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): August 12, 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 Market

Item 2.02. Results of Operations and Financial Condition

On August 12, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2020. 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 August 12, 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: August 12, 2020

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Announces Second Quarter 2020 Financial Results

DEER PARK, Ill., Aug 12, 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 second quarter ended June 30, 2020 and provided an update on business progress.

“Recent weeks have been the most productive in our company’s history. We submitted two NDAs, including one with orphan designation, and we made significant progress preparing for our expected launch of Alkindi Sprinkle,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “In the coming months, we expect to complete two more NDA submissions and continue working towards building an industry leading multi-product commercial organization. With our pipeline, we expect to launch as many as six branded products before the end of 2021, which I believe is unrivaled by any pharmaceutical company of our size,” Brynjelsen added.

Recent Milestones

- **Submission of Orphan Drug DS-100 (Dehydrated Alcohol Injection).** In July, Eton submitted an NDA for DS-100. The product has been granted orphan drug designation for the treatment of methanol poisoning. The incidence of methanol poisoning has increased significantly in 2020 due to COVID-19, as unprecedented demand for hand sanitizers has led some manufacturers to improperly use methanol in their products. The U.S. Food and Drug Administration (FDA) has in fact recommended manufacturers recall more than 100 different hand sanitizers that were found to contain methanol despite being labeled as ethanol.

- **Submission of ET-104 (Zonisamide Oral Suspension).** Eton’s patent-pending liquid formulation of zonisamide was submitted to the FDA for the treatment or partial seizures. ET-104 is one of three neurology-focused liquid products that Eton expects to launch in 2021

- **Increased Credit Facility.** Eton was able to amend and increase its existing credit facility with SWK Holdings. Under the new terms, the facility will increase from $10 million to $15 million upon FDA approval of Alkindi Sprinkle, and the interest rate will decrease when Eton achieves certain performance metrics in the future.

EM-100 Update

Eton was notified by its partner that due to a proprietary name change submission, the FDA has extended EM-100’s goal date to September 15th. The company is not aware of any deficiencies besides this labeling-related item and remains confident that the product will be approved shortly.

Alkindi® Sprinkle Update

Alkindi Sprinkle’s NDA is under review by the FDA for use as a replacement therapy for pediatric adrenal insufficiency. Eton and its development partner have been engaged in regular communication with the FDA, and Eton expects the FDA to meet the existing September 29, 2020 Prescription Drug User Fee Act (PDUFA) date without any disruption from COVID-19. Based on the communications received during the application’s ongoing review, Eton remains confident that the Alkindi Sprinkle application is approvable and is working aggressively on launch preparation activities. Eton has purchased initial commercial inventory and expects to be in position to launch the product shortly after the PDUFA date, if approved.

Biorphen Commercial Update

Biorphen sales continue to be impacted by COVID-19. While surgical procedure volumes have rebounded from March and April lows, hospital policies continue to restrict sales representatives from visiting with pharmacy directors and hospital staff. Eton plans to implement new targeting strategies and promotional campaigns in the third quarter that are expected to drive stronger sales in the second half of 2020.

Eton remains confident that there is strong demand for Biorphen in a vial presentation based on significant customer feedback. The company is on pace to submit a Prior Approval Supplement (PAS) for the vial conversion later this year, which should allow for a commercial launch of the vial in early 2021. Eton expects the vial product launch to significantly accelerate Biorphen adoption and help the company achieve its long-term goal of capturing 4 million of the estimated more than 20-million-unit market for ready-to-use phenylephrine injection.

Credit Agreement.

On August 11th, the company's existing credit facility with SWK Holdings was amended to provide Eton with the option to access additional capital and reduce the facility's interest rate. The facility will increase by $5 million to $15 million upon the FDA approval of Alkindi Sprinkle. Upon execution of the amendment, Eton agreed to draw an additional $2 million. In addition, the facility's interest rate will be reduced in the future when certain performance metrics are achieved. The facility reductions will be: 75 basis points when Eton receives approval for its next product and achieves quarterly revenue of $2.0 million; 150 basis points when Eton receives approval for two additional products and achieves quarterly revenue of $2.5 million; and a 225 basis point reduction when the company is EBITDA positive.

Pipeline Update

Eton now has six product candidates submitted to the FDA, and two additional product candidates that are expected to be submitted before the end of 2020.

Product	FDA Application Status	Details
Biorphen®	Approved	Commercial
EM-100 (Ketotifen Ophthalmic Soln.)	Submitted	T.A.D Sept 15, 2020
Alkindi® Sprinkle	Submitted	PDUFA Date: Sept 29, 2020
DS-100 (Dehydrated Alcohol Inj.)	Submitted	PDUFA date not yet assigned
ET-105 (Lamotrigine Oral Susp.)	Submitted	CRL response ongoing
ET-104 (Zonisamide Oral Susp.)	Submitted	PDUFA date not yet assigned
DS-300 (Cysteine Inj.)	Submitted	GDUFA Date: Oct 2020*
ET-101 (Topiramate Oral Soln.)	Submission Expected in 2020	
ET-203 (Ephedrine Inj.)	Submission Expected in 2020	

*Potential tentative approval. Final approval expected to be delayed due to ongoing Paragraph IV litigation

ET-105 (Lamotrigine for Oral Suspension). Eton and its development partner, Aucta Pharmaceuticals, are working to resolve the Complete Response Letter received in March 2020. During the second quarter, the FDA agreed to the protocol for the required human factors study. Study participant enrollment has been impacted by COVID-19, however, the company still believes the study results can submitted to the FDA before the end of 2020.

ET-101 (Topiramate Oral Solution). Eton remains on track to submit the product's NDA before year end.

ET-203 (Ephedrine Injection). Eton's partner expects to file the product's NDA before year end.

Financial Update

Revenue: Revenue was approximately $20,000 in the second quarter of 2020, which was from sales of Biorphen. As previously discussed, Eton's second quarter Biorphen sales were adversely impacted by the COVID-19 pandemic. Eton records sales for Biorphen when the product is shipped to wholesalers and distributors. As a result, reported revenue is not always aligned with end-user demand within a given period due to changes in inventory in this distribution channel. End-user demand for Biorphen exceeded Eton's reported sales in the second quarter of 2020 due to large stocking orders placed by wholesalers in the fourth quarter of 2019. Eton did not have any revenue in the second quarter of 2019.

Research and Development (R&D) Expenses: R&D expenses were $1.6 million for the second quarter of 2020 compared to $1.4 million for the same period in 2019.

General& Administrative (G&A) Expenses: G&A expenses were $2.9 million for the second quarter of 2020 compared to $1.9 million for the same period in 2019. The increase was primarily driven by legal expenses related to Eton's first-to-file paragraph IV patent challenge for its DS-300 product candidate and higher marketing and distribution expenses.

Net Loss: Eton reported a net loss for the second quarter of 2020 of $4.7 million compared to a net loss of $3.2 million for the same period of 2019.

Cash Position: As of June 30, 2020, Eton reported cash and cash equivalents of $10.3 million. On August 11, 2020 Eton executed an amendment to its credit facility with SWK Holdings which will add $5.0 million of additional capacity upon FDA approval of Alkindi Sprinkle. Upon closing of the amendment, Eton drew down $2.0 million and will have $8.0 million of available undrawn capacity after the approval of Alkindi Sprinkle.

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 2083737. 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 rare disease 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's lead pediatric product is the orphan drug Alkindi® Sprinkle, which is currently under review with the FDA. The company has an additional seven products under development, including five 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.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended		For the six months ended	
	June 30, 2020	**June 30, 2019**	**June 30, 2020**	**June 30, 2019**
Revenues:				
Product sales	$ 20	**$ —**	$ 119	$ —
Licensing revenue	**—**	**—**	**—**	500
Total revenues	**20**	**—**	**119**	**500**
Cost of product sales	**28**	**—**	**130**	**—**
Gross (loss) profit	**(8)**	**—**	**(11)**	**500**
Operating expenses:				
Research and development	1,609	1,439	7,877	7,904
General and administrative	2,921	1,910	5,531	3,499
Total operating expenses	**4,530**	**3,349**	**13,408**	**11,403**
Loss from operations	**(4,538)**	**(3,349)**	**(13,419)**	**(10,903)**
Other (expense) income:				
Interest and other (expense) income, net	(192)	100	(360)	244
Loss before income tax expense	**(4,730)**	**(3,249)**	**(13,779)**	**(10,659)**
Income tax expense	—	—	—	—
Net Loss	**$ (4,730)**	**$ (3,249)**	**$ (13,779)**	**$ (10,659)**
Net loss per share, basic and diluted	**$ (0.23)**	**$ (0.18)**	**$ (0.70)**	**$ (0.61)**
Weighted average number of common shares outstanding, basic and diluted	21,005	17,733	19,574	17,618

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

	June 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 10,270	$ 12,066
Accounts receivable, net	—	473
Inventory	1,709	380
Prepaid expenses and other current assets	844	2,090
Total current assets	**12,823**	**15,009**
Property and equipment, net	938	1,117
Intangible assets, net	650	725
Operating lease right-of-use assets, net	96	160
Other long-term assets, net	52	61
Total assets	**$ 14,559**	**$ 17,072**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,953	$ 575
PPP loan, current portion	159	—
Accrued liabilities	627	1,388
Total current liabilities	**2,739**	**1,963**
Long-term debt, net of discount and including accrued fees	4,587	4,540
Long-term portion of PPP loan	202	—
Operating lease liabilities, net of current portion	—	19
Total liabilities	**7,528**	**6,522**
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 20,956,033 and 17,877,486 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	21	18
Additional paid-in capital	84,977	74,720
Accumulated deficit	(77,967)	(64,188)
Total stockholders' equity	**7,031**	**10,550**
Total liabilities and stockholders' equity	**$ 14,559**	**$ 17,072**

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

	Six months ended June 30, 2020	Six months ended June 30, 2019
Cash flows from operating activities		
Net loss	$ (13,779)	$ (10,659)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,079	850
Common stock issued for product candidate licensing rights	1,264	—
Depreciation and amortization	326	178
Debt discount amortization	50	—
Changes in operating assets and liabilities:		
Accounts receivable	473	—
Inventory	(1,329)	—
Prepaid expenses and other assets	1,251	(1,052)
Accounts payable	1,378	(69)
Accrued liabilities	(783)	(211)
Net cash used in operating activities	**(10,070)**	**(10,963)**
Cash used in investing activities		
Purchases of property and equipment	**(4)**	**(1,030)**
Cash flows from financing activities		
Proceeds from sales of common stock, net of offering costs	7,756	—
Proceeds from PPP loan	361	—
Proceeds from employee stock purchase plan and stock option exercises	161	205
Net cash provided by financing activities	**8,278**	**205**
Change in cash and cash equivalents	**(1,796)**	**(11,788)**
Cash and cash equivalents at beginning of period	12,066	26,735
Cash and cash equivalents at end of period	$ 10,270	$ 14,947
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 358	$ —
Cash paid for income taxes	$ —	$ —

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