

**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 16, 2021

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)

60010-7278
(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, \$0.001 par value per share	ETON	NASDAQ Global Market

Item 2.02. Results of Operations and Financial Condition

On March 16, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 16, 2021 relating to financial results

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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 16, 2021

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Eton Pharmaceuticals Announces Fourth Quarter and Full Year 2020 Financial Results

DEER PARK, Ill., March 16, 2021 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided an update on business progress.

“2020 was a transformational year for Eton and the momentum has continued through the start of 2021. In recent months, we have seen two of our products commercially launched, completed an important value-creating transaction with our neurology portfolio, and expanded our ALKINDI SPRINKLE franchise to include Canada,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “With these recent events, we believe we have a clear pathway to achieve our goal of profitability by the end of 2021 and we expect to report more than \$25 million of revenue in 2021.”

Fourth Quarter and Recent Business Milestones

- **Launch of ALKINDI® SPRINKLE.** Eton launched ALKINDI SPRINKLE late in the fourth quarter of 2020. Initial reception from patients and pediatric endocrinologists has been strong and the company has already seen significant adoption of the product.
- **Launch of Alaway® Preservative Free.** Eton’s commercial partner, Bausch Health, launched Alaway Preservative Free in all major U.S. retailers in late January 2021. The launch triggered a \$1.5 million milestone payment to Eton, and Eton will receive royalties on commercial sales.
- **Completed the sale of neurology oral liquids portfolio.** In February 2021, Eton announced the sale of its neurology oral liquids portfolio to Azurity Pharmaceuticals for up to \$45 million plus royalties on future sales of the products.
- **Acquired Canadian Rights to ALKINDI SPRINKLE.** In January 2021, Eton announced that it acquired Canadian marketing rights to ALKINDI SPRINKLE. The company is actively working to bring the product to Canadian patients as quickly as possible.

ALKINDI SPRINKLE

Eton launched ALKINDI SPRINKLE in late 2020 and promotional activities have accelerated in 2021. The company’s pediatric endocrinology focused sales force has now reached a large number of the company’s initial targets. In addition to virtual meetings, sales reps are beginning to hold in-person meetings with prescribers as COVID restrictions have started to ease. The company expects the rate of in-person meetings to increase in the coming months, which is expected to drive even greater adoption of ALKINDI SPRINKLE. New patient starts have grown every month since launch, and the company expects the growth to continue.

Due to the strong initial reception to ALKINDI SPRINKLE in the United States and inbound interest from Canadian patients and physicians, Eton acquired the Canadian rights to ALKINDI SPRINKLE in January 2021. Eton is exploring the possibility of immediately supplying the product to patients through Canada’s Special Access Program while it works on compiling the product’s regulatory application to seek formal approval from Health Canada.

Neurology Oral Liquids Transaction

In February 2021, Eton announced the sale of its neurology oral liquid products to Azurity Pharmaceuticals for payments of up to \$45 million and royalties on future sales of the products. The transaction allows Eton to realize an attractive return on its investment and still maintain an economic interest in the products' sales. In addition, Eton will no longer need to invest in a neurology sales force in 2021, which will significantly increase near-term profitability and allow Eton's commercial team to focus on the high-value ALKINDI SPRINKLE opportunity. The transaction is expected to result in significant cash flow in 2021, which should provide Eton with capital to continue growing its orphan drug portfolio through the acquisition of additional products.

Biorphen

Biorphen has experienced steady volume growth as more hospitals have adopted the product, however, the company still expects that overall adoption will be limited until the product is converted from an ampule to a vial container. Eton expects to submit the Prior Approval Supplement needed to enact this container change later this year.

Pipeline Update

<u>Product</u>	<u>Status</u>
ALKDINDI [®] SPRINKLE	Commercial
Alaway Preservative Free [®]	Commercial
Biorphen [®]	Commercial
Dehydrated Alcohol Injection	Filed
Zonisamide Oral Susp.	Filed
Topiramate Oral Soln.	Filed
Lamotrigine for Susp.	Filed
Cysteine Injection	Filed
Ephedrine RTU Injection	Filed
ALKINDI [®] SPRINKLE - Canada	TBD

Dehydrated Alcohol Injection. The product is under review with the FDA, and Eton believes the application remains on track to be approved by its Prescription Drug User Fee Act ("PDUFA") date of May 27, 2021.

Zonisamide Oral Suspension. The product is under review with the FDA and has been assigned a PDUFA date of May 29, 2021.

Topiramate Oral Solution. The product is under review with the FDA and has been assigned a PDUFA date of August 6, 2021.

Lamotrigine for Oral Suspension. The product's human factor study is ongoing and expected to be completed shortly. The company expects the results to resubmitted to the FDA shortly, which would allow for an approval in 2021.

Cysteine Injection. The product is under review with the FDA and the company expects to receive tentative approval in 2021. The company's Paragraph IV litigation against the innovator product, Elcys, is ongoing. The application's 30-month stay expires in August 2022, which may allow the company to launch the product at-risk prior to the conclusion of litigation.

Ephedrine RTU Injection. The product's NDA was submitted by Eton's partner and the review is ongoing with a PDUFA date of June 18, 2021.

Financial Results

Revenue: Eton reported revenue of \$0.1 million for the fourth quarter of 2020. ALKINDI SPRINKLE revenue benefit was minimal in the period due to the product's commercial launch occurring late in the quarter. Eton reported \$0.5 million of revenue in the fourth quarter of 2019, which was composed of initial stocking orders related to the Biorphen product launch. Full year 2020 revenue was negatively impacted by a \$0.2 million reduction due a Biorphen price change that resulted in a shelf stock adjustment for inventory on hand with wholesale customers.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2020 were \$3.4 million, compared to \$0.2 million in the prior year period. The fourth quarter 2020 period included a \$1.4 million FDA filing fee related to the topiramate product candidate's New Drug Application submission, expenses associated converting Biorphen into a vial, and general product development related spending. For the full year 2020, R&D expenses were \$14.1 million versus \$11.6 million. The full year 2020 expense include approximately \$4.8 million related to the acquisition of rights to ALKINDI SPRINKLE and \$2.9 million worth of FDA filing fees.

Selling, General, and Administrative (SG&A) Expenses: SG&A expenses for the fourth quarter of 2020 were \$3.8 million compared with \$2.4 million in the prior year period. The increase was largely due to increased sales and marketing costs associated with the commercialization of ALKINDI SPRINKLE and costs related to the cysteine product candidate's Paragraph IV litigation. For the full year 2020, SG&A expenses increased to \$12.8 million compared with \$7.6 million in the prior year period, primarily due to increased sales and marketing costs associated with the commercialization ALKINDI SPRINKLE and legal costs related to the cysteine product candidate's Paragraph IV litigation.

Net Loss: Net loss for the fourth quarter of 2020 was \$7.7 million compared with \$2.7 million in the prior year period. The increase in the net loss was largely due to increased expenses in the 2020 period. For the full year 2020, net loss was \$28.0 million compared with \$18.3 million in 2019. The increase in net loss was largely due to increased expenses and lower revenue due to a one-time licensing payment received in 2019.

Cash Position: Eton reported cash and cash equivalents of \$21.3 million as of December 31, 2020. After the end of the quarter, Eton received \$9.5 million of proceeds from its transaction with Azurity Pharmaceuticals.

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 1891934. 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 an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The company currently owns or receives royalties from three FDA-approved products, including ALKINDI[®] SPRINKLE, Biorphen[®], and Alaway[®] Preservative Free, and has six additional products that have been submitted to 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,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	\$ 81	\$ 459	\$ 39	\$ 459
Licensing revenue	—	—	—	500
Total net revenues	81	459	39	959
Cost of product sales	300	453	286	453
Gross (loss) profit	(219)	6	(247)	506
Operating expenses:				
Research and development	3,401	233	14,104	11,555
General and administrative	3,800	2,429	12,760	7,552
Total operating expenses	7,201	2,662	26,864	19,107
Loss from operations	(7,420)	(2,656)	(27,111)	(18,601)
Other income (expense):				
Interest and other income (expense), net	(267)	(40)	(859)	281
Loss before income tax expense	(7,687)	(2,696)	(27,970)	(18,320)
Income tax expense	—	—	—	—
Net loss	\$ (7,687)	\$ (2,696)	\$ (27,970)	\$ (18,320)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.15)	\$ (1.33)	\$ (1.03)
Weighted-average number of common shares outstanding, basic and diluted	23,809	17,924	21,010	17,761

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

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,295	\$ 12,066
Accounts receivable, net	48	473
Inventory	1,242	380
Prepaid expenses and other current assets	2,116	2,090
Total current assets	24,701	15,009
Property and equipment, net	811	1,117
Intangible assets, net	575	725
Operating lease right-of-use assets, net	192	160
Other long-term assets, net	40	61
Total assets	\$ 26,319	\$ 17,072
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,344	\$ 575
PPP loan, current portion	280	—
Accrued liabilities	1,170	1,388
Total current liabilities	3,794	1,963
Long-term debt, net of discount and including accrued fees	6,532	4,540
Long-term portion of PPP and EIDL loans	231	—
Operating lease liabilities, net of current portion	99	19
Total liabilities	10,656	6,522
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized as of December 31, 2020 and 2019; 24,312,808 and 17,877,486 shares issued and outstanding at December 31, 2020 and 2019, respectively	24	18
Additional paid-in capital	107,797	74,720
Accumulated deficit	(92,158)	(64,188)
Total stockholders' equity	15,663	10,550
Total liabilities and stockholders' equity	\$ 26,319	\$ 17,072

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

	For the years ended December 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (27,970)	\$ (18,320)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,576	1,888
Common stock issued for product candidate licensing rights	1,264	—
Depreciation and amortization	651	447
Debt discount amortization	121	16
Changes in operating assets and liabilities:		
Accounts receivable	425	(473)
Inventory	(862)	(380)
Prepaid expenses and other assets	(20)	(1,361)
Accounts payable	1,769	(377)
Accrued liabilities	(300)	534
Net cash used in operating activities	(22,346)	(18,026)
Cash used in investing activities		
Purchases of property and equipment	(50)	(1,096)
Purchase of product licensing rights	—	(750)
Net cash used in investing activities	(50)	(1,846)
Cash flows from financing activities		
Proceeds from issuance of long-term debt, net of issuance costs	1,965	4,750
Proceeds from sales of common stock, net of offering costs	28,782	—
Proceeds from PPP and EIDL loans	511	—
Proceeds from employee stock purchase plan and stock option exercises	367	453
Net cash provided by financing activities	31,625	5,203
Change in cash and cash equivalents	9,229	(14,669)
Cash and cash equivalents at beginning of year	12,066	26,735
Cash and cash equivalents at end of year	<u>\$ 21,295</u>	<u>\$ 12,066</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 797	\$ —
Cash paid for income taxes	\$ —	\$ —

Investor Contact:

David Krempa
dkrempa@etonpharma.com
612-387-3740