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 14, 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	**60010**
(Address of Principal Executive Offices)	(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 May 14, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 14, 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: May 14, 2020

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Announces First Quarter 2020 Financial Results

DEER PARK, Ill., May 14, 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 first quarter ended March 31, 2020 and provided an update on business progress.

“The first quarter was an exciting period for Eton. We acquired marketing rights to orphan drug Alkindi Sprinkle and strengthened our balance sheet with an additional $9.8 million of liquidity,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “While COVID-19 has impacted our Biorphen commercial launch, we remain in a strong financial position and we look forward to the potential for multiple additional product launches later this year.”

First Quarter Milestones

- **Acquired U.S. marketing rights to Alkindi® Sprinkle**. Eton acquired U.S marketing rights to the product from Diurnal Group plc in March. Alkindi Sprinkle is an orphan product that is currently under review with the U.S. Food and Drug Administration (FDA) for use as a replacement therapy for pediatric adrenal insufficiency (AI), including congenital adrenal hyperplasia (CAH) in patients from birth to less than 17 years of age. The application was assigned a Prescription Drug User Fee Act (PDUFA) date of September 29, 2020.

- **Secured $9.8 million of additional liquidity.** In conjunction with the Alkindi Sprinkle transaction, Eton closed a $7.8 million equity raise, and amended its existing credit facility to grant Eton the immediate option to access $2.0 million at its discretion.

- **Announced first-to-file status on cysteine hydrochloride injection ANDA (DS-300).** During the quarter, Eton’s Abbreviate New Drug Application (ANDA) was accepted for review by the FDA. Eton was confirmed to be the first Paragraph IV ANDA filer referencing Exela Pharma Sciences’ Elcys product, which entitles Eton to 180 days of generic exclusivity upon successfully challenging the patent. In addition, Eton announced it plans to file Post Grant Reviews (PGR) with the U.S. Patent and Trademark Office (USPTO) to challenge the patents, which, if successful, could allow Eton to launch the product in 2021.

Biorphen Commercial Launch

Eton launched Biorphen, the only FDA-approved formulation of ready-to-use phenylephrine injection, in December 2019. Unfortunately, the commercial launch has been negatively impacted by the COVID-19 pandemic. Biorphen, like many hospital-based pharmaceutical products, has experienced reduced demand due to the unprecedented nationwide decline in surgical procedures.

In addition, COVID-19 has disrupted marketing and promotional activities surrounding the Biorphen launch. Hospitals across the country have enacted policies restricting in-person visits by field sales representatives, which has limited the company’s ability to market Biorphen in person to key decision-makers. Eton had also planned to introduce Biorphen to physicians and pharmacists throughout 2020 at industry conferences that have now been cancelled. In response to these marketing and promotional challenges, Eton has increased its digital promotional activities and rolled out online campaigns aimed at pharmacy directors and potential Biorphen users in intensive care units and emergency rooms.

Eton has seen a high rate of conversion from the nearly 200 unique institutions that have purchased Biorphen since launch, however, certain customer groups have stated that Biorphen’s ampule container system is the sole reason they have not converted to Biorphen despite their interest in an FDA-approved ready-to-use formulation of phenylephrine. In response to the feedback, Eton is working on a vial presentation of Biorphen. Eton believes it will be in position to launch the vial line extension in 2021, which is expected to accelerate adoption of the product.

During the quarter, Eton also held a meeting with the FDA to discuss what Eton believes to be illegal compounding of ready-to-use phenylephrine by 503B facilities. Eton believes the Federal Food, Drug, and Cosmetic Act prohibits 503B compounders from commercializing ready-to-use phenylephrine products that are essentially a copy of Biorphen. Eton also submitted a comment to the FDA requesting that phenylephrine hydrochloride for injectable products in certain concentrations not be included in the list of bulk drug substances that may be used in 503B compounding. Until the FDA makes that determination, Eton asked that the FDA not allow phenylephrine hydrochloride to be used in compounding such products. Eton believes the opportunity to discuss the issue directly with the FDA was beneficial, and the company is confident that the FDA understands the current situation in the ready-to-use phenylephrine market.

Alkindi Sprinkle Update

Eton recently announced that Paul Stickler has joined the company as Senior Vice President of Sales and Marketing to oversee the launch of Alkindi Sprinkle. Stickler joins Eton from Recordati Rare Disease, where he successfully led the sales and marketing activities of numerous orphan drug products. Eton has begun launch activities and is working closely with Diurnal Group to ensure that the product will be available for a launch in the fourth quarter of this year if it is approved on its PDUFA date of September 29, 2020.

Pipeline Update

At this time, Eton does not anticipate material disruption to its research and development or regulatory timelines due to COVID-19. Eton has continued to receive regular communications from the FDA regarding its product applications currently under review, and the company believes the FDA will be able to maintain the existing PDUFA and Target Action Dates that Eton and its partners have been assigned.

Product (Molecule)	Category	Estimated Submission Timing
Alkindi Sprinkle (hydrocortisone)	Pediatric	Filed
EM-100 (ketotifen)	Out-Licensed	Filed
ET-105 (lamotrigine)	Pediatric	Filed
DS-300 (cysteine hydrochloride)	Hospital	Filed
ET-104	Pediatric	2020
ET-101 (topiramate)	Pediatric	2020
DS-100	Hospital	2020
ET-203	Hospital	2020

EM-100 (Ketotifen PF Ophthalmic Solution). Eton believes all outstanding deficiencies were addressed in the product's December 2019 application amendment, and the company expects the product to be approved on its assigned Target Action Date of August 10, 2020.

ET-105 (Lamotrigine for Oral Suspension). The clinical study protocol for ET-105's human factor study has been submitted to the FDA. If the FDA agrees to the study protocol, Eton expects to complete the human factory study in the second quarter and submit results to the FDA in the third quarter of 2020.

DS-300 (Cysteine Hydrochloride Injection). In a press release issued last week Eton announced the first-to-file status of its cysteine hydrochloride ANDA and provided additional details on the project. Eton plans to file Post Grant Reviews later this month to challenge the validity of Exela Pharma Sciences' patents related to Elcys. If successful, the PGRs could allow Eton to launch its product as early as November 2021. Eton's ANDA was accepted for review during the quarter and was assigned a GDUFA date in October 2020.

ET-104. Eton is waiting on FDA acceptance of the proposed pediatric study protocol (PSP). The product's NDA is assembled and ready for submission upon the FDA's agreement to the PSP.

DS-100. In April, Eton terminated its previous licensing agreement for DS-100 and entered into a new licensing agreement with two unaffiliated third parties. Under terms of the new agreement, Eton is responsible for regulatory and clinical activities related to the product and the licensing partners will be responsible for manufacturing and commercial activities. The agreement does not require any licensing or milestone payments from Eton, and Eton's profit share percentage is unchanged at 50%.

ET-101 (Topiramate Oral Solution). During the quarter, Eton announced successful bioequivalence study results for ET-101. Eton expects to submit the product's NDA in the second half of 2020.

ET-103 (Levothyroxine Oral Solution). Eton has decided not to move forward with the ET-103 project due to concerns surrounding the product's bioequivalence study results. The investment that would have been required for the product's NDA filing fee and associated milestone payments will instead be reallocated to opportunities that the company believes can produce a more attractive risk adjusted returns.

ET-203. Eton's partner expects to file the product's NDA in the second half of 2020.

Financial Update

Revenue: Revenue was $0.1 million in the first quarter of 2020, which resulted from sales of Biorphen. 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. Customer demand for Biorphen exceeded Eton's reported sales in the first quarter of 2020 due to large stocking orders placed by wholesalers in the fourth quarter of 2019. As previously discussed, Biorphen sales volume was also adversely impacted by the COVID-19 pandemic. Eton's revenue of $0.5 million in the first quarter of 2019 resulted from the upfront payment associated with its EM-100 asset sale to Bausch Health in February 2019.

Research and Development (R&D) Expenses: R&D expenses were $6.3 million for the first quarter of 2020 compared to $6.5 million for the same period in 2019. R&D spending in the first quarter of 2020 included $4.8 million of one-time licensing payments to acquire the U.S. marketing rights to Alkindi Sprinkle. The first quarter of 2019 R&D spending included $3.4 million of licensing payments to acquire the rights to Biorphen, ET-203, and ET-104.

General& Administrative (G&A) Expenses: G&A expenses were $2.6 million for the first quarter of 2020, compared to $1.6 million for the same period in 2019. The increase was primarily driven by higher marketing and distribution costs for Biorphen commercialization, legal expenses associated with Eton's patent challenge against Exela Pharma Sciences' Elcys product, and higher employee compensation costs.

Net Loss: Eton reported a net loss for the first quarter of 2020 of $9.0 million compared to a net loss of $7.4 million for the same period of 2019.

Cash Position: As of March 31, 2020, Eton reported cash and cash equivalents of $12.3 million. In March, Eton announced a private placement of $7.8 million of common stock in conjunction with the Alkindi Sprinkle acquisition. $7.5 million of the stock proceeds were received in the first quarter, however, $0.3 million were received on April 2nd and were not included in the first quarter cash balance. Additionally, in May, the company received $0.4 million of proceeds from a loan through the Paycheck Protection Program under the Federal Coronavirus Aid, Relief, and Economic Security Act. Eton currently has $2.0 million of available liquidity undrawn from its credit agreement and will be entitled to an additional $3.0 million of capacity upon the approvals of EM-100 and 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 8498986. 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 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.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended	
	March 31, 2020	**March 31, 2019**
Revenues		
Product sales	$ 99	$ —
Licensing revenue	—	500
Total revenues	**99**	**500**
Cost of product sales	102	—
Gross (loss) profit	**(3)**	**500**
Operating expenses:		
Research and development	6,268	6,465
General and administrative	2,610	1,589
Total operating expenses	**8,878**	**8,054**
Loss from operations	**(8,881)**	**(7,554)**
Other (expense) income:		
Interest and other (expense) income, net	(168)	144
Loss before income tax expense	**(9,049)**	**(7,410)**
Income tax expense	—	—
Net loss	**$ (9,049)**	**$ (7,410)**
Net loss per share, basic and diluted	**$ (0.50)**	**$ (0.42)**
Weighted average number of common shares outstanding, basic and diluted	18,143	17,502

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

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 12,335	$ 12,066
Accounts receivable, net	205	473
Inventory	1,726	380
Prepaid expenses and other current assets	1,075	2,090
Total current assets	**15,341**	**15,009**
Property and equipment, net	1,025	1,117
Intangible assets, net	688	725
Operating lease right-of-use assets, net	129	160
Other long-term assets, net	58	61
Total assets	**$ 17,241**	**$ 17,072**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,183	$ 575
Accrued liabilities	868	1,388
Total current liabilities	**2,051**	**1,963**
Long-term debt, net of discount and including accrued fees	4,570	4,540
Operating lease liabilities, net of current portion	—	19
Total liabilities	**6,621**	**6,522**
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 20,761,960 and 17,877,486 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	21	18
Additional paid-in capital	83,836	74,720
Accumulated deficit	(73,237)	(64,188)
Total stockholders' equity	**10,620**	**10,550**
Total liabilities and stockholders' equity	**$ 17,241**	**$ 17,072**

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

	Three months ended March 31, 2020	Three months ended March 31, 2019
Cash flows from operating activities		
Net loss	$ (9,049)	$ (7,410)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	365	345
Common stock issued for product candidate licensing rights	1,264	—
Depreciation and amortization	162	55
Debt discount amortization	27	—
Changes in operating assets and liabilities:		
Accounts receivable	268	—
Inventory	(1,346)	—
Prepaid expenses and other assets	1,020	(1,187)
Accounts payable	608	1,736
Accrued liabilities	(536)	(306)
Net cash used in operating activities	**(7,217)**	**(6,767)**
Cash used in investing activities		
Purchases of property and equipment	**(4)**	**(388)**
Cash flows from financing activities		
Proceeds from sales of common stock, net of offering costs	7,459	—
Proceeds from employee stock option exercises	31	4
Net cash provided by financing activities	**7,490**	**4**
Change in cash and cash equivalents	**269**	**(7,151)**
Cash and cash equivalents at beginning of period	12,066	26,735
Cash and cash equivalents at end of period	$ 12,335	$ 19,584
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 189	$ —
Cash paid for income taxes	$ —	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Purchases of equipment included in accounts payable	$ —	$ 51

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