Eton Announces Second Quarter Financial Results and Highlights Business Progress

ET-203 NDA submitted, Three Additional Product Submissions Expected in 2019
ET-105 Acquisition Closed & Application Assigned PDUFA Date of March 17, 2020
Company to Host Conference Call and Webcast Today at 4:30p.m. ET (3:30 p.m. CT)

DEER PARK, Ill., Aug. 06, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc. (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, reported financial results for the second quarter ended June 30, 2019 and provided an update on business progress.

“We made significant progress in the second quarter expanding and advancing our portfolio of late-stage product candidates, including the acquisition of ET-105, which added an additional high-value, near-term product launch to our portfolio,” said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. “We are at an exciting inflection point as we anticipate becoming a commercial revenue generating company in the coming months. Our team is focused on preparing our commercial operations for the potential approvals of ET-202, our ready-to-use phenylephrine injection, in October of this year and ET-105, our patent-pending lamotrigine candidate, in March of 2020. We are also pleased to announce for the first time today that ET-203’s NDA has been submitted to the FDA, and if approved, could provide an additional mid-2020 product launch.”

Recent Business Milestones and Updates:

- Initiated clinical study of ET-104. In April 2019, Eton initiated a bioequivalence study for ET-104, one of the company’s patent-pending oral liquid neurology products. Eton anticipates receiving study results in the third quarter of 2019. Pending the successful completion of the study, Eton expects to submit the product’s NDA before year end.

- Acquired U.S. rights to ET-105. In June 2019, Eton acquired the U.S marketing rights to ET-105 from Aucta Pharmaceuticals. ET-105 is an innovative patent-pending formulation of lamotrigine to be delivered to patients as an oral liquid for the treatment of various forms of epilepsy. An NDA for ET-105 has been filed with the U.S Food and Drug Administration (FDA) and was assigned a PDUFA date of March 17, 2020. Lamotrigine is one of the most widely used anti-epilepsy medications with U.S sales exceeding $700 million annually but is currently only FDA-approved in tablet formulations.

- EM-100 Received Complete Response Letter from the FDA. As previously announced in July 2019, Eton’s partner, Bausch Health, received a Complete Response Letter (CRL) for EM-100. Eton believes that all of the FDA’s questions are addressable and expects Bausch Health to respond to the CRL within the coming months.

- ET-203 New Drug Application was submitted. In late July 2019, the NDA for ET-203 was submitted to the FDA. ET-203 is a ready-to-use formulation of a widely used and frequently compounded injectable product. ET-203 is expected to be complementary to Eton’s ET-202, which has been assigned a PDUFA date of October 21, 2019.

Potential Upcoming Business Milestones:

- ET-104 Clinical Results (Third Quarter 2019)
- ET-103 Clinical Results (Third Quarter 2019)
- ET-202 PDUFA Date (October 21, 2019)
- Potential ET-103 NDA Submission (Fourth Quarter 2019)
- Potential ET-104 NDA Submission (Fourth Quarter 2019)
- Potential DS-300 ANDA Submission (Fourth Quarter 2019)
- EM-100 Amendment Submission (Fourth Quarter 2019)
- ET-105 PDUFA Date (March 17, 2020)
- Potential EM-100 FDA Response (First Quarter 2020)

Pipeline Update:

Eton currently has four products submitted to the FDA and seven additional product candidates in late-stage development, three of which are expected to be submitted to the FDA before year end:

ET-104: Eton expects bioequivalence study results by September 2019. If the study is successful, Eton expects to submit an NDA for ET-104 in the fourth quarter of 2019.

DS-300: DS-300 was previously submitted to the FDA as an NDA under a Rolling Review. As previously disclosed, the FDA has requested that Eton re-file the DS-300 application as an ANDA due to the approval of a competing product with the same molecule. Eton remains in discussions with the FDA for clarity on the pathway. If the application is required to be re-filed as an ANDA, Eton expects to submit the application before year end.

ET-103: Eton expects bioequivalence study results by September 2019. If the study is successful, Eton expects to submit an NDA for ET-103 in the fourth quarter of 2019.

Product (Molecule)	Dosage Form	Category	Expected Submission Timing	Reference Product Market Size
ET-202 (Phenylephrine)	Injectable	Hospital	Submitted	$50 million +
ET-105 (Lamotrigine)	Oral Liquid	Neurology	Submitted	$700 million +
EM-100 (Ketotifen)	Ophthalmic	OTC***	Submitted	$50 million +
ET-203	Injectable	Hospital	Submitted	$90 million +
ET-104	Oral Liquid	Neurology	2019	$75 million +
DS-300	Injectable	Hospital	2019**	$75 million* +
ET-103 (Levothyroxine)	Oral Liquid	Endocrinology	2019	$2.5 billion +
DS-100	Injectable	Hospital	2020	$100 million* +
ET-101	Oral Liquid	Neurology	2020	$800 million +

ET-102	Oral Liquid	Neurology	2020	$100 million +
ET-201	Injectable	Injectable	2020	$10 million +

Note: Reference product market sizes based on IQVIA data unless noted.
*Based on management estimates
** Product was previously submitted as an NDA. The FDA has requested resubmission as an ANDA
*** Bausch Health acquired U.S Rights and will be responsible for commercialization

Second Quarter Financial Results

Revenue: Eton reported no revenue in the second quarter of 2019 and no revenue for the same period in 2018.

Research and Development (R&D) Expenses: R&D expenses were $1.4 million for the second quarter of 2019 versus $1.7 million for the same period in 2018. The decline was primarily driven by reduced product-specific development costs in the period, partially offset by increased costs associated with headcount and the operation of the company's R&D laboratory facility that was set up in late 2018.

General and Administrative (G&A) Expenses: G&A expenses were $1.9 million for the second quarter of 2019 versus $1.0 million for the same period in 2018. The increase was primarily driven by higher employee-related costs from increased headcount, public company expenses, and marketing expenses associated with product launch preparation activities. Excluding non-cash expenses, G&A expenses for the quarter were $1.5 million versus $0.6 million in the prior year period.

Net Loss: Eton reported a net loss for the second quarter of 2019 of $3.2 million versus $3.1 million for the same period of 2018.

Cash Position: As of June 30, Eton reported cash and cash equivalents of $14.9 million compared to $26.7 million as of December 31, 2018 and $19.6 million as of March 31, 2019. Subsequent to the quarter-end, in early July, Eton received a $1.3 million refund from the FDA for an NDA filing fee which had been paid in March 2019.

Conference Call and Webcast Information:
Eton Pharmaceuticals will host a conference call and webcast today at 4:30 p.m. ET (3:30 p.m. CT). To access the conference call, please dial 1-866-795-8473 (domestic) or 1-470-495-9161 (international)and refer to conference ID 4659811. The webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at https://ir.etonpharma.com. The webcast will be archived and made available for replay on the company's website approximately two hours after the call and will be available for 30 days.

About Eton Pharmaceuticals
Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently pending regulatory approval with the FDA.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Eton to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding Eton's business strategy, Eton's plans to develop and commercialize its product candidates, the safety and efficacy of Eton's product candidates, Eton's plans and expected timing with respect to regulatory filings and approvals, and the size and growth potential of the markets for Eton's product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's development programs and financial position are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Eton Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended		For the six months ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Revenue	$ —	$ —	$ 500	$ —
Operating expenses:				
Research and development	1,439	1,707	7,904	2,981
General and administrative	1,910	990	3,499	2,680
Total operating expenses	3,349	2,697	11,403	5,661
Loss from operations	(3,349)	(2,697)	(10,903)	(5,661)
Other income (expense):				

Interest and other income, net	100	28	244	57
Change in fair value of warrant liability	—	(413)	—	(496)
Loss before income tax expense	(3,249)	(3,082)	(10,659)	(6,100)
Income tax expense	—	—	—	—
Net loss	(3,249)	(3,082)	(10,659)	(6,100)
Accrued dividends on redeemable convertible preferred stock	—	(304)	—	(600)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	(418)	—	(828)
Net loss attributable to common stockholders	$ (3,249)	$ (3,804)	$ (10,659)	$ (7,528)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.79)	$ (0.61)	$ (1.80)
Weighted average number of common shares outstanding, basic and diluted	17,733	4,786	17,618	4,172

Eton Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 14,947	$ 26,735
Prepaid expenses & other current assets	1,808	767
Total current assets	16,755	27,502
Property and equipment, net	1,223	773
Operating lease right-of-use assets, net	222	—
Other long-term assets, net	44	52
Total assets	$ 18,244	$ 28,327
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 883	$ 1,421
Accrued liabilities	576	603
Total current liabilities	1,459	2,024
Operating lease liabilities, net of current portion	86	—
Total liabilities	1,545	2,024
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 17,763,045 and 17,607,928 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	18	18
Additional paid-in capital	73,208	72,153
Accumulated deficit	(56,527)	(45,868)
Total stockholders' equity	16,699	26,303
Total liabilities and stockholders' equity	$ 18,244	$ 28,327

Eton Pharmaceuticals, Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Six months ended June 30, 2019	Six months ended June 30, 2018
Cash flows from operating activities		
Net loss	$ (10,659)	$ (6,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	850	1,466
Depreciation and amortization	178	23
Change in fair value of warrant liability	—	496
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,052)	(304)
Accounts payable	(69)	329
Accrued liabilities	(211)	12
Net cash used in operating activities	(10,963)	(4,078)
Cash used in investing activities		
Purchases of property and equipment	(1,030)	(132)
Cash flows from financing activities		
Proceeds from employee stock purchase plan and stock option exercises	205	—
Net cash provided by financing activities	205	—
Change in cash and cash equivalents	(11,788)	(4,210)
Cash and cash equivalents at beginning of period	26,735	13,156
Cash and cash equivalents at end of period	$ 14,947	$ 8,946
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	$ —	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Accrued dividends on redeemable convertible preferred stock	$ —	$ 600
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	$ —	$ 828

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