Melinta Therapeutics Inc

Small/medium-sized enterprise
Stock exchange: NASDAQ • Ticker: MLNT • HQ: New Jersey, USA • Employees: 290

PERFORMANCE

Melinta performs above average in Research & Development when compared to other small and medium-sized enterprises in scope.

R&D: Largest pipeline with 11 antibacterial projects for priority pathogens. Granted approval in 2019 for one antibacterial medicine. Reports access plans to expand availability to access countries.

SALES AND OPERATIONS Filed for bankruptcy in December 2019

Therapeutic areas: Antibiotics
Products on the market: 4 antibacterial medicines: delafloxacin (Baxdela®), meropenem/vaborbactam (Vabomere®), minocycline (Minocin®), and oritavancin (Orbactiv®)

R&D grants received since 2016: At least USD 2.3 million, awarded by one funder (CARB-X). The award, worth USD 2.3 million, was granted in May 2018 to support development of its pyrrololate compounds, part of its ESKAPE Pathogen Programme.

Financing and Investment Structure: Melinta is a publicly listed company. It gained a public listing on NASDAQ on merging with Cempra in November 2017, following five funding series, raising USD 180.5 million. The company’s lead investors were EuclidSR Partners, Oxford Bioscience Partners, Sanofi Aventis, SR One, Vatera Healthcare Partners and Warburg Pincus. Its post IPO equity, debt, and other venture funding amounts to USD 360.7 million.


PIPELINE for diseases in scope

Pipeline size: 11 projects for priority pathogens* (11 antibacterial medicines)
Development stages: 8 clinical projects, including two Phase I projects for oritavancin (Orbactiv®) and meropenem/vaborbactam (Vabomere®) to expand indications for use in treating bacterial infections in paediatric patients, and 3 pre-clinical projects

Novelty: No novel clinical-stage medicine projects

Regulatory approvals: 0 approvals for priority pathogens

Access plans: 2 of 2 late-stage R&D projects with project-specific access plans, both of which are licensing agreements to expand availability to access countries, though these plans do not address affordability

Stewardship plans: Neither of its 2 late-stage R&D medicine projects have project-specific stewardship plans.

PORTFOLIO for diseases in scope

Portfolio size: 5 products (4 unique INNs): 5 antibacterial medicines

Essential medicines: None

AWaRe medicines**: None

Anti-TB medicines**: None

Revenues by product (2018)

Antibiotics 46

Total revenue 50.4

Revenues by region (2018)

Antibiotics 96.4 mn USD

Other

* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

** Listed on the 2019 WHO EML (Section 6).
OPPORTUNITIES FOR MELINTA

Work with partners to improve availability, affordability and stewardship for meropenem/vaborbactam (Vabomere®) and for delafloxacin (Baxdela®) in more LMICs. Melinta is part of an agreement with Menarini Group which grants Menarini Group the exclusive rights to co-develop and commercialize meropenem/vaborbactam and delafloxacin in 68 countries in Europe, Asia-Pacific and the Commonwealth of Independent States (CIS). Melinta can work with Menarini to ensure that meropenem/vaborbactam will be available and affordable in low- and middle-income countries and appropriately used globally. Melinta is also part of an agreement with Eurofarma Laboratorios, which grants Eurofarma Laboratorios the exclusive rights to co-develop and commercialize delafloxacin in Brazil. Melinta can also look for multiple licensees in other regions of the world. As above, examples of access and stewardship plans for Melinta and its partners, including Menarini Group and Eurofarma Laboratorios, would be developing an equitable pricing strategy and decoupling sales incentives from sales volumes, respectively.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT Evaluated: medicine & vaccine pipelines for priority* bacteria & fungi

A.1 R&D investments Melinta invested USD 104.9 million in the development of antibacterial medicines in 2017 and 2018. As with all other small and medium-sized enterprises (SMEs) evaluated, Melinta was not scored in this indicator.

A.2.1 Pipeline size of 11 projects Melinta reports 11 projects targeting priority pathogens in its pipeline. The company focuses on antibacterial medicine development, and has eight projects in clinical development, and three in pre-clinical development.

A.2.2 No clinical-stage novel projects Melinta’s clinical-stage medicine pipeline for priority pathogens consists entirely of adapted R&D projects. It does not currently include candidates that are considered novel. However, Melinta is developing eight clinical-stage adapted R&D projects, including studies on the efficacy and safety of meropenem/vaborbactam (Vabomere®) in children.

A.2.3 Vaccines in the pipeline Melinta is not eligible for this indicator as it is not active in vaccine development.

Pipeline targeting priority pathogens: 11  As at 16 October 2019

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<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
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<tr>
<td>Enhanced macrolide programme, proprietary discovery platform - Drug-resistant Pneumococcus spp. and Staphylococcus spp. (including MRSA)</td>
<td>Delafloxacin (Baxdela®) - GNB (including Enterobacteriaceae and P. aeruginosa) and GPB (including MRSA, group A and group B Streptococcus spp. and E. faecalis) - Adaptation (additional indication) - cUTI</td>
<td>Meropenem/vaborbactam (Vabomere®) - GNB and GPB - Adaptation (additional target population: paediatric patients)</td>
<td>Minocycline (Minocin®) - GNB - Adaptation (high-dosing regimen)</td>
<td>Minocycline (Minocin®) - GNB - Adaptation (additional target population: renally impaired patients)</td>
<td>Oritavancin (Obractiv®) - GPB - Adaptation (new formulation with a shorter infusion time, less volume and ability to reconstitute with saline)</td>
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<td>ESKEAP programme: pyrrololysosine class compound (RX-P2382), proprietary discovery platform - Enterobacteriaceae, P. aeruginosa, A. baumannii, S. aureus, Enterococcus spp. and N. gonorrhoeae</td>
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<td>ESKEAP programme: pyrrololysosine lead compounds (RX-P2117) - N. gonorrhoeae</td>
<td>Delafloxacin (Baxdela®) - CABP (including Enterobacteriaceae and P. aeruginosa)</td>
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* Bacteria and fungi that have been identified as priority R&D targets for limiting AMR, by either the WHO and/or the Centers for Disease Control and Prevention (CDC). See Appendix V.

CHANGES SINCE 2018

- Filed for Chapter 11 bankruptcy in December 2019 and reports it will continue to operate in ordinary course throughout the process.
- Received FDA approval for its supplemental New Drug Application for delafloxacin (Baxdela®) in October 2019, expanding the previous indication to community-acquired bacterial pneumonia in adult patients.
- Launched a new antibacterial stewardship programme, including post-marketing susceptibility testing, stewardship-focused promotional standards, and educational programmes with healthcare professionals (HCPs).

** Delafloxacin (Baxdela®) received FDA market approval in October 2019 for the treatment of CABP.
A.2.4 Three candidates targeting critical and/or urgent priorities
Melinta’s clinical pipeline includes an adapted medicine in Phase III, for its marketed product meropenem/vaborbactam (Vabomere©) that targets CRE. Its ESKAPE programme includes two pre-clinical candidates: one that targets resistant strains of Enterobacteriaceae, A. baumannii, and P. aeruginosa; and another that targets N. gonorrhoeae. These pathogens are among those that are considered critical and/or urgent R&D priorities for limiting AMR, as identified by WHO and/or the US Centers for Disease Control and Prevention (CDC).

A.3 Intellectual capital sharing
As an SME, Melinta was not scored for this indicator, in line with the external stakeholder consensus defined by the Foundation.

A.4 Access plan for two of two projects; no stewardship plans
Melinta has two late-stage R&D projects targeting priority pathogens. Melinta has a licensing agreement covering both projects that enables the Menarini Group to market the successful products in 68 countries in Europe, Asia-Pacific, and CIS. Additionally, Melinta and Eurofarma Laboratórios, one of the largest pharmaceutical companies in Brazil and present in more than 20 countries in Latin America, entered into an agreement for the development and commercialisation of delafloxacin in Brazil. Melinta does not report specific clauses regarding affordability or accessibility in its agreements, or any stewardship plan.

B RESPONSIBLE MANUFACTURING
As an SME, Melinta is not evaluated in this Research Area. It has antibacterial products on the market. The Benchmark notes that Melinta reports having conducted environmental risk-assessments for its nine suppliers of antibacterial APIs and/or drug products. These assessments included estimations of the presence of antibacterial APIs in waste streams. The assessments were carried out in order to develop a specific strategy for each supplier and to ensure a harmonised company-wide global strategy. Melinta was not scored on these activities.

C APPROPRIATE ACCESS & STEWARDSHIP
As an SME, Melinta is not evaluated in this Research Area. It does, however, have antibacterial and/or antifungal products on the market. The Benchmark notes that Melinta reports making its antibacterials available outside the United States, including in access countries, through partnerships with other pharmaceutical companies.

Melinta also has some strategies in place to mitigate conflict of interest (COI) for its educational programmes aimed at HCPs. Specifically, two of Melinta’s five AMR-related educational programmes aimed at HCPs are accredited by an independent body that evaluates potential COI.

Melinta adapts marketing materials to ensure the appropriate use of antibacterial and/or antifungal medicines. Its marketing materials reflect emerging resistance trends and include guidelines for HCPs to raise awareness of AMR and address appropriate use.

Further, Melinta is active in one AMR surveillance programme, and publishes its results openly. Melinta is also active in SENTRY, a long-term AMR surveillance programme. This is a multinational programme that is managed by JMI laboratories with support from Melinta, among other companies. Its results are shared in an open-access data platform. Melinta was not scored for these activities.

† 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.