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): March 5, 2020

Eton Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38738**	**37-1858472**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 [X]

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. [X]

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, $0.001 par value per share	ETON	NASDAQ Global Select Market

Item 2.02. Results of Operations and Financial Condition

On March 5, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Eton Pharmaceuticals, Inc. on March 5, 2020 relating to financial results

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: March 6, 2020

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Announces Fourth Quarter and Full Year 2019 Financial Results

DEER PARK, Ill., Mar. 5, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today reported financial results for the fourth quarter ended December 31, 2019 and provided an update on business progress.

“2019 was an important year for Eton. Our team achieved a number of major milestones in the advancement of our pipeline, the most significant of which was the approval and launch of Biorphen, our first commercial product,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “We are excited to transition to a commercial revenue company and we look forward to earning additional product approvals in 2020.”

Fourth Quarter Milestones

- **FDA approval and commercial Launch of Biorphen.** Biorphen, Eton’s first commercial product, was launched in December. More than 100 different institutions have already placed orders for Biorphen.
- **DS-300 ANDA filing.** In December, Eton submitted an ANDA for DS-300. The application was accepted for review and was confirmed to be the first-to-file ANDA against the innovator product. The innovator product represents an estimated market size of more than $60 million.
- **EM-100 amendment submitted.** In December, Eton’s licensing partner submitted an amendment to the EM-100 application in response to the Complete Response Letter received in July 2019. Eton believes the amendment fully addressed all issues raised by the FDA and expects EM-100 to be approved in 2020.

Biorphen Commercial Launch Update

During the fourth quarter, Eton launched Biorphen, the first and only FDA-approved ready-to-use formulation of phenylephrine injection. The product was approved in October and launched in December. Initial customer demand for the product has resulted in more than 100 different institutions purchasing the product. Customers have specifically cited Biorphen’s lack of dilution, three-year shelf-life, and FDA-approved status as significant benefits that led to their institutions’ conversion to the product.

Eton recently announced that it entered into a co-promotion arrangement with Xellia Pharmaceuticals for the promotion of Biorphen. Under the arrangement, Xellia’s existing U.S hospital-based sales force is actively promoting Biorphen to certain customer segments. Eton expects the arrangement to significantly reduce Eton’s Biorphen-related sales expenses in 2020, while also driving faster customer adoption of Biorphen due to Xellia’s existing relationships with hospitals that have adopted ready-to-use products. Xellia’s sales force was previously focused on the promotion of Vanco Ready, a ready-to-use formulation of vancomycin injection, which has the same call points and a similar value proposition to Biorphen.

Ongoing phenylephrine supply disruptions from 503B compounding facilities, including the announced shutdown of compounding industry leader PharMedium in January, have highlighted the critical need for Biorphen. During the quarter, Eton sent 503B facilities notices referencing that FDA-approved Biorphen is now commercially available and as a result, there is no longer a clinical need for compounded phenylephrine injection. Eton believes that selling compounded phenylephrine after the introduction of Biorphen is a violation of FDA regulations, and Eton is actively engaged in communications with the FDA to discuss the enforcement of the existing compounding regulations.

The overall market opportunity for ready-to-use phenylephrine is estimated to be more than 20 million units of Biorphen annually, and Eton's long-term goal is to capture at least four million units per year.

Eton has also initiated the development of line extensions to convert Biorphen into vial and pre-filled syringe container systems to address the needs and preferences of certain customer segments. The line extension products are expected to launch as early as next year.

Pipeline Update

Eton currently has eight product candidates in its late-stage pipeline, including three products under review with the FDA:

Product (Molecule)	Dosage Form	Category	Expected Submission Timing	Reference Product Market Size
EM-100 (Ketotifen)	Ophthalmic	OTC**	Submitted	$50 million +
ET-105 (Lamotrigine)	Oral Liquid	Pediatric	Submitted	$700 million +
DS-300	Injectable	Hospital	Submitted	$60 million* +
ET-104	Oral Liquid	Pediatric	2020	$65 million +
ET-103 (Levothyroxine)	Oral Liquid	Pediatric	2020	$2.5 billion +
ET-203	Injectable	Hospital	2020	$70 million +
DS-100	Injectable	Hospital	2020	$100 million* +
ET-101	Oral Liquid	Pediatric	2020	$800 million +

Note: Pipeline only includes product candidates that Eton expects to submit within twelve months.
Reference product market sizes based on IQVIA data unless noted.
*Based on management estimates
**Product will be marketed by Bausch Health

EM-100. In December, the company's licensing partner, Bausch Health, submitted an amendment to the EM-100 product application, and Eton believes the amendment fully addresses all issues raised by the FDA in the July 2019 Complete Response Letter (CRL). The amendment was classified as a major amendment and was assigned a Generic Drug User Fee Act(GDUFA) target action date in August 2020.

ET-105. As previously disclosed, Eton received comments from the FDA requesting changes to the Dosage and Administration section of the product's Prescribing Information to simplify the dosing information for intended users, and the FDA requested a human factors validation study with the revised labeling to demonstrate that the intended users can accurately prepare and administer the oral suspension. As a result, Eton expects to receive a CRL on its PDUFA date of March 17, 2020. The company has begun drafting the human factors study protocol and expects to have the study completed and resubmitted to the FDA in the second or third quarter of this year, which would allow for final approval of the NDA before year end. During the quarter, Eton's partner was granted a patent by the United States Patent and Trademark Office for ET-105's unique formulation. Eton expects the patent to be Orange Book listed after product approval.

DS-300. Eton submitted the ANDA for DS-300 in December. The application was accepted for review and assigned a GDUFA target action date in October 2020, however, anticipated Paragraph IV litigation related to the innovator's patent is likely to delay the product's final approval beyond the target action date. In February 2020, Eton amended its agreement with its licensing partner for DS-300. Eton will now be entitled to 62.5% of product profits, up from 50%, in exchange for managing the application's patent litigation.

ET-104. Eton is awaiting final FDA acceptance of its pediatric study protocol (PSP) for ET-104. The product's NDA is expected to be submitted once agreement is reached on the PSP.

ET-103. Eton is in discussions with the FDA regarding the product's bioequivalence data results to ensure compliance with FDA requirements prior to submission of the NDA. If Eton receives agreement from the FDA, it expects the product's NDA to be submitted in the first half of 2020.

ET-203. Eton's development partner, Sintetica, expects to resubmit the NDA for ET-203 in 2020. Due to ET-203's original new drug application receiving a refuse-to-file letter from the FDA, Eton received a refund of its initial $1 million licensing fee paid to Sintetica. If the product's application is resubmitted and accepted for review, Eton will repay the $1 million licensing fee.

DS-100. NDA compilation is under way and Eton expects to submit the NDA in 2020.

ET-101. The product's bioequivalence study is ongoing, and Eton is in discussions with the FDA regarding the application's Pediatric Study Plan. If successful, Eton expects to submit the product's NDA in the second half of 2020.

Fourth Quarter and Full Year 2019 Financial Results

Revenue: Revenue for the fourth quarter of 2019 was $0.5 million. Revenue included initial Biorphen stocking orders placed by wholesalers during the quarter. Eton reported no sales in the fourth quarter of 2018. Full year 2019 revenue was $1.0 million and consisted of a $0.5 million milestone payment received from Bausch Health for the acquisition of EM-100 marketing rights, as well as initial Biorphen sales. Eton reported no revenue for the full year 2018.

Cost of Product Sales: Cost of product sales for the fourth quarter of 2019 was $0.5 million. The expense consisted primarily of profit share payments made to Eton's licensing partner on Biorphen. Under terms of the licensing agreement, Eton's partner was entitled to receive the first $0.5 million of profit from commercialization of the product. Cost of product sales for the full year 2019 was $0.5 million. There was no cost of product sales associated with the $0.5 million milestone payment received from Bausch Health.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2019 totaled $0.2 million compared with $1.1 million in the fourth quarter of 2018. R&D expenses in the fourth quarter of 2019 were reduced by $1.0 million due to Eton receiving a refund of its original licensing payment for ET-203. The $1.0 million licensing payment had originally been expensed in the first quarter of 2019.

For the full year 2019, R&D expenses were $11.6 million compared to $5.6 million for the full year 2018. The increase was primarily driven by $4.0 million of total expenses for the initial licensing payments for Biorphen (ET-202) and ET-105, as well as increased headcount and operation costs associated with the company's research and development lab that was opened in late-2018.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses for the fourth quarter of 2019 were $2.4 million compared with $1.2 million in the fourth quarter of 2018. The increase was primarily due to increased sales, marketing and distribution costs associated with the commercialization of Biorphen, higher employee-related costs from increased headcount, and higher expenses associated with being a public company.

For the full year 2019, SG&A expenses were $7.6 million compared to $4.7 million for the full year 2018. The increase was primarily due to higher employee-related costs from increased headcount, increased expenses associated with being a public company, and costs associated with the commercialization of Biorphen.

Net Loss: Net loss for the fourth quarter of 2019 was $2.7 million compared with $2.3 million in the fourth quarter of 2018. The increase was driven by higher SG&A expenses, partially offset by reduced R&D expenses.

For the full year 2019, net loss was $18.3 million compared with $12.7 million for the full year 2018. The increased loss was driven by increased SG&A and R&D expenses in 2019.

Cash Position: As of December 31, 2019, Eton reported cash and cash equivalents of $12.1 million.

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 5119269. 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, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and pediatric oral liquid products. The company’s first commercial product, Biorphen, is the only FDA approved ready-to-use formulation of phenylephrine injection and was launched in December 2019. The company has an additional eight products under development, including three that are under review 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)		For the years ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales	$ 459	$ —	$ 459	$ —
Licensing revenue	—	—	500	—
Total revenues	459	—	959	—
Cost of product sales	453	—	453	—
Gross Profit	6	—	506	—
Operating expenses:				
Research and development	233	1,102	11,555	5,627
General and administrative	2,429	1,184	7,552	4,694
Total operating expenses	**2,662**	**2,286**	**19,107**	**10,321**
Loss from operations	**(2,656)**	**(2,286)**	**(18,601)**	**(10,321)**
Other income (expense):				
Interest and other income (expense), net	(40)	82	281	164
Change in fair value of warrant liability	—	(1,526)	—	(2,583)
Loss before income tax expense	**(2,696)**	**(3,730)**	**(18,320)**	**(12,740)**
Income tax expense	—	—	—	—
Net loss	**(2,696)**	**(3,730)**	**(18,320)**	**(12,740)**
Accrued dividends on redeemable convertible preferred stock	—	(148)	—	(1,048)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	(437)	—	(1,694)
Deemed dividends for beneficial conversion feature of redeemable convertible preferred stock	—	(21,747)	—	(21,747)
Net loss attributable to common stockholders	**$ (2,696)**	**$ (26,062)**	**$ (18,320)**	**$ (37,229)**
Net loss per share attributable to common stockholders, basic and diluted	**$ (0.15)**	**$ (2.24)**	**$ (1.03)**	**$ (5.80)**
Weighted-average number of common shares outstanding, basic and diluted	17,924	11,640	17,761	6,418

Eton Pharmaceuticals, Inc.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 12,066	$ 26,735
Accounts receivables, net	473	—
Inventory	380	—
Prepaid expenses and other current assets	2,090	767
Total current assets	**15,009**	**27,502**
Property and equipment, net	1,117	773
Intangible assets, net	725	—
Operating lease right-of-use assets, net	160	—
Other long-term assets, net	61	52
Total assets	**$ 17,072**	**$ 28,327**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 575	$ 1,421
Accrued liabilities	1,388	603
Total current liabilities	**1,963**	**2,024**
Long-term debt, net of discount and including accrued fees	4,540	—
Operating lease liabilities, net of current portion	19	—
Total liabilities	**6,522**	**2,024**
Commitments and contingencies (Note 16)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of December 31, 2019 and 2018; 17,877,486 and 17,607,928 shares issued and outstanding at December 31, 2019 and 2018, respectively	18	18
Additional paid-in capital	74,720	72,153
Accumulated deficit	(64,188)	(45,868)
Total stockholders' equity	**10,550**	**26,303**
Total liabilities and stockholders' equity	**$ 17,072**	**$ 28,327**

Eton Pharmaceuticals, Inc.
STATEMENTS OF CASH FLOWS
(In thousands)

	For the years ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (18,320)	$ (12,740)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,888	1,850
Depreciation and amortization	447	63
Debt discount amortization	16	—
Change in fair value of warrant liability	—	2,583
Changes in operating assets and liabilities:		
Accounts receivable	(473)	—
Inventory	(380)	—
Prepaid expenses and other assets	(1,361)	(663)
Accounts payable	(377)	413
Accrued liabilities	534	349
Net cash used in operating activities	**(18,026)**	**(8,145)**
Cash used in investing activities		
Purchases of property and equipment	(1,096)	(236)
Purchase of product licensing rights	(750)	—
Net cash used in investing activities	**(1,846)**	**(236)**
Cash flows from financing activities		
Proceeds from issuance of long-term debt, net of issuance costs	4,750	—
Proceeds from initial public offering, net of underwriting discounts and commissions	—	22,803
Payments of initial public offering costs	—	(843)
Proceeds from employee stock purchase plan and stock option exercises	453	—
Net Cash provided by financing activities	**5,203**	**21,960**
Change in cash and cash equivalents	**(14,669)**	**13,579**
Cash and cash equivalents at beginning of period	26,735	13,156
Cash and cash equivalents at end of period	$ 12,066	$ 26,735
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	$ —	$ —

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