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): October 24, 2019

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

DELAWARE	001-35405	45-4440364
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

44 Whippany Road, Morristown, NJ	07960
(Address of principal executive offices)	(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 8.01 Other Events.

On October 24, 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. The press release announces the U.S. Food and Drug Administration (the "FDA") has approved BAXDELA® (delafloxacin) for the treatment of adult patients with community-acquired bacterial pneumonia.

Exhibit No.	Description
99.1	Press Release titled “Melinta Therapeutics Announces U.S. FDA Approval of Supplemental New Drug Application for BAXDELA® (delafloxacin) for the Treatment of Community-Acquired Bacterial Pneumonia (CABP)."

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: October 24, 2019

Melinta Therapeutics, Inc.

By: /s/ Peter J. Milligan

Peter J. Milligan

Chief Financial Officer

Melinta Therapeutics Announces U.S. FDA Approval of Supplemental New Drug Application for BAXDELA® (delafloxacin) for the Treatment of Community-Acquired Bacterial Pneumonia (CABP)

~ Approval Based on Positive Phase III Trial Results of BAXDELA for Treatment of CABP in Adults~

~ Company Delays Launch of CABP Indication Until Further Visibility Into Liquidity Position ~

MORRISTOWN, N.J., October 24, 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 announced the U.S. Food and Drug Administration (FDA) has approved BAXDELA® (delafloxacin) for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria. This supplemental approval follows FDA priority review based on the previous Qualified Infectious Disease Product (QIDP) designation, which provides certain incentives for the development of antibacterial and antifungal treatments for serious or life-threatening infections.

“We are pleased to announce the approval of BAXDELA for the treatment of CABP in adults,” said Jennifer Sanfilippo, interim chief executive officer of Melinta. “As previously disclosed, we are closely managing our liquidity position and continue to evaluate our potential strategic and other alternatives. As such, while we believe that BAXDELA will play a significant role in the treatment of this potentially life-threatening illness, we are delaying the commercial launch of CABP until we have greater insight into our ability to secure additional sources of liquidity.”

The FDA approval of BAXDELA for the treatment of CABP is based on positive results from a Phase III, randomized, double-blind, study that compared the efficacy and safety of BAXDELA to moxifloxacin. The study results demonstrated that BAXDELA met all key primary and secondary endpoints in the trial. In the intent-to-treat population (ITT), IV-to-oral BAXDELA met the FDA primary endpoint of statistical non-inferiority for the Early Clinical Response at 96 hours (± 24 hours) after initiation of therapy (88.9% ECR in BAXDELA patients) compared to IV/oral moxifloxacin (89.0%).

BAXDELA also met the FDA secondary endpoint of statistical non-inferiority (90.5%) compared to moxifloxacin (89.7%) based on the investigator’s assessment of Success at the Test of Cure visit (5-10 days after last dose) in the ITT population. Data further showed that IV/oral BAXDELA successfully eradicated key respiratory pathogens at rates comparable to moxifloxacin. Both intravenous (IV) and oral BAXDELA were well-tolerated among study participants. Overall adverse event rates were similar between treatment arms. The most common treatment-emergent adverse events in the BAXDELA arm (≥ 2%) were diarrhea and transaminase increases, which were generally mild and did not lead routinely to treatment discontinuation.

BAXDELA was approved by the FDA in 2017 for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

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 liquidity , financial performance, cash position and operations; potential strategic transactions and alternatives; compliance with our financial commitments; compliance with our debt facilities; discussions with our creditors; as well as statements regarding our plans for BAXDELA. 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, risks related to potential alternative transactions, including a sales process, a reorganization or other restructuring, including seeking relief through a filing under the U.S. Bankruptcy Code, or other actions with respect to our debt and operations; risks related to our liquidity, including uncertainties of cash flows and inability to meet working capital needs as well as other milestones, royalty and payment obligations, including as a result of the outcome of the pending litigation with respect to (including the outcome with respect to our related counter claims), and any requirement to make payments potentially due under our purchase agreement with, 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, which may require successfully defending against The Medicines Company or consensually resolving that dispute; our substantial indebtedness; risks related to compliance with the covenants under our facilities with Vatera and Deerfield; our need for future capital and risks related to our ability to obtain additional capital to fund future operations; the fact that we have incurred significant operating losses since inception and will incur continued losses for the foreseeable future; our limited operating history; 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 unlikelihood that we will be able to satisfy the closing conditions for the remaining disbursement amount; risks related to the unlikelihood that we will be able to satisfy the conditions to borrowing additional amounts under the Deerfield facility agreement; 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, and our ability to fund commercialization and promotion 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 Cempra 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, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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.

About BAXDELA® (delafloxacin)
BAXDELA tablets and intravenous injection are approved by the U.S. Food and Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) in adults caused by designated susceptible bacteria. BAXDELA was approved for the treatment of ABSSSI by the FDA in 2017 based on its efficacy against both gram-positive and gram-negative pathogens, including MRSA, and for the treatment of CABP in October 2019 based on its efficacy against gram-positive, gram-negative and other microorganisms. It was given priority review by the FDA due to its designation as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act of 2012. The QIDP designation qualifies BAXDELA for certain incentives related to the development of new antibiotics, including a five-year extension of any non-patent exclusivity period awarded to the drug.

INDICATION & USAGE
BAXDELA is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, and *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.

BAXDELA is indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae* , *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae.*

IMPORTANT SAFETY INFORMATION:

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, and EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:
- **Tendinitis and tendon rupture**
- **Peripheral neuropathy**
- **Central nervous system effects**

Discontinue BAXDELA immediately and avoid the use of fluoroquinolones, including BAXDELA, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid BAXDELA in patients with known history of myasthenia gravis.

Contraindications
BAXDELA is contraindicated in patients with known hypersensitivity to BAXDELA or other fluoroquinolones.

Warnings and Precautions
Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions. Avoid use in patients who have experienced any of the following serious adverse reactions. If these reactions occur in patients receiving BAXDELA, discontinue BAXDELA immediately and institute appropriate treatment:
- Tendinitis, tendon rupture, with increased risk in elderly, patients taking corticosteroids and in patients with organ transplants
- Peripheral neuropathy, such as pain, burning, tingling, numbness, and/or weakness or other alterations of sensation in touch and/or motor strength
- Central nervous system adverse reactions such as seizures, increased intracranial pressure, dizziness, and tremors
- Exacerbation of myasthenia gravis, including death and requirement for ventilator

Fluoroquinolones, including BAXDELA, have been associated with an increased risk of psychiatric adverse reactions, including: toxic psychosis; hallucinations, or paranoia; depression, or suicidal thoughts or acts; delirium,

disorientation, confusion, or disturbances in attention; anxiety, agitation, or nervousness; insomnia or nightmares; memory impairment. These adverse reactions may occur following the first dose.

Hypersensitivity reactions have been reported in patients receiving fluoroquinolones, including BAXDELA. Reactions can be serious and occasionally fatal (anaphylactic). Discontinue BAXDELA at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported with nearly all systemic antibacterial agents, including BAXDELA, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Fluoroquinolones have been associated with an increased risk of aortic aneurysm and dissection, especially in elderly patients. In patients with a known aortic aneurysm or patients who are at greater risk for aortic aneurysms, reserve BAXDELA for use only when there are no alternative antibacterial treatments available.

Prescribing BAXDELA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Fluoroquinolones have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia. Severe cases of hypoglycemia resulting in coma or death have been reported with other fluoroquinolones. Monitor blood glucose carefully in diabetic patients receiving oral hypoglycemic agents or insulin. Discontinue BAXDELA and initiate appropriate therapy immediately if a hypoglycemic reaction occurs.

Adverse Reactions
The most common adverse reactions (incidence ≥ 2%) in patients treated with BAXDELA are nausea, diarrhea, headache, transaminase elevations, and vomiting.

Please see full Prescribing Information, including **Boxed Warning**, and Patient Medication Guide, available at www.baxdela.com.

For More Information:

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