
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): July 16, 2019

MELINTA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-35405
(Commission
File Number)

45-4440364
(I.R.S. Employer
Identification No.)

44 Whippany Road, Morristown, NJ
(Address of principal executive offices)

07960
(Zip Code)

Registrant's telephone number, including area code (908) 617-1309

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:

- 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))

Title of each class	Trading Symbols(s)	Name of each exchange of which registered
Common Stock, \$0.001 Par Value	MLNT	Nasdaq Global Market

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 July 16, 2019, Melinta Therapeutics, Inc. (the “Company”) issued the press release that is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated in this Item 2.02 by reference, which press release includes certain preliminary unaudited estimated financial information as of, and for the fiscal quarter ended, June 30, 2019, and provides certain other corporate updates.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, unless expressly incorporated by reference in such filing.

Item 8.01 Other Items

On July 16, 2019, the Company also provided the following corporate updates:

- On July 10, The World Health Organization (WHO) added Vabomere® (meropenem and vaborbactam) to its Essential Medicines List for its ability to target multidrug-resistant infections caused by pathogens deemed a "critical priority" by the WHO, including carbapenem-resistant Enterobacteriaceae.
- The U.S. Food and Drug Administration (FDA) recently accepted for priority review a supplemental New Drug Application (sNDA) for Baxdela® (delafloxacin) seeking to expand the current indication to include adult patients with community-acquired bacterial pneumonia (CABP); the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date (proposed review deadline) of October 24, 2019.
- Sixteen scientific presentations and posters of portfolio and pipeline data have been accepted for presentation at the Infectious Diseases Society of America IDWeek 2019 meeting, being held October 1-6, 2019, in Washington, D.C. and at the American College of Chest Physicians (ACCP) CHEST Meeting, being held October 19-23, 2019, in New Orleans, LA.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release titled “Melinta Therapeutics Announces Preliminary Second Quarter 2019 Financial Results and Provides Corporate Update ”</u>

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.

Date: July 16, 2019

Melinta Therapeutics, Inc.

By: /s/ Peter J. Milligan
Peter J. Milligan
Chief Financial Officer

Melinta Therapeutics Announces Preliminary Second Quarter 2019 Financial Results and Provides Corporate Update

~ Expects to Report Second Quarter 2019 Net Product Sales of Approximately \$13.8 Million, Which Represents an Increase of 17 Percent Over the First Quarter of 2019 ~

~ Anticipates Having Approximately \$90 Million of Cash and Cash Equivalents on Hand at the End of the Second Quarter 2019 ~

~ Targeting Full-Year 2019 Operating Expense Reductions of Approximately \$70 Million ~

*~ Plans to Report Final Second Quarter 2019 Financial Results on August 7, 2019
at 8:30 a.m. ET ~*

MORRISTOWN, N.J., July 16, 2019 – Melinta Therapeutics, Inc. (NASDAQ: MLNT), a commercial-stage company focused on the development and commercialization of novel antibiotics to treat serious bacterial infections, today reported preliminary and unaudited financial results and provided a corporate update for the second quarter ended June 30, 2019.

“Melinta’s preliminary second quarter 2019 results demonstrate that the actions taken to improve upon the Company's operational and financial efficiencies are continuing to drive progress,” said John H. Johnson, chief executive officer of Melinta. “As we enter into the third quarter of 2019, we remain focused on driving sales efforts, preparing for the potential Baxdela® (delafloxacin) community-acquired bacterial pneumonia (CABP) approval and launch, while also continuing to identify additional ways to reduce expenses. We believe in the strength of our long-term strategy to best position Melinta for future success and remain committed to delivering upon our mission of leading the global fight against antimicrobial resistance and providing antibiotic solutions to patients and healthcare providers.”

Preliminary Second Quarter 2019 Financial Results

Melinta anticipates that it will report net product sales of approximately \$13.8 million for the second quarter of 2019, which is an increase of 51 percent over the second quarter of 2018 and an increase of 17 percent over the first quarter of 2019.

Melinta also expects to report quarter-end cash and cash equivalents of approximately \$90 million, and the Company is targeting to reduce full-year 2019 operating expenses by approximately \$70 million.

The figures in the foregoing sentences are all based upon preliminary estimates and remain subject to change as the Company finalizes its results for the second quarter of 2019.

The Company will announce its full second quarter 2019 financial results on August 7, 2019 at 8:30 a.m. ET and plans to host a conference call at that time.

Recent Corporate Updates

- On July 10, The World Health Organization (WHO) added Vabomere® (meropenem and vaborbactam) to its Essential Medicines List for its ability to target multidrug-resistant infections caused by pathogens deemed a "critical priority" by the WHO, including carbapenem-resistant Enterobacteriaceae
- The U.S. Food and Drug Administration (FDA) recently accepted for priority review a supplemental New Drug Application (sNDA) for Baxdela® (delafloxacin) seeking to expand the current indication to include adult patients with community-acquired bacterial pneumonia (CABP); the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date (proposed review deadline) of October 24, 2019
- Sixteen scientific presentations and posters of portfolio and pipeline data have been accepted for presentation at the Infectious Diseases Society of America IDWeek 2019 meeting, being held October 1 – 6, 2019 in Washington, D.C. and at the American College of Chest Physicians (ACCP) CHEST Meeting, being held October 19 – 23, 2019 in New Orleans, LA

Second Quarter 2019 Conference Call and Webcast

Melinta’s earnings conference call for the second quarter of 2019 will be broadcast at 8:30 a.m. ET on August 7, 2019. Investors wishing to participate in the call should dial: 877-377-7553 and international investors should dial: 253-237-1151, using the conference

ID# 5166674. A live webcast of the call will be available online from the Investor Relations section of the company website at www.melinta.com and will be archived there for 30 days. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID# 5166674.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is the largest pure-play antibiotics company, dedicated to saving lives threatened by the global public health crisis of bacterial infections through the development and commercialization of novel antibiotics that provide new therapeutic solutions. Its four marketed products include Baxdela[®] (delafloxacin), Vabomere[®] (meropenem and vaborbactam), Orbactiv[®] (oritavancin), and Minocin[®] (minocycline) for Injection. This portfolio provides Melinta with the unique ability to provide providers and patients with a range of solutions that can meet the tremendous need for novel antibiotics treating serious infections. Visit www.melinta.com for more information.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this communication constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions, including statements related to guidance. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made and include statements regarding: expectations with respect to our financial position, results and performance. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations, strategies or prospects will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control.

Risks and uncertainties for Melinta include, but are not limited to, the fact that we have incurred significant operating losses since inception and will incur continued losses for the foreseeable future; our limited operating history; our need for future capital and risks related to our ability to obtain additional capital to fund future operations; risks related to our failure to close on the full amount of the two disbursements under the Vatera loan financing and risks related to the satisfaction of the closing conditions for the remaining disbursement amount, including the inability to close on such disbursement; risks related to our ability to borrow additional amounts under the Deerfield facility agreement; risks related to compliance with the covenants under our facilities with Vatera and Deerfield; risks related to our future liquidity, including uncertainties of cash flows and inability to meet working capital needs as well as other milestone, royalty and payment obligations, including as a result of the outcome of the pending litigation with respect to, and any requirement to make, payments potentially due under our purchase agreement with to The Medicines Company; risks that may arise from the Vatera loan financing and the Deerfield facility agreement, including potential dilution to our stockholders and the fact that Vatera beneficially owns a substantial portion of our common stock; risks related to our ability to continue as a going concern unless we can secure additional sources of liquidity; our substantial indebtedness; risks related to potential strategic transactions; risks related to the commercial launches of our products and our inexperience as a company in marketing drug products; the degree of market acceptance of our products among physicians, patients, health care payors and the medical community; the pricing we are able to achieve for our products; failure to obtain and sustain an adequate level of reimbursement for our products by third-party payors; inaccuracies in our estimates of the market for and commercialization potential of our products; failure to maintain optimal inventory levels to meet commercial demand for any of our products; risks that our competitors are able to develop and market products that are preferred over our products; our dependence upon third parties for the manufacture and supply of our marketed products; failure to achieve the benefits of our recently completed transactions with Cembra and The Medicines Company; failure to establish and maintain development and commercialization collaborations; uncertainty in the outcome or timing of clinical trials and/or receipt of regulatory approvals for our product candidates; undesirable side effects of our products; failure of third parties to conduct clinical trials in accordance with their contractual obligations; our ability to identify, develop, acquire or in-license products; difficulties in managing the growth of our company; the effects of recent comprehensive tax reform; risks related to failure to comply with extensive laws and regulations; product liability risks related to our products; failure to retain key personnel; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; risks relating to third party infringement of intellectual property rights; our ability to maintain effective internal control over financial reporting; unfavorable outcomes in any of the class action and shareholder derivative lawsuits currently pending against the Company; and the fact that a substantial number of shares of common stock may be sold into the public markets by one or more of our large stockholders in the near future. Many of these factors that will determine actual results are beyond Melinta’s ability to control or predict.

Other risks and uncertainties are more fully described in our Annual Report on Form 10-K for the year ended December 31, 2018, our Revised Definitive Proxy Statement filed January 29, 2019, and in other filings that Melinta makes and will make with the SEC.

Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made in this press release speak only as of the date stated herein, and subsequent events and developments may cause our expectations and beliefs to change. While we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date after the date stated herein.

For More Information:

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