# Melinta Therapeutics Reports First Quarter 2018 Financial Results

*Strong Product Sales Performance Across Entire Portfolio*

*Continuing to Optimize Operations to Achieve Cost Synergies*

*Important Achievements for Development and Discovery Efforts Including CARB-X Funding Award*

NEW HAVEN, Conn., May 08, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ:MLNT), a commercial-stage company discovering, developing and commercializing novel antibiotics to treat serious bacterial infections, today reported financial results and provided an update on commercial activities for the quarter ended March 31, 2018. Melinta reported revenue of $14.8 million for the quarter ended March 31, 2018, which includes product sales of $11.8 million and contract revenue of $3.0 million. In addition, the company earned $2.7 million in funding from the Biomedical Advanced Research and Development Authority (BARDA), which it recorded as other income. This quarter was the first including sales from all four of the company's antibiotic brands.

"The new Melinta is off to a strong start in 2018, as we completed our first quarter as a combined company following the close of our acquisition of The Medicines Company's infectious disease business on January 5, 2018," said Dan Wechsler, President and CEO of Melinta. "During the quarter we launched Baxdela™ (delafloxacin) in the U.S. and continued our launch of Vabomere™ (meropenem and vaborbactam) in the U.S., and generated strong sales performance across all four of our brands, powered by our experienced antibiotics-focused salesforce. Our salesforce is now fully cross-trained with all reps selling all products beginning in May, significantly expanding our share of voice.

"Within our pipeline we saw continued advancement, with our partners Menarini Group and Eurofarma Laboratórios submitting Marketing Authorization Applications for delafloxacin in the E.U. and Argentina, respectively. We also announced an agreement with CARB-X, one of the world's largest public-private partnerships devoted to early development antibacterial R&D, that will provide us funding to advance the development of a novel antimicrobial from our ESKAPE pathogen program.

"From a financial perspective, we have received significant interest to partner outside of the U.S. on our products. In addition, we have strong support from shareholders and others to provide a foundation for the continued growth of our company."

**Q1 2018 and Recent Business Highlights**

- January 5, 2018 - acquired the infectious disease business of The Medicines Company, including approved products Vabomere, Orbactiv® (oritavancin) and Minocin® (minocycline) for Injection

- In Q1:
  - added well-experienced talent across the entire organization, including sales and marketing, medical affairs and other expertise
  - completed integration
  - had no disruption to product launches or performance
- February 6, 2018 – launched Baxdela in the United States
- February 20, 2018 – partner Eurofarma Laboratórios submitted the first of many anticipated marketing authorization applications (MAA) in Latin America, in Argentina, for delafloxacin for treatment of adult patients with acute bacterial skin and skin structure infection (ABSSSI)
  - additional MAA submitted in Peru on May 4, 2018
- March 6, 2018 – partner Menarini submitted an MAA to the European Medicines Agency (EMA) for delafloxacin (Quofenix) for treatment of adult patients with ABSSSI

**Q1 2018 Financial Results**

Melinta reported product sales for the first time in the first quarter of 2018 totaling $11.8 million, which included the addition of Vabomere, Minocin and Orbactiv as of January 5, 2018, the close of The Medicines Company acquisition, as well as the launch of Baxdela in February.

For the quarter, total net revenue was $14.8 million compared to total net revenue of $22.5 million for the same period in 2017, when Melinta was a private company. The composition of revenue in the first quarter of 2018 was significantly different than that recognized in the first quarter of 2017. In the first quarters of 2018 and 2017, we recognized contract research revenue totaling $3.0 million and $2.6 million, respectively. In the first quarter of 2017, we also recognized $19.9 million in upfront consideration from Menarini in connection with the execution of our ex-U.S. Baxdela licensing arrangement.

| *in USD millions* | **2018** | **2017** |
|---|---|---|
| Product sales | $11.8 | 0.0 |
| Contract revenue | 3.0 | 2.6 |
| Licensing revenue | 0.0 | 19.9 |
| **Total net revenue *** | **$14.8** | **$22.5** |
| * Excludes BARDA grant funding included in Other Income | | |

Cost of goods sold was $7.7 million for the quarter ended March 31, 2018. Notably, $4.7 million of the $7.7 million was comprised of non-cash, amortization of intangible assets. There were no product sales and therefore no costs of goods sold in the prior year period.

Research and development (“R&D”) expenses were $16.1 million for the quarter ended March 31, 2018, compared to $12.9 million for the same period in 2017. The increase was driven by additional headcount and development activities resulting from the recent merger with Cempra, the acquisition of the infectious disease business from The Medicines Company and accelerated patient enrollment for our ongoing community-acquired bacterial pneumonia (CABP) registration trial for Baxdela.

Selling, general and administrative (“SG&A”) expenses were $34.6 million for the quarter ended March 31, 2018, compared to $8.0 million for the same period in 2017. The increase was driven by costs to support a larger, public, commercial organization after the Cempra merger and the acquisition of the infectious disease business from The Medicines Company, including additional headcount and commercial infrastructure, and acquisition-related severance and other non-

recurring expenses. Approximately $4.3 million was a result of acquisition-related costs and other non-GAAP adjustments.

Net loss available to shareholders was $29.4 million, or $0.95 per share, for the quarter ended March 31, 2018 compared to a net loss of $5.8 million for the same period in 2017. Net loss per share is impacted by changes in our share count as a result of the Cempra merger and financing related to the acquisition of the infectious disease business from The Medicines Company.

As of March 31, 2018, Melinta had cash and cash equivalents of $91.5 million. Cash and cash equivalents for this quarter was negatively impacted by the timing of certain payments and receipts of reimbursement expenses of approximately $10 million.

**Q1 2018 and Recent Pipeline and Publication Highlights**

- Complete Results from the Phase 3 TANGO-1 Data for Vabomere Published in *The Journal of the American Medical Association (JAMA)*
- 2nd Pivotal Phase 3 Baxdela ABSSSI Trial Data Published in *Clinical Infectious Diseases*
- 12 Presentations at ECCMID 2018 including six from Vabomere TANGO-2 trial, as well as new in vitro and in vivo findings for Baxdela and a pyrrolocytosine lead molecule
    - Pyrrolocytosine compound RX-P2382 against ESKAPE pathogens at ECCMID 2018
    - TANGO-2 Trial at ECCMID 2018, highlighting outcomes in vulnerable patient populations
    - Discovery Platform Oral Presentations at ECCMID 2018 and American Society for Microbiology (ASM Microbe) Highlighting Progress Towards Leads for Drug-resistant Neisseria gonorrhoeae and Multidrug- and Extremely Drug-resistant ESKAPE Pathogens

**2018 Upcoming Potential Catalysts**

- Pivotal Phase 3 data for Baxdela in CABP
- Vabomere EMA regulatory approval decision
- TANGO-2 additional data and potential publication
- Additional ex-U.S. submissions for Baxdela in Central and South America
- Ex-U.S. partnership opportunities for Vabomere, Orbactiv and Minocin for Injection
- IND-enabling studies for the lead ESKAPE compound

**Conference Call and Webcast**

Melinta's earnings conference call for the quarter ended March 31, 2018 will be broadcast at 4:30pm EDT on May 8, 2018. The live webcast can be accessed under "Events and Presentations" in the Investor Relations section of Melinta's website at www.melinta.com.

Investors wishing to participate in the call should dial: 877-377-7553 and international investors should dial: 253-237-1151. The conference ID is 6689334. Investors can also access the call at http://ir.melinta.com/events/event-details/melinta-therapeutics-q1-2018-earnings-call.

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 # 6689334.

**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. It also has an extensive pipeline of preclinical and clinical-stage products representing many important classes of antibiotics, each targeted at a different segment of the anti-infective market. Together, 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.

As more fully described in our Annual Report on Form 10-K for the year ended December 31, 2017, the former private company Melinta was determined to be the accounting acquirer in our November 2017 reverse merger with Cempra and, accordingly, historical financial information for the first quarter of 2017 presented in this press release reflects the standalone former private company Melinta and, therefore, period-over-period comparisons may not be meaningful.

**Non-GAAP Financial Measures**

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we have included information about non-GAAP adjusted EBITDA, a non-GAAP financial measure, as a useful operating metric. We believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information to analysts, investors, lenders, and our management in assessing the Company's performance and results from period to period. These non-GAAP measures closely align with the way management measures and evaluates the Company's performance. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. Non-GAAP Adjusted EBITDA is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude interest income, interest expense, depreciation and amortization, stock-based compensation expense, changes in the fair value of our warrant liability, gain or loss on extinguishment of debt, acquisition-related costs, and other adjustments, including severance. Non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

***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. 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. 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 or strategies 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; uncertainties of cash flows and inability to meet working capital needs as well as other milestone, royalty and payment obligations; the fact that our independent registered public accounting firm's report on the Company's 2016 and 2017 financial statements contains an explanatory paragraph that states that the our recurring losses from operations and our need to obtain additional capital raises substantial doubt about our ability to continue as a going concern; our substantial indebtedness; risks related to our 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 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 amount of shares of common stock may be sold into the public markets by one or more of our large shareholders 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, 2017, 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.*

**Melinta Therapeutics**
**Condensed Consolidated Balance Sheets**

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| | (Unaudited) | |
| | **(in 000s)** | |
| **Assets** | | |
| Cash and cash equivalents | $ 91,479 | $ 128,387 |
| Trade receivables, net | 10,455 | - |
| Other receivables | 11,619 | 7,564 |
| Inventory | 28,220 | 10,825 |
| Prepaid expenses and other current assets | 7,322 | 2,988 |
| Total current assets | 149,095 | 149,764 |
| Property and equipment, net | 2,276 | 1,596 |
| Goodwill | 13,059 | - |
| Intangible assets | 260,825 | 7,500 |
| Other assets | 22,678 | 1,413 |
| **Total assets** | $ 447,933 | $ 160,273 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Accounts payable and accrued expenses | $ 41,084 | $ 31,446 |
| Warrant liability | 9,179 | - |
| Deferred and contingent purchase price | 22,830 | - |
| Contingent milestones | 27,184 | - |
| Other current liabilities | - | 284 |
| Total current liabilities | 100,277 | 31,730 |
| Debt facilities, net of discounts | 106,090 | 39,555 |
| Deferred revenues | - | 10,008 |
| Deferred and contingent purchase price | 33,393 | - |
| Other long-term liabilities | 8,340 | 6,644 |
| **Total liabilities** | 248,100 | 87,937 |
| | | |
| Convertible preferred stock | - | - |
| | | |
| **Stockholders' equity** | | |
| Common stock | 31 | 22 |
| Additional paid in capital | 791,885 | 644,973 |
| Accumulated deficit | (592,083) | (572,659) |
| **Total stockholders' equity** | 199,833 | 72,336 |
| **Total liabilities and stockholders' equity** | $ 447,933 | $ 160,273 |

The Company has recorded goodwill and intangible assets, as well as deferred and contingent consideration, in connection with the acquisition of the infectious disease business from The Medicines Company on a preliminary basis and based on its best estimates. The Company will record adjustments as necessary as it completes the valuation process, which may impact the value of intangible assets and related amortization expense included in our financial statements. Under GAAP, the Company has one year to finalize the purchase accounting for the acquisition.

**Melinta Therapeutics**
**Condensed Consolidated Statements of Operations**
(In thousands, except per share amounts)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| | (Unaudited) | |
| | **(in 000s)** | |
| **Revenue** | | |
| Product sales, net | $ 11,846 | $ - |
| License revenue | - | 19,905 |
| Contract revenue | 2,995 | 2,558 |
| Total revenue | 14,841 | 22,463 |
| **Operating expenses** | | |
| Cost of product sales | 7,686 | - |
| Research and development | 16,129 | 12,917 |
| Selling, general and administrative | 34,624 | 7,973 |
| Total operating expenses | 58,439 | 20,890 |
| Income (loss) from operations | (43,598) | 1,573 |
| **Other income (expense), net** | | |
| Grant income | 2,658 | - |
| Interest expense | (10,196) | (1,622) |
| Change in fair value of warrant liability | 24,085 | (55) |
| Loss on extinguishment of debt | (2,595) | - |
| Interest and other income, net | 214 | 30 |
| Total other income (expense), net | 14,166 | (1,647) |
| **Net loss** | $ (29,432) | $ (74) |
| Accretion of convertible preferred stock dividends | - | (5,720) |
| **Net loss available to common shareholders** | $ (29,432) | $ (5,794) |
| | | |
| Basic and diluted net loss per share | $ (0.95) | $ (208.16) |
| Basic and diluted weighted-average shares outstanding | 30,918 | 28 |

**Melinta Therapeutics**
**Condensed Consolidated Statement of Cash Flows**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| | (Unaudited) | |
| | **(in 000s)** | |
| **Net loss** | $ (29,432) | $ (74) |
| Adjustments to reconcile net income (loss) to net cash used in operations: | | |
| Depreciation and amortization | 4,805 | 123 |
| Change in fair value of warrants | (24,085) | 56 |
| Loss on extinguishment of debt | 2,595 | - |
| Non-cash interest expense | 5,954 | 1,155 |
| Stock-based compensation | 955 | 572 |
| Changes in operating assets and liabilities: | | |
| Receivables | (5,052) | (2,623) |
| Inventory | (2,002) | - |
| Prepaids and other assets/liabilities | (3,508) | 992 |
| Accounts payable and accrued expenses | (1,650) | 3,364 |
| **Net cash provided by (used in) operating activities** | **(51,420)** | **3,565** |
| Cash flows from investing activities: | | |
| Cash acquired from acquisition of IDB | (166,383) | - |
| Purchases of property, plant and equipment | (504) | (109) |
| **Net cash used in investing activities** | **(166,887)** | **(109)** |
| Cash flows from financing activities: | | |
| Proceeds from the issuance of common stock, net | 40,003 | 95 |
| Proceeds from the issuance of debt instruments | 190,000 | 8,010 |
| Principal payments on notes payable | (40,000) | (2,844) |
| Debt extinguishment costs | (2,150) | - |
| Debt issuance costs | (6,454) | - |
| **Net cash provided by financing activities** | **181,399** | **5,261** |
| **Net increase (decrease) in cash and cash equivalents** | **(36,908)** | **8,717** |
| Cash and cash equivalents at beginning of period, including restricted cash | 128,587 | 11,409 |
| **Cash and cash equivalents at end of period, including restricted cash** | **$ 91,679** | **$ 20,126** |

**Melinta Therapeutics**
**Reconciliation of Reported Net Loss to Adjusted EBITDA**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2018** | **2017** |
| | (Unaudited) | |
| | **(in 000s)** | |
| **Net loss** | **$ (29,432)** | **$ (74)** |
| EBITDA adjustments: | | |
| Interest expense | 10,196 | 1,622 |
| Interest income | (210) | (5) |
| Depreciation and amortization | 4,805 | 114 |
| Total EBITDA adjustments | 14,791 | 1,731 |
| **EBITDA** | **$ (14,641)** | **$ 1,657** |
| Other adjustments: | | |
| Stock-based compensation | 955 | 572 |
| Changes in fair value of warrant liability | (24,085) | 55 |
| Loss on extinguishment of debt | 2,595 | - |
| Acquisition-related costs | 2,069 | - |
| Other | 1,532 | - |
| Total other adjustments | (16,934) | 627 |
| **Adjusted EBITDA** | **$ (31,575)** | **$ 2,284** |

**Melinta Therapeutics**
**GAAP to Non-GAAP Adjustments**
**for the Three Months Ended March 31, 2018 and March 31, 2017**

| Three Months Ended March 31, 2018 (Unaudited) | Revenue | Cost of Product Sales | R&D | SG&A | Other Income (Expense), Net | Total |
|---|---|---|---|---|---|---|
| As reported under GAAP | $ 14,841 | $ (7,686) | $ (16,129) | $ (34,624) | $ 14,166 | $ (29,432) |
| Adjustments: | | | | | | |
| Interest expense | - | - | - | - | 10,196 | 10,196 |
| Interest income | - | - | - | - | (210) | (210) |
| Depreciation and amortization | - | 4,683 | 53 | 69 | - | 4,805 |
| Stock-based compensation | - | 37 | 217 | 701 | - | 955 |
| Change in fair value of warrant liability | - | - | - | - | (24,085) | (24,085) |
| Loss on extinguishment of debt | - | - | - | - | 2,595 | 2,595 |
| Acquisition-related costs | - | - | - | 2,069 | - | 2,069 |
| Other | - | - | - | 1,532 | - | 1,532 |
| Total adjustments | $ - | $ 4,720 | $ 270 | $ 4,371 | $ (11,504) | $ (2,143) |
| **Adjusted EBITDA** | **$ 14,841** | **$ (2,966)** | **$ (15,859)** | **$ (30,253)** | **$ 2,662** | **$ (31,575)** |

| Three Months Ended March 31, 2017 | Revenue | R&D | SG&A | Other Income (Expense), Net | Total |
|---|---|---|---|---|---|
| As reported under GAAP | $ 22,463 | $ (12,917) | $ (7,973) | $ (1,647) | $ (74) |
| Adjustments: | | | | | |
| Interest expense | - | - | - | 1,622 | 1,622 |
| Interest income | - | - | - | (5) | (5) |
| Depreciation and amortization | - | 82 | 32 | - | 114 |
| Stock-based compensation | - | 140 | 432 | - | 572 |
| Change in fair value of warrant liability | - | - | - | 55 | 55 |
| Total adjustments | $ - | $ 222 | $ 464 | $ 1,672 | $ 2,358 |
| **Adjusted EBITDA** | **$ 22,463** | **$ (12,695)** | **$ (7,509)** | **$ 25** | **$ 2,284** |

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