

Eton Pharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results and Highlights Business Progress

NDA filing for ET-202 Accepted for Review and Assigned PDUFA Date of October 21, 2019

DEER PARK, Ill., March 25, 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 fourth quarter and full year ended December 31, 2018 and provided a business update.

"2018 was an important year in Eton's history as we made tremendous progress both clinically and operationally, including the successful completion of our IPO. The momentum has continued into 2019, as we have already executed three significant transactions this year, including Bausch Health's acquisition of EM-100, and we now have a total of four product candidates filed with the FDA," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "As we move further into 2019, we look forward to continuing with the advancement of our pipeline and preparing to become a commercial revenue company."

Business Updates:

- NDA filing for ET-202 accepted for review by FDA. The U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ET-202. The product candidate has been assigned a PDUFA target action date of October 21, 2019. Eton has begun preparing for a commercial launch internally.
- First patient dosed for ET-103 clinical study. Eton dosed the first patient in its clinical study for ET-103. Results are expected in the third quarter of 2019, and, if successful, Eton anticipates an NDA submission before year end 2019.
- Patent application filed for ET-104. A patent application was filed for ET-104, Eton's recently acquired innovative oral liquid product candidate for the treatment of a neurological condition. A clinical study of ET-104 is expected to initiate in the second quarter of 2019. If successful, Eton anticipates an NDA submission before year end 2019.
- Established Internal R&D laboratory. Eton has begun testing in its new, state of the art Research and Development (R&D) laboratory in Lake Zurich, Illinois. The addition of this facility provides Eton with internal capabilities for analytical testing activities and product development.

Fourth Quarter and Full Year 2018 Financial Results

Cash Position: As of December 31, 2018, Eton reported cash and cash equivalents of \$26.7 million compared to \$13.2 million at December 31, 2017. The increase in the company's cash position was primarily attributable to the \$22.0 million in net proceeds from the initial public offering (IPO), which closed in November 2018.

Research and Development (R&D) Expenses: R&D expenses were \$1.1 million for the fourth quarter of 2018 compared to \$0.9 million for the same period in 2017. The increase was primarily driven by increased R&D headcount and the addition of laboratory related expenses in 2018. R&D expenses for the full year 2018 were \$5.6 million compared to \$3.9 million for the full year 2017. The increase was primarily driven by increased headcount and higher product development spending in 2018 and 2017 including only a partial year since the company's inception in April 2017.

General & Administrative (G&A) Expenses: G&A expenses were \$1.2 million for the fourth quarter of 2018, compared to \$1.3 million for the same period in 2017. The decrease was primarily driven by a decline in stock-based compensation partially offset by increased employee compensation costs and public company expenses. G&A expenses for the full year 2018 were \$4.7 million, compared to \$3.2 million for the full year 2017. The increase was primarily driven by higher employee compensation expenses due to increased headcount and a full year of operations in 2018, partially offset by lower stock-based compensation expenses.

Net Loss: Eton reported a net loss for the fourth quarter of 2018 of \$3.7 million compared to a net loss of \$2.2 million for the same period of 2017. Fourth quarter 2018 results included a \$1.5 million non-cash expense due to change in fair value of warrant liability. For the full year 2018, Eton reported a net loss of \$12.7 million compared to \$7.2 million for 2017. The increase was primarily driven by higher operating expenses due to increased headcount and our expenses reflecting only a partial year for 2017. Full year 2018 results included a \$2.6 million non-cash expense due to change in fair value of warrant liability.

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.
Statements of Operations
(In thousands, except per share amounts)

	Three months ended December 31, (Unaudited)		Year ended December 31,	Period from April 27, 2017 (Inception) to December 31, 2017
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 1,102	\$ 863	\$ 5,627	\$ 3,930
General and administrative	1,184	1,333	4,694	3,220
Total operating expenses	2,286	2,196	10,321	7,150
Loss from operations	(2,286)	(2,196)	(10,321)	(7,150)
Other income (expense):				
Interest and other income, net	82	26	164	35
Change in fair value of warrant liability	(1,526)	—	(2,583)	(41)
Loss before income tax expense	(3,730)	(2,170)	(12,740)	(7,156)
Income tax expense	—	—	—	—
Net loss	(3,730)	(2,170)	(12,740)	(7,156)
Accrued dividends on redeemable convertible preferred stock	(148)	(300)	(1,048)	(643)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	(437)	(401)	(1,694)	(840)
Deemed dividends for beneficial conversion feature of redeemable convertible preferred stock	(21,747)	—	(21,747)	—
Net loss attributable to common stockholders	\$ (26,062)	\$ (2,871)	\$ (37,229)	\$ (8,639)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.24)	\$ (0.81)	\$ (5.80)	\$ (2.50)
Weighted-average number of common shares outstanding, basic and diluted	11,640	3,525	6,418	3,453

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,735	\$ 13,156
Prepaid expenses	767	136
Total current assets	27,502	13,292
Property and equipment, net	773	119
Other long-term assets, net	52	32
Total assets	\$ 28,327	\$ 13,443
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		

Accounts payable	\$ 1,421	\$ 539
Accrued liabilities	603	254
Total current liabilities	2,024	793
Warrant liability	—	520
Total liabilities	2,024	1,313
Commitments and contingencies		
Redeemable convertible preferred stock – Series A		
\$0.001 par value, 10,000,000 shares authorized as of December 31, 2018 and 2017; no shares and 6,685,082 shares issued and outstanding as of December 31, 2018 and 2017, respectively; aggregate liquidation preference of \$0 and \$20,698 as of December 31, 2018 and 2017, respectively	—	19,004
Stockholders' equity (deficit)		
Common stock, \$0.001 par value; 50,000,000 shares authorized as of December 31, 2018 and 2017; 17,607,928 and 6,000,000 shares issued and outstanding at December 31, 2018 and 2017, respectively	18	6
Additional paid-in capital	72,153	1,759
Accumulated deficit	(45,868)	(8,639)
Total stockholders' equity (deficit)	26,303	(6,874)
Total liabilities, redeemable convertible preferred stock and Stockholders' equity (deficit)	\$ 28,327	\$ 13,443

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

	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
Cash flows from operating activities		
Net loss	\$ (12,740)) \$ (7,156)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,850	1,761
Depreciation and amortization	63	13
Change in fair value of warrant liability	2,583	41
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(663)) (170)
Accounts payable	413	539
Accrued liabilities	349	254
Net cash used in operating activities	(8,145)) (4,718)
Cash used in investing activities		
Purchases of property and equipment	(236)) (130)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discounts and commissions	22,803	—
Payments of initial public offering costs	(843)) —
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	18,000
Proceeds from sale of common stock, net of issuance costs	—	4
Net cash provided by financing activities	21,960	18,004
Change in cash and cash equivalents	13,579	13,156
Cash and cash equivalents at beginning of period	13,156	—

Cash and cash equivalents at end of period	\$ 26,735	\$ 13,156
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	\$ 1,048	\$ 643
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	\$ 1,694	\$ 840
Common stock warrant liability issued with redeemable convertible preferred stock financing	\$ —	\$ 479
Purchase of equipment included in accounts payable	\$ 469	\$ —
Beneficial conversion feature on redeemable convertible preferred stock	\$ 21,747	\$ —
Reclassification of common stock warrants from liability to additional paid in capital	\$ 3,103	\$ —

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