# Melinta Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results

*Baxdela™(delafloxacin) Launched February 6, 2018, in U.S. for Adults with ABSSSI*

*Acquired Infectious Disease Business from The Medicines Company on January 5, 2018*

*First Earnings Report as a Public Company*

NEW HAVEN, Conn., March 13, 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 and regulatory activities for the quarter ended December 31, 2017. During the quarter, the Company completed its reverse merger with Cempra, Inc. (Cempra) to become a publicly traded company. Fourth quarter and full year 2017 results include the addition of the Cempra business as of the merger date of November 3, 2017. Immediately following the quarter, the Company acquired the infectious disease business of The Medicines Company, including products Vabomere™ (meropenem and vaborbactam), Orbactiv® (oritavancin) and Minocin® (minocycline) for Injection. This press release includes highlights from The Medicines Company infectious disease business as of acquisition close on January 5, 2018.

“Following Melinta becoming a public company on November 3, we swiftly acquired the infectious disease business from The Medicines Company, transforming Melinta into the largest global, pure-play antibiotics company. Today, we have a strong portfolio of products including Vabomere, Orbactiv and Minocin for Injection, together with our first drug Baxdela that we launched just this quarter,” said Dan Wechsler, president and CEO of Melinta.

“We have a strong combined team, including the addition of over 150 seasoned professionals at the time of The Medicines Company transaction, and a leading pipeline of development and discovery assets including those from our own Nobel Prize-winning discovery platform. 2018 will be an exciting year for Melinta, and we look forward to launching our products, furthering our pipeline and telling our story focused on bringing life-saving anti-infective products to areas of unmet need and, in turn, building strong shareholder value over the long-term,” Mr. Wechsler concluded.

**Full Year 2017 and Recent Business Highlights**

- March 2, 2017 - entered into commercial and co-development agreement with Menarini Group for delafloxacin in 68 countries outside of the United States

- >$100 million of upfront and potential milestone payments and double-digit royalties on sales in partnered territories
- Menarini pays 50% of future delafloxacin indication-expansion efforts

- June 19, 2017 - the U.S. Food and Drug Administration (FDA) approved Baxdela indicated in adults for treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria
  - A fluoroquinolone that exhibits activity against both Gram-positive and Gram-negative pathogens, including the distinction of being the only approved drug in its class that covers methicillin-resistant *Staphylococcus aureus* (MRSA)
  - A fixed-dose therapy with limited disease or drug interactions and is available in interchangeable intravenous and oral formulations
- September 26, 2017 - announced the expansion of agreement with Eurofarma Laboratorios S.A. (Eurofarma) to include 19 countries in South and Central America and the Caribbean
  - Eurofarma has submitted a marketing authorization for delafloxacin in Argentina
- November 3, 2017 - completed the reverse merger with Cempra to become a publicly traded company
- January 5, 2018 - acquired the infectious disease business of The Medicines Company, including approved products Vabomere, Orbactiv and Minocin for Injection
  - Added a well-experienced commercial, medical affairs and commercial support organization
  - Integration nearing completion
  - Minimal disruption to product launches or performance, including Vabomere, which was recently launched
- February 6, 2018 - launched Baxdela in the United States
- March 8, 2018 - partner Menarini submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for delafloxacin for treatment of adults with ABSSSI

**Q4 and Full Year 2017 Financial Results**

Melinta reported a net loss available to shareholders of $20.9 million, or $1.48 per share, for the quarter ended December 31, 2017 compared to a net loss of $27.7 million for the same period in 2016. For the full year ended December 31, 2017, the Company reported net loss available to shareholders of $78.2 million.

Research and development expenses were $11.6 million for the quarter ended December 31, 2017, compared to $16.3 million for the same period in 2016. The decrease was driven primarily by fourth quarter 2016 New Drug Application (NDA)-related fees and milestone payments and lower manufacturing costs. For the full year ended December 31, 2017, the Company reported R&D expenses of $49.5 million.

Selling, general and administrative expenses were $37.3 million for the quarter ended December 31, 2017, compared to $4.6 million for the same period in 2016. The increase was driven primarily by commercial launch preparation activities for

Baxdela and transaction- and integration-related costs, including severance and stock-based compensation, due to the merger. For the full year ended December 31, 2017, the Company reported selling, general and administrative expenses of $63.3 million.

As of December 31, 2017, Melinta had cash and cash equivalents of $128.4 million. In addition, the Company has available debt capacity under the Deerfield agreement. It is anticipated that Melinta may strengthen its cash position through the completion of business development activities, similar to the transaction completed with Menarini. The Company also recently filed a universal shelf registration statement on Form S-3 with the SEC, which will allow the Company to provide more timely and efficient access to the capital markets should the Company decide to issue securities in the future, subject to market conditions.

## 2017 and Recent Pipeline and Publication Highlights

*Includes highlights from The Medicines Company infectious disease business as of acquisition close on January 5, 2018.*

- Publication of Baxdela Outcomes in ABSSSI Patients with Fluoroquinolone-resistant *S. aureus* Isolates
- Presented Outcomes of Baxdela Treatment of Gram-Positive and Gram-Negative Pathogens at IDWeek 2017
- Announced Topical Radezolid (partnered product) Well Tolerated in Phase 1 Study for Treatment of Acne, Initiation of Program in Patients with Bacterial Vaginosis, and Qualified Infectious Disease Product (QIDP) Designation for Bacterial Vaginosis
- Publication in *Journal of Antimicrobial Chemotherapy* of 1st Pivotal Phase 3 Baxdela Trial Data in ABSSSI
- 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*
- Discovery Platform Oral Presentations at European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) 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 community-acquired bacterial pneumonia (CABP)
- Vabomere EMA regulatory approval decision
- TANGO-2 additional data and potential publications
- Additional ex-US approvals for Baxdela in Central and South America
- Ex-US partnership opportunities for Vabomere, Orbactiv and Minocin for Injection
- IND-enabling studies for lead ESKAPE compound

## Conference Call and Webcast

Melinta's earnings conference call for the quarter ended December 31, 2017 will be broadcast at 8:30am EDT on March 13, 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 7787858. Investors can also access the call at http://ir.melinta.com/events/event-details/melinta-therapeutics-q4-2017-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 # 7787858.

**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 and better 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.

**About Baxdela (delafloxacin)**

For more information about Baxdela, including the Medication Guide and important safety information, including the Boxed Warning, see www.baxdela.com.

***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; 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, which we expect to file promptly with the SEC, 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.*

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| | (in 000s) | |
| **Assets** | | |
| Cash and cash equivalents | $ 128,387 | $ 11,409 |
| Receivables | 7,564 | 454 |
| Inventory | 10,825 | - |
| Prepaid expenses and other current assets | 2,988 | 3,226 |
| Total current assets | 149,764 | 15,089 |
| Property and equipment, net | 1,596 | 1,101 |
| Intangible assets | 7,500 | - |
| Other assets | 1,413 | 444 |
| **Total assets** | $ 160,273 | $ 16,634 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Accounts payable and accrued expenses | $ 31,446 | $ 11,496 |
| Notes payable, net | - | 11,075 |
| Other current liabilities | 284 | 848 |
| Total current liabilities | 31,730 | 23,419 |
| Notes payable, net of current and debt discount | 39,555 | 12,647 |
| Convertible promissory notes | - | 45,127 |
| Deferred revenue | 10,008 | 9,008 |
| Other long-term liabilities | 6,644 | 1,541 |
| **Total liabilities** | 87,937 | 91,742 |
| | | |
| Convertible preferred stock | - | 218,343 |
| | | |
| **Stockholders' equity** | | |
| Common stock | 22 | - |
| Additional paid in capital | 644,973 | 220,292 |
| Accumulated deficit | (572,659) | (513,743) |
| **Total stockholders' equity** | 72,336 | (293,451) |
| **Total liabilities and stockholders' equity** | $ 160,273 | $ 16,634 |

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| | (in 000s) | | | |
| **Revenue** | | | | |
| Contract revenue | $ 4,231 | $ - | $ 13,959 | $ - |
| License | - | - | 19,905 | - |
| Total revenue | 4,231 | - | 33,864 | - |
| **Operating expenses** | | | | |
| Research and development | 11,599 | 16,302 | 49,475 | 49,791 |
| Selling, general and administrative | 37,349 | 4,586 | 63,325 | 19,410 |
| Total operating expenses | 48,948 | 20,888 | 112,800 | 69,201 |
| Loss from operations | (44,717) | (20,888) | (78,936) | (69,201) |
| **Other income (expense), net** | | | | |
| Interest income | 130 | 6 | 155 | 30 |
| Interest expense | (1,859) | (1,478) | (7,624) | (4,406) |
| Change in fair value of tranche assets and liabilities | - | - | - | (1,313) |
| Change in fair value of warrant liability | - | (64) | 335 | 781 |
| Loss on extinguishment of debt | - | - | (607) | - |
| Other income | 3 | 42 | 98 | 177 |
| Bargain purchase gain | 27,663 | | 27,663 | - |
| Total other income (expense), net | 25,937 | (1,494) | 20,020 | (4,731) |
| **Net loss** | $ (18,780) | $ (22,382) | $ (58,916) | $ (73,932) |
| Accretion of convertible preferred stock dividends | (2,098) | (5,334) | (19,259) | (21,117) |
| **Net loss available to common shareholders** | $ (20,878) | $ (27,716) | $ (78,175) | $ (95,049) |
| Basic and diluted net loss per share | $ (1.48) | $ (1,186.17) | $ (21.86) | $ (4,119.67) |
| Basic and diluted weighted-average shares outstanding | 14,105 | 23 | 3,577 | 23 |

## For More Information:


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