

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## MEDICINES CO /DE

**Form: 8-K**

**Date Filed: 2019-02-27**

Corporate Issuer CIK: 1113481

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **February 27, 2019**

**The Medicines Company**

(Exact Name of Registrant as Specified in Charter)

**Delaware**

(State or Other Jurisdiction  
of Incorporation)

**000-31191**

(Commission  
File Number)

**04-3324394**

(IRS Employer  
Identification No.)

**8 Sylvan Way  
Parsippany, New Jersey**

(Address of Principal Executive Offices)

**07054**

(Zip Code)

Registrant's telephone number, including area code: **(973) 290-6000**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02. Results of Operations and Financial Condition.**

On February 27, 2019 The Medicines Company (the "Company") announced financial results for the three months and year ended December 31, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits**

## (d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

- 99.1 Press release dated February 27, 2019 entitled "The Medicines Company Reports Fourth-Quarter and Full-Year 2018 Business and Financial Results"
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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THE MEDICINES COMPANY

Date: February 27, 2019

By: /s/ Stephen M. Rodin  
Stephen M. Rodin  
Executive Vice President and General Counsel

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	Press release dated February 27, 2019 entitled "The Medicines Company Reports Fourth-Quarter and Full-Year 2018 Business and Financial Results"

**Contacts:**

**Investor Relations**

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**FOR IMMEDIATE RELEASE**

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**The Medicines Company Reports Fourth-Quarter and Full Year 2018 Business and Financial Results**

- *Continued progress in inclisiran's development, with no material safety issues to date, paves the way for topline pivotal trial readouts expected in 3Q*
- *Inclisiran's unique profile, vast global market opportunity and long-dated exclusivity set the stage for significant shareholder value creation*

PARSIPPANY, N.J. - February 27, 2019 - The Medicines Company (NASDAQ: MDCO) today reported its financial results for the fourth quarter and full year ended December 31, 2018.

"During 2018 we successfully restructured our business and executed on our development plan for inclisiran, a first-in-class drug candidate with the potential to deliver potent, durable, and consistent lowering of LDL-C levels via twice-a-year dosing. 2019 is an exciting year for the Medicines Company, as we count down to topline Phase 3 ORION program results in the third quarter and subsequent NDA and MAA submissions," said Mark Timney, Chief Executive Officer of The Medicines Company.

Fourth quarter 2018 highlights and recent developments include the following:

- In January 2019, the Independent Data Monitoring Committee (IDMC) for the ongoing inclisiran Phase III clinical trials conducted its fifth planned review of un-blinded safety and efficacy data from the trials, and recommended that they continue as designed and conducted, without modification. At the time of the IDMC's review, more than 2,450 patient years of safety data had been accumulated, with substantially all randomized patients having received three doses of inclisiran or placebo, and more than 2,000 patients having completed their 60-day follow up after the third dose of study medication.
- In December 2018, the Company announced and subsequently completed its offering of \$172.5 million aggregate principal amount of 3.50% convertible senior notes due 2024 (inclusive of the over-allotment option). The net proceeds from the offering (inclusive of the full exercise of the over-allotment option) were \$166.7 million, after deducting the commissions and the Company's offering expenses, significantly enhancing the company's capital position.

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#### **Fourth-Quarter 2018 Financial Summary from Continuing Operations**

On a GAAP basis, loss from continuing operations in the fourth quarter of 2018 was \$44.3 million, or \$0.60 per share, compared to a loss of \$159.4 million, or \$2.19 per share, in the fourth quarter of 2017. Included in loss from continuing operations for the fourth quarter of 2018 was a non-cash, mark-to-market reduction in fair value of approximately \$10.5 million associated with the Company's common stock ownership in Melinta Therapeutics, Inc. (Melinta), offset by a \$21.6 million gain from the sale of pre-clinical products associated with our infectious disease business. On a non-GAAP basis, adjusted loss <sup>(1)</sup> from continuing operations in the fourth quarter of 2018 was \$45.6 million, or \$0.62<sup>(1)</sup> per share, compared to a loss of \$44.4 million, or \$0.61<sup>(1)</sup> per share, in the fourth quarter of 2017.

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#### **Full Year 2018 Financial Summary from Continuing Operations**

On a GAAP basis, loss from continuing operations for the full year 2018 was \$235.2 million, or \$3.20 per share, compared to a loss of \$607.7 million, or \$8.40 per share, for the full year 2017. Included in loss from continuing operations for 2018 were non-cash, mark-to-market reduction in fair value of approximately \$51.9 million associated with the Company's common stock ownership in Melinta; restructuring charges of \$11 million; and a \$5.1 million non-cash impairment charge related to fixed assets associated with the early-stage infectious disease products; partially offset by a \$21.6 million gain from the sale of pre-clinical products associated with our infectious disease business, and a \$7.0 million gain from the sale of the Company's rights to branded Angiomax in the United States to Sandoz Inc. On a non-GAAP basis, adjusted loss <sup>(1)</sup> from continuing operations for 2018 was \$199.8 million, or \$2.72<sup>(1)</sup> per share, compared to a loss of \$142.4 million, or \$1.97<sup>(1)</sup> per share, for 2017.

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#### **Full Year 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 (including Melinta common stock then valued at \$55 million) and deferred payments, tiered royalty payments of 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 for the full year 2018 was \$112.1 million, compared to a net loss of \$100.7 million for the full year 2017. Net income from discontinued operations for 2018 included a pre-tax gain of approximately \$169.0 million from the sale of the Company's infectious disease business to Melinta.

At December 31, 2018, the Company had \$238.3 million in cash and cash equivalents, compared to \$151.4 million at the end of 2017.

<sup>(1)</sup> 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.

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#### **Fourth-Quarter 2018 Conference Call and Webcast Information**

The Company will host a conference call and webcast today, February 27, 2019 at 8:30 a.m., Eastern Standard Time, to discuss its fourth-quarter and full year 2018 financial results and provide clinical and operational updates. The dial-in information to access the call is as follows:

U.S./Canada: (877) 407-0312  
International: (201) 389-0899  
Conference ID: 13687492

A taped replay of the conference call will be available after the call concludes, and may be accessed by telephone as follows:

U.S./Canada: (877) 660-6853  
International: (201) 612-7415  
Conference ID: 13687492

A live audio webcast of the conference call may be accessed in the "Investors" section of The Medicines Company website. An archived webcast will be available after the call concludes.

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#### **About Inclisiran**

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

The Medicines Company and Alnylam Pharmaceuticals, Inc. (Alnylam) are collaborating in the advancement of inclisiran pursuant to their 2013 agreement. 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.

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#### **Commercial opportunity**

In the US alone, 67.5 million individuals are estimated to have sufficient cardiovascular risk to warrant lipid-lowering therapy. 27.5 million of these individuals are at a significantly elevated risk, either because of confirmed cardiovascular disease or LDL-C levels above 190 mg/dl. Of this higher risk group, 15.1 million are currently treated with lipid-lowering therapies, but only one out of five (or 2.4 million) is successfully reaching LDL-C targets with current therapies. This implies a population of at least 12.7 million Americans who could benefit from inclisiran, a first in class therapy with the potential to deliver potent, durable and consistent lowering of LDL-C levels via twice-a-year dosing.

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## **About The Medicines Company**

The Medicines Company is a biopharmaceutical company driven by an overriding purpose - to save lives, alleviate suffering and contribute to the economics of healthcare. The Company's goal is to create transformational solutions to address the most pressing healthcare needs facing patients, physicians, and providers in cardiovascular care. The Company is headquartered in Parsippany, New Jersey. For more information, please visit [www.themedicinescompany.com](http://www.themedicinescompany.com) and follow us on Twitter [@MDCONews](https://twitter.com/MDCONews).

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## **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," "plans," "expects," "should," and "potential" and similar expressions, are intended to identify forward-looking statements. These forward-looking statements involve 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 ability of the Company to effectively develop inclisiran; whether inclisiran will advance in the clinical trials process on a timely basis or at all, or 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 success of inclisiran, if approved; the strength, durability and life of the Company's patent protection for inclisiran and whether the Company will be successful in extending exclusivity; 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 (SEC), including, without limitation, the risk factors detailed in the Company's Current Report on Form 8-K filed with the SEC on December 12, 2018, which are incorporated herein by reference. The Company specifically disclaims any obligation to update these forward-looking statements.

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## **NON-GAAP FINANCIAL PERFORMANCE MEASURES**

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted loss from continuing operations and adjusted loss per share from continuing operations attributable to The Medicines Company. The Company believes these measures 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 loss from continuing operations excludes share-based compensation expense, amortization of acquired intangible assets, asset impairment charges, inventory adjustments, restructuring charges, charges and gains associated with product discontinuance, changes in contingent purchase price, milestone payments, legal settlements, changes in short-term investments and non-cash interest expense. The Company believes these non-GAAP financial measures help indicate underlying trends in the Company's business and are important in comparing current results with prior period results and understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ongoing results. See the attached "Reconciliations of GAAP to Adjusted Loss from Continuing Operations and Adjusted Loss per Share" for explanations of the amounts excluded and included to arrive at adjusted net loss and adjusted loss per share amounts for the three- and twelve-months ended December 31, 2018 and 2017.

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. 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.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**UNAUDITED**

*(In thousands, except per share amounts)*

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net revenues	\$ —	\$ 8,595	\$ 6,138	\$ 44,789
Operating expenses:				
Cost of revenues	697	20,438	7,255	47,193
Asset impairment charges	—	63,000	5,073	392,097
Research and development	29,611	55,600	133,007	138,370
Selling, general and administrative	(4,576)	29,644	52,214	132,225
Total operating expenses	<u>25,732</u>	<u>168,682</u>	<u>197,549</u>	<u>709,885</u>
Loss from operations	(25,732)	(160,087)	(191,411)	(665,096)
Co-promotion and license income	266	5,266	1,019	7,549
Loss on short-term investment	(10,465)	—	(51,881)	—
Interest expense	(12,913)	(11,811)	(49,411)	(48,564)
Other income	1,039	248	5,580	1,840
Loss from continuing operations before income taxes	(47,805)	(166,384)	(286,104)	(704,271)
Benefit from income taxes	3,513	6,968	50,888	96,576
Loss from continuing operations	(44,292)	(159,416)	(235,216)	(607,695)
Income (loss) from discontinued operations, net of tax	1,818	(18,846)	112,060	(100,678)
Net loss	<u>\$ (42,474)</u>	<u>\$ (178,262)</u>	<u>\$ (123,156)</u>	<u>\$ (708,373)</u>
Basic (loss) earnings per common share:				
Loss from continuing operations	\$ (0.60)	\$ (2.19)	\$ (3.20)	\$ (8.40)
Earnings (loss) from discontinued operations	0.02	(0.26)	1.52	(1.39)
Basic loss per share	<u>\$ (0.58)</u>	<u>\$ (2.45)</u>	<u>\$ (1.68)</u>	<u>\$ (9.79)</u>
Diluted (loss) earnings per common share:				
Loss from continuing operations	\$ (0.60)	\$ (2.19)	\$ (3.20)	\$ (8.40)
Earnings (loss) from discontinued operations	0.02	(0.26)	1.52	(1.39)
Diluted loss per share	<u>\$ (0.58)</u>	<u>\$ (2.45)</u>	<u>\$ (1.68)</u>	<u>\$ (9.79)</u>
Weighted average number of common shares outstanding:				
Basic	73,593	72,950	73,571	72,356
Diluted	73,593	72,950	73,571	72,356

**THE MEDICINES COMPANY**  
**BALANCE SHEET ITEMS**  
**UNAUDITED**  
*(In thousands)*

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Cash and cash equivalents	\$ 238,310	\$ 151,359
Short-term investment	\$ 2,627	\$ —
Total assets	\$ 841,686	\$ 872,983
Convertible senior notes (due 2022, 2023 and 2024)	\$ 792,752	\$ 649,198
The Medicines Company stockholders' (deficit) equity	\$ (22,264)	\$ 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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Loss from continuing operations	\$ (44,292)	\$ (159,416)	\$ (235,216)	\$ (607,695)
Before tax adjustments:				
Cost of product revenues:				
Share-based compensation expense	(1) 67	110	178	722
Amortization of acquired intangible assets	(2) —	—	—	4,486
Inventory adjustments	(3) —	14,661	(407)	11,348
Restructuring charges	(4) —	(7)	565	(55)
Market withdrawal of Ionsys	(5) —	—	—	8,458
Asset impairment charges				
Asset Impairment	(6) —	—	5,073	—
Market withdrawal of Ionsys	(5) —	—	—	264,097
Discontinuance of MDCO 700	(7) —	—	—	65,000
Impairment of contingent purchase price	(8) —	63,000	—	63,000
Research and development:				
Share-based compensation expense	(1) 841	556	4,409	2,906
Restructuring charges	(4) (20)	1,435	3,080	1,794
Milestone charges	(9) —	20,000	—	20,000
Market withdrawal of Ionsys	(5) —	—	—	1,032
Selling, general and administrative:				
Share-based compensation expense	(1) 3,806	6,332	13,375	25,886
Restructuring charges	(4) 223	2,341	7,355	3,348
Additional severance charges	(10) 854	—	854	—
Changes in contingent purchase price	(11) —	—	(258)	692
Gain on sale of pre-clinical ID products	(12) (21,556)	—	(21,556)	—
Gain on sale of assets	(13) —	—	(7,025)	—
One-time facility charges	(14) 685	—	685	—
Legal settlements	(15) —	—	3,550	—
Market withdrawal of Ionsys	(5) —	—	—	3,434
Discontinuance of MDCO 700	(7) —	—	—	(14,701)
Other:				
Non-cash interest expense	(16) 7,389	6,543	27,915	26,868
Change in short-term investments	(17) 10,010	—	48,652	—
Net loss tax adjustments	(18) (3,623)	—	(51,030)	(22,988)
Loss from continuing operations - Adjusted	\$ (45,616)	\$ (44,445)	\$ (199,801)	\$ (142,368)
Loss from continuing operations per share - Adjusted				
Basic	\$ (0.62)	\$ (0.61)	\$ (2.72)	\$ (1.97)
Diluted	\$ (0.62)	\$ (0.61)	\$ (2.72)	\$ (1.97)
Weighted average number of common shares outstanding:				
Basic	73,593	72,950	73,571	72,356
Diluted	73,593	72,950	73,571	72,356

Explanation of Adjustments:

- (1) Excludes share-based compensation of \$4,714 and \$6,998 for the three months ended December 31, 2018 and 2017 and \$17,962 and \$29,514 for the year ended December 31, 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 to Chiesi USA, Inc.
- (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 non-cash asset impairment charges associated with the pre-clinical infectious disease products.
- (7) Excludes costs associated with the decision to discontinue the MDCO-700 program.
- (8) Excludes impairment of fair value of the contingent purchase price related to the discontinuation of Raplix by Mallinckrodt plc.
- (9) Excludes upfront milestone payment for the first patient dosing in a pivotal study of inclisiran.
- (10) Excludes additional severance costs for employees excluded from the initial restructuring plan.
- (11) Excludes changes in fair value of the contingent price related to the acquisition of Rempex Pharmaceuticals, Inc. that were not included in the sale to Melinta.
- (12) Excludes gain from the sale of pre-clinical infectious disease products.
- (13) Excludes gain from the sale of the Angiomax business in the United States.
- (14) Excludes one-time non cash charges associated with the Parsippany facility.
- (15) Excludes net loss from one-time legal settlements in 2018.
- (16) Excludes non-cash interest expense which is in excess of the actual interest expense paid on the convertible senior notes.
- (17) Excludes changes in fair value with our investment in Melinta net of guaranteed payment accretion associated with the sale of our infectious disease business.
- (18) Excludes the estimated non-cash tax effect related to adjustments above.

*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.*