

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2019

**Eton Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38738**  
(Commission  
File Number)

**37-1858472**  
(IRS Employer  
Identification No.)

**21925 W. Field Parkway, Suite 235**  
**Deer Park, Illinois**  
(Address of Principal Executive Offices)

**60010**  
(Zip Code)

Registrant's telephone number, including area code: **(847) 787-7361**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	ETON	NASDAQ

**Item 2.02. Results of Operations and Financial Condition**

On May 7, 2019, we issued a press release announcing our financial results for the first quarter ended March 31, 2019. A copy of the press release is attached hereto as Exhibit 99.1. The information in this Item 2.02 and the attached Exhibit 99.1 are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached exhibit shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Eton Pharmaceuticals, Inc. on May 7, 2019 relating to financial results</a>

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Eton Pharmaceuticals, Inc.**

Date: May 7, 2019

*/s/ W. Wilson Troutman*

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W. Wilson Troutman

Chief Financial Officer and Secretary

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- *Four Products Currently Under Review with the FDA* -

- *Expecting Multiple Product Launches in Second Half of 2019* -

- *Company to Host Conference Call and Webcast today at 4:30 p.m. ET (3:30 p.m. CT)* -

DEER PARK, Ill., May. 7, 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 first quarter ended March 31, 2019 and provided a business update.

“2019 is off to a great start as we began the year with a very productive first quarter. We added three late-stage product candidates to our pipeline, executed a partnership with Bausch Health for the commercialization of EM-100, and submitted the NDA for DS-200,” said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. “We remain on track to reach our goal of becoming a commercial revenue company in 2019 as we expect multiple product launches in the second half of this year. We have begun preparing for the launch of ET-202, our ready-to-use injectable formulation of phenylephrine which, if approved, could be the first and only FDA-approved ready-to-use phenylephrine product in the market.”

**First Quarter Business Milestones:**

- **Acquired rights to ET-104.** In January, Eton acquired marketing rights to ET-104, a patent-pending oral liquid product candidate for 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.
  - **Acquired rights to two late-stage hospital ready-to-use products.** In February, Eton acquired marketing rights from Sintetica SA for ET-202 and ET-203. Both products are innovative, ready-to-use injectable products administered in the hospital setting. The NDA for ET-202 has been filed with the FDA, and the NDA for ET-203 is expected to be submitted by the third quarter of 2019.
  - **Established commercialization partnership with Bausch Health for EM-100.** In February, Eton announced an agreement with Bausch Health for the commercialization of EM-100, its innovative ophthalmic solution currently under review with the FDA. If approved, EM-100 is expected to be the first and only preservative-free product that is FDA-approved for the treatment of allergic conjunctivitis.
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**Product Portfolio Update:**

<b>Product</b>	<b>Dosage Form</b>	<b>Expecting Filing Year</b>
ET-202	Injectable	Submitted
DS-300	Injectable	Submitted
DS-200	Injectable	Submitted
EM-100	Ophthalmic	Submitted
ET-203	Injectable	2019
ET-103	Oral Liquid	2019
ET-104	Oral Liquid	2019
DS-200	Injectable	2020
ET-101	Oral Liquid	2020
ET-102	Oral Liquid	2020
ET-201	Injectable	2020
CT-100	Injectable	TBD

Eton now has twelve products under various stages of development. Four of these products have been submitted to the FDA, which the company believes could be approved and launched within the next twelve months, including:

**ET-202.** During the first quarter, ET-202, Eton's ready-to-use injectable formulation of phenylephrine for increasing blood pressure in adults with clinically significant hypotension resulting primarily from vasodilation in such settings as septic shock or anesthesia, was assigned a Prescription Drug User Fee Act (PDUFA) date of October 21, 2019.

Currently, FDA-approved phenylephrine is only available in highly concentrated doses that require dilution prior to administration. As a result, phenylephrine is believed to be one of the most frequently compounded products in the hospital setting. Compounded drugs do not have to undergo FDA premarket review for safety, effectiveness and quality. Due to this lower regulatory standard, compounded drugs are at higher risk for medication error and patient safety issues. In 2018, the FDA released a 2018 Compounding Priorities Plan restricting the use of compounded drugs when an FDA-approved drug is available.

Upon ET-202's approval, hospitals will no longer need to rely on compounders for ready-to-use phenylephrine. In addition, ET-202 will align with best practice recommendations from the American Society of Hospital Pharmacists (ASHP), which recommends that hospitals use standardized concentrations, use commercially available products instead of compounded products, and dispense medications in the most ready-to-administer form available.

Eton believes ET-202 could provide significant benefits to hospitals over the current compounded or manually diluted products, including: reduced risk of dilution or compounding errors, significantly reduced waste due to improved shelf-life, reduced labor costs, and improved sterility assurance.

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According to IQVIA data, more than 7 million vials of phenylephrine concentrate were sold last year and the entire vasopressor market is estimated to be more than 25 million vials and \$650 million in sales annually.

Eton has begun preparing for commercial launch of ET-202 and, if approved on its PDUFA date, Eton plans to launch the product in the fourth quarter of 2019.

**DS-300.** DS-300 is an injectable nutrition product administered in the hospital setting. Its NDA was submitted under a Rolling Review and has not been assigned a PDUFA date.

**DS-200.** DS-200 is an injectable nutrition product administered in the hospital setting. Its NDA was submitted under a Rolling Review and has not been assigned a PDUFA date.

**EM-100.** EM-100 is Eton's preservative-free ophthalmic solution for the treatment of allergic conjunctivitis. The product is currently under review with the FDA and has been assigned a target action date of May 2019 or July 2019 depending on whether the FDA chooses to inspect EM-100's manufacturing site. Bausch Health is responsible for all commercialization activities for the product.

### **First Quarter 2019 Financial Results**

**Cash Position:** As of March 31, 2019, Eton reported cash and cash equivalents of \$19.6 million compared to \$26.7 million at December 31, 2018.

**Revenue:** Revenue was \$0.5 million in the first quarter of 2019 which resulted from the upfront payment associated with Eton's EM-100 asset sale to Bausch Health in February. Eton had no revenue in the prior year period.

**Research and Development (R&D) Expenses:** R&D expenses were \$6.5 million for the first quarter of 2019 compared to \$1.3 million for the same period in 2018. The increase was primarily driven by \$3.4 million of licensing payments to acquire the rights to ET-104, ET-202, and ET-203. In addition, Eton recognized a \$1.5 million milestone expense associated with its DS-200 NDA submission in March and incurred increased headcount and operating costs related to the start-up of its research and development laboratory.

**General & Administrative (G&A) Expenses:** G&A expenses were \$1.6 million for the first quarter of 2019, compared to \$1.7 million for the same period in 2018. The decrease was primarily driven by a decline in stock-based compensation partially offset by increased employee compensation costs for staff additions and public company expenses.

**Net Loss:** Eton reported a net loss for the first quarter of 2019 of \$7.4 million compared to a net loss of \$3.0 million for the same period of 2018. The increase in the loss was primarily driven by higher R&D expenses for licensing fees and milestone expenses combined with increased headcount and operating costs related to the start-up of its research and development laboratory, partially offset by lower stock-based compensation expenses.

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**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 2165318. The webcast can be accessed under “Events & Presentations” in the Investors section of the Company’s website at <https://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.

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

	For the three months ended March 31, 2019	For the three months ended March 31, 2018
<b>Revenues</b>	<b>\$ 500</b>	<b>\$ —</b>
<b>Operating expenses:</b>		
Research and development	6,465	1,274
General and administrative	1,589	1,690
<b>Total operating expenses</b>	<b>8,054</b>	<b>2,964</b>
<b>Loss from operations</b>	<b>(7,554)</b>	<b>(2,964)</b>
<b>Other income (expense):</b>		
Interest and other income, net	144	29
Change in fair value of warrant liability	—	(83)
<b>Loss before income tax expense</b>	<b>(7,410)</b>	<b>(3,018)</b>
Income tax expense	—	—
<b>Net loss</b>	<b>(7,410)</b>	<b>(3,018)</b>
Accrued dividends on redeemable convertible preferred stock	—	(296)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	(410)
<b>Net loss attributable to common stockholders</b>	<b>\$ (7,410)</b>	<b>\$ (3,724)</b>
<b>Net loss per share attributable to common stockholders, basic and diluted</b>	<b>\$ (0.42)</b>	<b>\$ (1.05)</b>
Weighted average number of common shares outstanding, basic and diluted	17,502	3,551

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

	<u>March 31, 2019</u> (unaudited)	<u>December 31, 2018</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 19,584	\$ 26,735
Prepaid expenses and other current assets	1,943	767
<b>Total current assets</b>	<b>21,527</b>	<b>27,502</b>
Property and equipment, net	1,190	773
Operating lease right-of-use assets, net	252	—
Other long-term assets, net	48	52
<b>Total assets</b>	<b>\$ 23,017</b>	<b>\$ 28,327</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 3,208	\$ 1,421
Accrued liabilities	448	603
<b>Total current liabilities</b>	<b>3,656</b>	<b>2,024</b>
Operating lease liabilities, net of current portion	119	—
<b>Total liabilities</b>	<b>3,775</b>	<b>2,024</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 17,627,928 and 17,607,928 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	18	18
Additional paid-in capital	72,502	72,153
Accumulated deficit	(53,278)	(45,868)
<b>Total stockholders' equity</b>	<b>19,242</b>	<b>26,303</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 23,017</b>	<b>\$ 28,327</b>

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

	Three months ended March 31, 2019	Three months ended March 31, 2018
<b>Cash flows from operating activities</b>		
Net loss	\$ (7,410)	\$ (3,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	345	1,050
Depreciation and amortization	55	10
Change in fair value of warrant liability	—	83
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,187)	(129)
Accounts payable	1,736	262
Accrued liabilities	(306)	(108)
<b>Net cash used in operating activities</b>	<b>(6,767)</b>	<b>(1,850)</b>
<b>Cash used in investing activities</b>		
Purchases of property and equipment	(388)	(91)
<b>Cash flows from financing activities</b>		
Proceeds from stock option exercises	4	—
<b>Net cash provided by financing activities</b>	<b>4</b>	<b>—</b>
<b>Change in cash and cash equivalents</b>	<b>(7,151)</b>	<b>(1,941)</b>
Cash and cash equivalents at beginning of period	26,735	13,156
Cash and cash equivalents at end of period	\$ 19,584	\$ 11,215
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	\$ —	\$ —
Cash paid for income taxes	\$ —	\$ —
<b>Supplemental disclosures of non-cash investing and financing activities:</b>		
Accrued dividends on redeemable convertible preferred stock	\$ —	\$ 296
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	\$ —	\$ 410
Purchases of equipment included in accounts payable	\$ 51	\$ —

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