Momenta Pharmaceuticals Reports Second Quarter 2019 Financial and Operating Results

August 2, 2019

— Launches adaptive Phase 2/3 study of nipocalimab (M281) in Warm Autoimmune Hemolytic Anemia (wAIHA), the Company's third study of its FcRn inhibitor; top-line data expected by end of 2021 —

— Company receives FDA Fast Track Designation for nipocalimab in wAIHA and HDFN —

CAMBRIDGE, Mass., Aug. 02, 2019 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), a biotechnology company focused on discovering and developing novel biologic therapeutics to treat rare immune-mediated diseases, today reported its financial results for the second quarter ended June 30, 2019.

"At Momenta, we are focused on leveraging our team's expertise in the engineering of biologics and our deep understanding of immune biology to develop treatments for rare immune-mediated disorders," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We are committed to rapidly advancing our expanding clinical pipeline with the recent launch of our third clinical study of nipocalimab in Warm Autoimmune Hemolytic Anemia, and continued progress in our ongoing trials. Over the next 12-15 months, we anticipate key readouts from our clinical candidates, including top-line data in 2020 from our Phase 2 studies of nipocalimab in generalized myasthenia gravis and M254 in Immune Thrombocytopenic Purpura."

"In connection with the recent Amphastar settlement and our contractual obligations to GSK, we incurred one-time operating expenses in the second quarter. Importantly, as these charges are also connected with long-term cost-savings, these charges do not impact our forecasted cash runway and we continue to expect our available funds will take us beyond our clinical read outs in 2020," said Michelle Robertson, Chief Financial Officer at Momenta Pharmaceuticals.

Second Quarter 2019 Highlights, Recent Events and Anticipated Upcoming Milestones

Novel Therapeutics Pipeline:

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

- The Company recently announced that it commenced an adaptive Phase 2/3 clinical study of nipocalimab in Warm Autoimmune Hemolytic Anemia (wAIHA). This followed acceptance of its Investigational New Drug (IND) application and the granting of Fast Track designation in this indication by the U.S. Food and Drug Administration (FDA). Clinical sites are currently being activated and patient recruitment is underway. The Company expects to report top-line data from this study by the end of 2021.

- Vivacity-MG, the Company's Phase 2 clinical study of nipocalimab in generalized myasthenia gravis (gMG), continues to open sites and enroll patients and the Company expects to report top-line data in the second or third quarter of 2020.

- Unity, the Company's global multi-center Phase 2 clinical study of nipocalimab in hemolytic disease of the fetus and newborn (HDFN), continues to open sites and enroll patients and the Company expects to report top-line data in 2021. Nipocalimab has been granted Fast Track designation by the FDA for this indication.

- In the second quarter 2019, the Company completed an infusion study of nipocalimab, supporting improved infusion rates versus the current two-hour protocol, and confirmed the safety profile observed in the Phase 1 study. Infusion rates as low as 7.5 minutes for 30 mg/kg dose or 15 minutes for 60 mg/kg dose were well tolerated.

M254 (hsIgG): a hypersialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg)

- The Company's Phase 1/2 clinical trial in idiopathic thrombocytopenic purpura (ITP) is progressing. The multi-part study has completed Part A, which evaluated M254 in a single ascending dose (SAD) cohort of healthy volunteers, and has advanced into Part B, which will evaluate M254 in a SAD cohort of ITP patients. Parts C and D include a randomized cross-over study comparing M254 to IVIg and a multiple ascending dose (MAD) study of M254, respectively. Enrollment for this trial is ongoing and the Company expects to report preliminary data from this study in the first half of 2020.

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

- A Phase 1 clinical trial to evaluate the safety and tolerability of M230 in healthy volunteers is ongoing and Momenta's partner, CSL is exploring the use of a subcutaneous formulation, which is expected to extend Phase 1.

Legacy Products:

Glatopa® 20 mg and 40 mg: FDA approved generic versions of COPAXONE 20 mg and 40 mg, developed and commercialized in collaboration with Sandoz

- In the second quarter of 2019, Momenta recorded $3.3 million in product revenue from Sandoz's sales of Glatopa products.

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

- Today, Momenta announced the Company will cease active development of M923 at this time, due to changes in the market opportunity associated with Humira patent litigation settlements.

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

- Mylan continues its pivotal clinical trial in patients with diabetic macular edema to compare safety, efficacy and immunogenicity of M710 with EYLEA.

Corporate:

- In June 2019, Momenta and Sandoz reached a settlement agreement with Amphastar, resolving all pending litigation between the parties related to Enoxaparin sodium injection, an FDA-approved, substitutable generic LOVENOX, which Momenta developed in collaboration with Sandoz. As a result of the settlement, the Company paid Amphastar $21.0 million at the end of the second quarter and expects to recover its $36.1 million bond in the third quarter 2019.

- In July 2019, Momenta entered into an amendment to its office and laboratory space lease at 320 Bent Street in Cambridge, Massachusetts, reducing the Company's footprint at the location. The Company will incur a $3.1 million termination fee in the third quarter 2019 and will reduce its remaining lease payments through February 2027 by approximately $62.7 million.

Second Quarter 2019 Financial Results

Revenue:

In the second quarter of 2019, the Company recorded $3.3 million in product revenue from Sandoz's sales of Glatopa, net of a deduction of $0.3 million for legal fees. In the second quarter of 2018, the Company recorded $11.8 million in product revenue, net a deduction of $0.2 million for legal fees. The decrease in product revenue from the prior year period was primarily due to continued competition.

Research and development revenue for the second quarter of 2019 was $1.8 million, compared to $1.3 million in the same quarter in 2018. The increase in research and development revenue of $0.6 million, or 48%, was primarily due to higher revenue recognized on the collaborative upfront payment from Mylan of $1.0 million, offset in part by lower reimbursement revenue for Glatopa expenses of $0.4 million.

Total revenue for the second quarter of 2019 was $5.2 million compared to $13.0 million for the same period in 2018.

Operating Expenses:

Research and development expenses for the second quarter of 2019 were $32.1 million, compared to $31.3 million for the same period in 2018. The decrease of $0.8 million, or 3%, was primarily due to lower personnel costs following the Company's workforce reduction in the fourth quarter of 2018 and lower lease costs, offset by increased costs related to Momenta's nipocalimab and M254 clinical trials.

General and administrative expenses for the second quarter of 2019 were $46.6 million, compared with $22.5 million for the same period in 2018. The increase of $24.1 million, or 107%, was primarily due to $21.0 million paid to Amphastar in June 2019 reflecting our portion of the required settlement payment.

Other operating expenses in the second quarter of 2019 included a $42.9 million charge to be paid between the end of 2020 and 2022, related to a take-or-pay purchase obligation under Momenta's manufacturing agreement with GSK, the supplier of M923. Following the Company's decision to cease active development activity relating to M923, Momenta has incurred these charges as it has canceled its manufacturing runs scheduled through 2020 and may not use manufacturing runs scheduled for 2021 and 2022. In the second quarter of 2018, other operating expenses included $30.0 million with respect to a contract amendment to the same supply agreement with GSK.

Total GAAP operating expenses were $121.8 million in the second quarter of 2019. Second quarter 2019 non-GAAP operating expense was $117.7 million, reflecting $63.9 million in expenses associated with the Amphastar settlement and the GSK agreement. Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. 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 loss of $114.0 million, or $1.16 per share for the second quarter of 2019 compared to a net loss of $69.9 million, or $0.91 per share for the same period in 2018.

Liquidity: At June 30, 2019, Momenta had $380.2 million in cash, cash equivalents, marketable securities and restricted cash released in the third quarter 2019, compared to $449.4 million at December 31, 2018 in cash, cash equivalents, and marketable securities.

2019 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 expense, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. Momenta is providing its average quarterly non-GAAP operating expense guidance of $45 - $55 million for the remainder of 2019.

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, restructuring expense and collaborative reimbursement revenue. 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 “2019 Financial Guidance.”

Conference Call Information

Management will host a conference call and webcast today at 8:30 a.m. 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 3896218.

About Momenta

Momenta Pharmaceuticals is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases and advancing its late stage biosimilar portfolio. The company is headquartered in Cambridge, MA.

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

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; the Company’s ability to meet its development and strategic goals; market potential and revenue of our products and product candidates, design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, safety, potency, tolerability, convenience and commercial potential of our product candidates, including their potential as best-in-class agents; future legal proceedings; expectations regarding accounting treatment for and recognition of consideration and revenue under the Company’s collaborations; reconciling information; non-GAAP operating expense guidance; and anticipated collaborative reimbursement revenue. 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 March 31, 2019, 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)

	June 30, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 344,074	$ 449,411
Collaboration receivable	4,398	11,371
Restricted cash	37,898	37,898
Other assets	93,316	32,883
Total assets	$ 479,686	$ 531,563
Liabilities and Stockholders' Equity		
Current liabilities	$ 41,755	$ 51,511
Deferred revenue, net of current portion	1,112	1,774
Other long-term liabilities	124,100	17,270
Stockholder's equity	312,719	461,008
Total liabilities and stockholders' equity	$ 479,686	$ 531,563

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Statements of Operations and Comprehensive Loss

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenues:				
Product revenue	$ 3,333	$ 11,779	$ 5,685	$ 15,300
Research and development revenue	1,849	1,252	3,610	2,583
Total collaboration revenue	5,182	13,031	9,295	17,883
Operating expenses:				
Research and development	32,131	31,340	60,103	64,582
General and administrative	46,609	22,531	70,815	43,143
Other operating expense	42,936	30,000	42,936	30,000
Restructuring	132	—	158	—
Total operating expenses	121,808	83,871	174,012	137,725
Loss from operations	(116,626)	(70,840)	(164,717)	(119,842)
Other income, net	2,657	955	5,905	2,326
Net loss	$ (113,969)	$ (69,885)	$ (158,812)	$ (117,516)
Net loss per share:				
Basic and diluted	$ (1.16)	$ (0.91)	$ (1.61)	$ (1.55)
Shares used in calculating net loss per share				
Basic and diluted	98,595	76,543	98,396	76,002
Comprehensive loss	$ (113,705)	$ (69,611)	$ (158,206)	$ (117,677)

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 June 30,		Six Months Ended June 30	
	2019	2018	2019	2018
GAAP operating expenses	$ 121,808	$ 83,871	$ 174,012	$ 137,725
Adjustments:				
Restructuring	(132)	—	(158)	—
Non-cash stock compensation expense	(3,662)	(5,172)	(7,136)	(10,046)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(343)	(735)	(763)	(1,318)
Non-GAAP operating expenses	$ 117,671	$ 77,964	$ 165,955	$ 126,361

Source: Momenta Pharmaceuticals, Inc.