Momenta Pharmaceuticals Reports Fourth Quarter and Year End 2017 Financial Results and Provides Corporate Update

February 21, 2018

--Ended 2017 with a healthy cash position of $380M --

--Recently announced FDA approval and launch of Glatopa® 40 mg--

CAMBRIDGE, Mass., Feb. 21, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the fourth quarter and year ended December 31, 2017 and provided a corporate update.

“In 2017 we made important progress, despite facing delays and challenges, and we are beginning to see the fruits of our diligent work pay off. With the recent approval and launch of Glatopa 40 mg, the significant advancements we've made across our novel drug portfolio, and the furthering of both M923, our biosimilar HUMIRA® candidate, and M710, our biosimilar EYLEA® candidate in collaboration with Mylan, we are well-positioned for a positive year ahead,” said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals.

Wheeler continued, “Operationally, with Sandoz’s launch of Glatopa 40 mg we should gain more clarity on this product’s future revenue potential. The Glatopa 40 mg delay and the entry of another generic COPAXONE® 20 mg and 40 mg in 2017, however, has impacted our long-term ability to fund our broad and advancing product pipeline. We initiated a strategic review of our current business to proactively address this challenge, including the potential for new partnerships across our portfolio, additional cost reduction strategies, and the sale of certain assets. Momenta remains focused on maximizing shareholder value and I look forward to updating you on our progress.”

Fourth Quarter Highlights and Recent Events

Complex Generics:

Glatopa® 40 mg: a fully substitutable, AP-rated generic version of three-times-a-week COPAXONE 40 mg for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- On February 13, 2018, Momenta announced that the FDA had approved Sandoz's Abbreviated New Drug Application for Glatopa 40 mg and that Sandoz initiated the launch of the product in the US.

Glatopa® 20 mg: First FDA-approved, substitutable generic daily COPAXONE® 20 mg (glatiramer acetate injection) for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- In the fourth quarter of 2017, Momenta recorded $13.0 million in product revenues from Sandoz’s sales of Glatopa 20 mg, reflecting $13.6 million in profit share, net a deduction of $0.6 million in reimbursement to Sandoz for the Company's share of Glatopa-related legal expenses.

Enoxaparin Sodium Injection: First FDA-approved, substitutable generic LOVENOX® (Enoxaparin Sodium Injection) used for the prevention and treatment of deep vein thrombosis developed in collaboration with Sandoz

- On February 7, 2018, the U.S. District Court of Massachusetts issued its decision in the Company’s patent litigation against Amphastar involving U.S. Patent No. 7,575,886, covering methods for the manufacturing control of generic LOVENOX. In July 2017, the jury in this case issued its verdict finding that the Company’s ‘886 patent was infringed by two separate methods used by Amphastar, but invalid for lack of written description and enablement. The jury also provided the court with an advisory verdict recommending that the court find the patent unenforceable by the Company against Amphastar for both of their infringing methods. This recent court decision narrows the advisory verdict finding the patent to be unenforceable against only one of the two infringing methods used by Amphastar. The Company is evaluating its plans for appeal.
- In the fourth quarter of 2017, Momenta recorded $0.3 million in product revenue on Sandoz's sales of Enoxaparin Sodium Injection.

Biosimilars:

M923: a fully-owned proposed biosimilar to HUMIRA® (adalimumab)

- In January 2018, the Company announced that the Biologics License Application (BLA) for M923 is prepared to be filed with the FDA. At this time, the timing of Momenta's filing of the BLA is dependent on the identification of a collaboration partner for M923.

M834: a proposed biosimilar to ORENCIA® (abatacept) being developed in collaboration with Mylan

- In November 2017, Momenta announced that M834 did not meet its primary pharmacokinetic endpoints in a Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834 to US- and EU-sourced ORENCIA in normal healthy volunteers. Momenta and Mylan continue to investigate these results in order to determine the next steps for the program.

M710: a proposed biosimilar to EYLEA® (aflibercept) candidate being developed in collaboration with Mylan

- In January 2018, Momenta and Mylan disclosed that M710 is a proposed biosimilar to EYLEA.
- An Investigational New Drug (IND) application has been accepted and the companies plan to initiate a pivotal clinical trial in patients in the first half of 2018.

Novel Drugs for Autoimmune Indications:

M281 (anti-FcRn): a fully human anti-neonatal Fc receptor (FcRn) aglycosylated immunoglobulin G (IgG1) monoclonal antibody (mAb)

- In January 2018, the Company reported positive top-line data showing safety, tolerability and proof of mechanism for M281 in a phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study of normal human volunteers. Over the 98-day MAD study, M281 exhibited no serious adverse events, was well tolerated, and decreased circulating IgG levels up to 89% with a mean reduction of 84%.
- Momenta is finalizing its development strategy for M281 and is planning to initiate a proof of concept clinical trial in the second half of 2018, pending regulatory feedback.

M230 (CSL730): a recombinant Fc multimer being developed in collaboration with CSL

- In late January 2018, CSL began dosing subjects in the Phase 1 trial in healthy volunteers to evaluate the safety and tolerability of M230. The Phase 1 study is expected to be completed within one year.

M254 (hsIVIg): a hyper-sialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg) to remediate limitations of that therapeutic approach

- The Company began an IND-enabling toxicology study in the fourth quarter of 2017 and is targeting the initiation of a clinical trial in the second half of 2018.

Fourth Quarter and Year End 2017 Financial Results

Revenue: In the fourth quarter of 2017, the Company recorded $13.0 million in product revenues from Sandoz's sales of Glatopa 20 mg reflecting $13.6 million in profit share, net a deduction of $0.6 million in reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $15.8 million for the same period in 2016, reflecting $19.4 million in profit share, net a deduction of $3.6 million in reimbursement to Sandoz for the Company's share of Glatopa-related legal expenses. For the year ended December 31, 2017, the Company recorded $66.5 million in product revenues from Sandoz's sales of Glatopa 20 mg reflecting $68.2 million in profit share, net a deduction of $1.7 million in reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses, compared to $74.6 million for the same period in 2016, reflecting $78.1 million in profit share, net a deduction of $3.5 million in reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses. The decreases in product revenues of $2.8 million, or 18%, and $8.1 million, or 11%, from the fourth quarter of 2016 to the fourth quarter of 2017, and from the year ended 2016 to the year ended 2017, respectively, were primarily due to higher sales deductions for Medicaid rebates and lower net sales from price adjustments relating to Mylan's entry into the COPAXONE market. In addition, under the terms of the collaboration agreement with Sandoz, a $10.0 million commercial milestone payment Momenta earned from Sandoz in July 2017 was deducted from net profit prior to the calculation of Momenta's 50% profit share for the year ended 2017.

Research and development revenue for the fourth quarter of 2017 was $51.2 million compared to $18.4 million recorded in the same quarter last year. The increase in research and development revenue of $32.8 million, or 178%, was primarily due to revenue recognition of the $50.0 million upfront payment from CSL in the fourth quarter of 2017, partially offset by revenue of $14.6 million in the fourth quarter of 2016 representing the remaining balance of the upfront and license payments from Baxalta as the Company had no further performance obligations under that collaboration agreement as of December 31, 2016. For the year ended December 31, 2017, research and development revenue was $72.1 million compared to $35.0 million recorded in the same period in 2016. The increase in research and development revenue of $37.1 million, or 106%, resulted from revenue recognition of the $50.0 million upfront payment from CSL and the $10.0 million commercial milestone payment the Company earned on July 1, 2017 in connection with Glatopa 20 mg being the sole FDA-approved generic of COPAXONE at the time and achieving a certain level of contractually defined profits in the United States. These increases were partially offset by revenue of $22.0 million in the 2016 period representing the remaining balance of deferred revenue from Baxalta.

Total revenues for the fourth quarter of 2017 were $64.6 million compared to $34.2 million for the same period in 2016. For the year ended December 31, 2017, total revenues were $138.9 million compared to $109.6 million for the same period in 2016.

Operating Expenses: Total GAAP operating expenses were $52.0 million in the fourth quarter of 2017. For the year ended December 31, 2017, total GAAP operating expenses were $231.4 million.

Research and development expenses for the fourth quarter of 2017 were $36.1 million, compared to $26.4 million for the same period in 2016. The increase of $9.7 million, or 37%, was primarily due to increased spending on the Company's biosimilars programs, of which $5.1 million was related to M923 development activities for which Momenta was responsible effective December 31, 2016. For the year ended December 31, 2017, research and development expenses were $149.2 million, compared to $119.9 million for the same period in 2016. The increase of $29.3 million, or 24%, was due to increased spending on the Company's biosimilars programs of $45.1 million, of which $37.9 million related to M923. These increases were partially offset by decreases in spend of $14.9 million on the Company's novel therapeutic programs, of which $8.4 million was related to the necuparanib program, which the Company discontinued in August 2016, and $5.4 million was related to M230, as those costs became shared with CSL effective August 2017. Other decreases include the reversal of previously recognized share-based compensation expense associated with performance-based stock awards.

General and administrative expenses for the fourth quarter of 2017 were $15.8 million, compared with $18.2 million for the same period in 2016. The decrease of $2.4 million, or 13%, was primarily driven by lower share-based compensation expense mainly associated with performance-based restricted stock awards. For the year ended December 31, 2017, general and administrative expenses were $82.2 million, compared to $64.5 million for the same period in 2016. The increase of $17.7 million, or 27%, was driven by $15.5 million of legal costs primarily relating to the Company's ongoing litigation.

Fourth quarter non-GAAP operating expense was $51.6 million, within the range of previously provided guidance of $43 - $53 million. Full year 2017 non-GAAP operating expense was $208.2 million. Non-GAAP operating expense is total operating expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense and collaborative reimbursement revenues. See "Non-GAAP Financial Information and Other Disclosures" and the table below entitled "Reconciliation of GAAP Results to Non-GAAP Financial Measures" for a reconciliation of GAAP operating expense to non-GAAP operating expense.

Net Income (Loss): The Company reported a net income of $13.8 million, or $0.18 per share for the fourth quarter of 2017 compared to a net income of $41.5 million, or $0.60 per share for the same period in 2016. Net income in the 2017 period was driven by the recognition of the $50.0 million upfront payment from CSL as revenue. Net income in the 2016 period includes the one-time asset return payment of $51.2 million from Baxalta for the early termination of the M923 collaboration. For the year ended December 31, 2017, the Company reported a net loss of $(88.1) million, or $(1.20) per share compared to a net loss of $(21.0) million, or $(0.31) per share for 2016.

Cash Position: At December 31, 2017, Momenta had $379.9 million in cash, cash equivalents and marketable securities compared to $423.1 million at September 30, 2017.

2018 Financial Guidance

Momenta provides non-GAAP operating expense guidance, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP financial measures. Refer to the section of this press release below entitled “Non-GAAP Financial Information and Other Disclosures” for further discussion of this subject.

Non-GAAP operating expense is total operating expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense and collaborative reimbursement revenues. Today, Momenta is providing non-GAAP operating expense guidance of approximately $180 - $220 million for 2018 and $45 - $55 million for the first quarter of 2018. The Company expects to continue to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. The Company also estimates that collaborative reimbursement revenues will be approximately $0 - $2 million per quarter in 2018. The Company's guidance for 2018 is subject to potential changes in operating plans with respect to the strategic review initiated in January 2018.

Non-GAAP Financial Information and Other Disclosures

Momenta uses a non-GAAP financial measure, non-GAAP operating expense, to provide operating expense guidance. Momenta believes this non-GAAP financial measure is useful to investors because it provides greater transparency regarding Momenta’s operating performance as it excludes non-cash stock compensation expense and collaborative reimbursement revenues. This non-GAAP financial measure should not be considered a substitute or an alternative to GAAP total operating expense and should not be considered a measure of Momenta’s liquidity. Instead, non-GAAP operating expense should only be used to supplement an understanding of Momenta’s operating results as reported under GAAP. Momenta has not provided GAAP reconciliation for its forward-looking non-GAAP annual or quarterly operating expense because Momenta cannot reliably predict without unreasonable efforts the timing or amount of the factors that substantially contribute to the projection of stock compensation expense, which is excluded from the forward-looking non-GAAP financial measure. The Company has provided the estimated reconciling information that is available without unreasonable effort in the section of this press release above entitled “2018 Financial Guidance.”

Conference Call Information

Management will host a conference call and webcast today at 10:00 am ET to discuss these results and provide an update on the Company. A live webcast of the conference call may be accessed on the “Investors” section of the Company’s website, www.momentapharma.com. Please go to the site at least 15 minutes prior to the call in order to register, download, and install any necessary software. An archived version of the webcast will be posted on the Momenta website approximately two hours after the call.

To access the call you may also dial (877) 224-9084 (domestic) or (720) 545-0022 (international) prior to the scheduled conference call time and provide the access code 6799797. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through 6799797. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 6799797.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for autoimmune indications.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press

release.

Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

Forward Looking Statements

Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements about the timing of our regulatory filings for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates; development timelines, including next steps for M834; the Company's ability to meet its development and strategic goals; market potential and product revenues of our products and product candidates, including the potential future revenue from Glatopa 40 mg profits; our strategic review; timing of clinical trials and the timing, availability and announcement of data and results; future legal proceedings; the CSL cost and profit sharing arrangement; expectations regarding accounting treatment for and recognition of consideration and revenues under the Company's collaborations; reconciling information; non-GAAP operating expense guidance; and anticipated collaborative reimbursement revenues. Forward-looking statements may be identified by words and phrases such as "advance," "anticipate," 'being developed," "believe," "continue," "expect," "guidance," "look forward to," "may," "plan," "possible," "potential," "progress," "propose," "remains," "target," "will," "working toward" and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this press release as of this date and assumes no obligations to update the information included in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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MOMENTA PHARMACEUTICALS, INC.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	379,890	353,151
Collaboration receivable	15,048	70,242
Restricted cash	23,032	21,761
Other assets	41,461	32,583
Total assets	$ 459,431	$ 477,737
Liabilities and Stockholders' Equity		
Current liabilities	44,487	70,676
Deferred revenue, net of current portion	30,751	31,360
Other long-term liabilities	10,039	3,793
Stockholder's equity	374,154	371,908
Total liabilities and stockholders' equity	$ 459,431	$ 477,737

MOMENTA PHARMACEUTICALS, INC.
Unaudited Condensed Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Collaboration revenues:				
Product revenue	$ 13,369	$ 15,817	$ 66,803	$ 74,648
Research and development revenue	51,239	18,378	72,079	34,971
Total collaboration revenue	64,608	34,195	138,882	109,619

Operating expenses:

Research and development	36,148	26,382	149,226	119,880
General and administrative	15,827	18,165	82,207	64,466
Total operating expenses	51,975	44,547	231,433	184,346
Income (loss) from operations	12,633	(10,352)	(92,551)	(74,727)
Other income, net	1,126	51,891	4,455	53,724
Net income (loss)	$ 13,759	$ 41,539	$ (88,096)	$ (21,003)
Net income (loss) per share:				
Basic	$ 0.18	$ 0.60	$ (1.20)	$ (0.31)
Diluted	$ 0.18	$ 0.60	$ (1.20)	$ (0.31)
Shares used in calculating net income (loss) per share				
Basic	74,770	69,003	73,136	68,656
Diluted	75,033	69,362	73,136	68,656
Comprehensive income (loss)	$ 13,572	$ 41,375	$ (88,322)	$ (20,921)

MOMENTA PHARMACEUTICALS, INC.

Reconciliation of GAAP Results to Non-GAAP Financial Measures

(In thousands)

(unaudited)

A reconciliation of historical GAAP operating expenses to Non-GAAP operating expenses is as follows:

	Three Months Ended December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
GAAP operating expenses	$ 51,975	$ 44,547	$ 231,433	$ 184,346
Adjustments:				
Non-cash stock compensation expense	183	(3,566)	(16,127)	(18,322)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(523)	(1,961)	(7,064)	(6,620)
Non-GAAP operating expenses	$ 51,635	$ 39,020	$ 208,242	$ 159,404

Primary Logo

Source: Momenta Pharmaceuticals, Inc.