the respective periods.
s restructuring charges for the workforce reorganization related to the sale of the non-core cardiovascular products.
s charges associated with the voluntary discontinuation and withdrawal of Ionsys from the market in the United States and cessation of mercial activities.
s costs associated with the decision to discontinue the MDCO-700 program.
s upfront and milestone payments for research and development collaboration arrangements and manufacturing scale up for MDCO-216.
s changes in fair value of the contingent price related to the acquisitions of Targanta, Incline Therapeutics, Rempex and Annovation.
s transaction costs related to the sale of the Non-Core ACC Products.(10) Excludes non-cash interest expense which is in excess of the st expense paid on the Convertible Senior Notes.
s gain on the sale of the Non-Core ACC Products.
s loss on the repurchase of $220.0 million in aggregate principal amount of the 2017 Notes.
s tax adjustments reflect the estimated tax effect of the costs associated with the decision to discontinue the MDCO-700 program and the n of Vabomere IPR&D.

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

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