

**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**

May 13, 2021  
**Date of Report (Date of earliest event reported):**

**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 60010-7278**  
(Address of principal executive offices) (Zip code)

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

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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ETON	NASDAQ Global Market

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]

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

On May 13, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Eton Pharmaceuticals, Inc. on May 13, 2021 relating to financial results</a>

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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: May 13, 2021

*/s/ W. Wilson Troutman*

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W. Wilson Troutman  
Chief Financial Officer and Secretary

## Eton Pharmaceuticals Reports Record Revenue and Earnings

- First quarter 2021 revenue of \$11.9 million
- First quarter 2021 operating earnings of \$5.4 million; EPS of \$0.19
- Eton now has three commercial, revenue-generating products

DEER PARK, Ill., May 13, 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 first quarter ended March 31, 2021 and provided an update on business progress.

“We are proud to report record revenue and the first profitable quarter in Eton’s history,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “We have begun seeing the results of the years of hard work developing our product candidates. We now have three approved and revenue generating products, and we expect to have a number of additional products launched later this year as a result of the four upcoming PDUFA dates over the next three months,” added Brynjelsen.

### Q1 Business Highlights

**First quarter revenue of \$11.9 million and operating income of \$5.4 million.** Revenue included sales or royalties received on three commercial products plus payments related to the sale of Eton’s neurology oral liquids products.

**Launch of Alaway Preservative Free.** In February, Bausch Health launched Alaway Preservative Free in major U.S. retailers. Eton collected a \$1.5 million launch milestone plus a royalty on the product’s sales in the first quarter.

**Completed sale of neurology oral liquid products.** Eton completed the sale of its neurology portfolio to Azurity Pharmaceuticals. Eton will receive milestone payments of up to \$45 million, \$9.5 million of which was received in the first quarter, and a single digit royalty on product sales.

### ALKINDI® SPRINKLE

Eton remains focused on the commercial launch of ALKINDI SPRINKLE in the United States. The first quarter of 2021 was the first full quarter of the product’s launch. The company’s sales representatives have already engaged with more than 90% of their initial targets in the pediatric endocrinology community, and sales representatives have been met with a positive reception from physicians, nurses, and caretakers.

Although initial sales force communications have largely been virtual due to COVID-19 related restrictions, certain physicians’ offices and hospitals have recently begun accepting in-person meetings. Given the expectation for higher conversion rates on in-person meetings, Eton has adopted a sales force strategy that focuses resources most heavily in states where in-person meetings are taking place, rather than the traditional regional allocation of territories. The new strategy will allow all sales representatives to focus on maximizing in-person meetings, even if their previously assigned geography comprises states that are not accepting in-person visits. Eton will continue to refine the resource allocation in the coming weeks and months as additional states begin accepting in-person visits.

In April, Eton presented virtually at the Pediatric Endocrinology Nursing Society national conference and the Pediatric Endocrinology Society annual meeting, the first two conferences since the product’s launch.

The company has seen strong adoption of ALKINDI SPRINKLE, and prescriptions continue to grow month over month. Over 100 new patient prescriptions have been written this year, and the company continues to work towards its goal of more than 400 new patient prescriptions by the end of the year.

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## Pipeline Update

Eton owns or has economic interests in six pipeline products that are currently under review with the FDA, four of which have been assigned Prescription Drug User Fee Act (PDUFA) dates:

- May 27: Dehydrated Alcohol Injection
- May 29: Zonisamide Oral Suspension
- June 18: Ready-to-Use Ephedrine Injection
- August 6: Topiramate Oral Solution

Eton expects these products to be approved and launched later this year. In addition, given the company's strong financial position, it remains actively pursuing business development opportunities to add high-value late-stage orphan product candidates to its portfolio.

### Current Product Portfolio & Pipeline

Product	Status
ALKINDI® SPRINKLE	Commercial
Alaway® Preservative Free	Commercial
Biorphen®	Commercial
Dehydrated Alcohol Injection	Filed
Zonisamide Oral Suspension	Filed
Topiramate Oral Solution	Filed
Lamotrigine for Suspension	Filed
RTU Ephedrine Injection	Filed
Cysteine Injection	Filed
ALKINDI® SPRINKLE - Canada	Pre-Filing

## Financial Results

**Revenue:** Eton reported revenue of \$11.9 million for the first quarter of 2021, which included \$9.5 million from the sale of its neurology oral liquid products and a \$1.5 million milestone payment from Bausch Health for the launch of Alaway Preservative Free. In the prior-year period, the company reported revenue of \$0.1 million.

**General and Administrative (G&A) Expenses:** G&A expenses for the first quarter of 2021 were \$4.1 million compared to \$2.6 million in the prior-year period. The increase was largely due to increased costs related to the commercialization of ALKINDI SPRINKLE. G&A expenses for the first quarter of 2021 included \$0.7 million of non-cash expenses.

**Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2021 were \$0.9 million compared to \$6.3 million in the prior-year period. The prior-year period included \$4.8 million of one-time licensing payments for the acquisition of marketing rights to ALKINDI SPRINKLE. Absent any new business development transaction, the company expects full year 2021 R&D expenses to be substantially below 2020 levels.

**Net Income:** Eton reported net income of \$5.1 million for the first quarter of 2021, compared to a net loss of \$9.0 million in the prior-year period. Eton reported diluted earnings per share (EPS) of \$0.19 in the first quarter of 2021, compared to a loss of \$0.50 per share in the prior year period.

**Cash Position:** Eton reported cash and cash equivalents of \$25.1 million as of March 31, 2021.

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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 5847989. 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.

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

	<b>For the three months ended</b>	
	<b>March 31, 2021</b>	<b>March 31, 2020</b>
<b>Revenues:</b>		
Licensing revenue	\$ 11,500	\$ —
Product sales and royalties	397	99
<b>Total net revenues</b>	<b>11,897</b>	<b>99</b>
<b>Cost of sales</b>		
Licensing revenue	1,500	—
Product sales and royalties	90	102
<b>Total cost of sales</b>	<b>1,590</b>	<b>102</b>
<b>Gross profit (loss)</b>	<b>10,307</b>	<b>(3)</b>
<b>Operating expenses:</b>		
Research and development	886	6,268
General and administrative	4,058	2,610
<b>Total operating expenses</b>	<b>4,944</b>	<b>8,878</b>
<b>Income (loss) from operations</b>	<b>5,363</b>	<b>(8,881)</b>
<b>Other expense:</b>		
Interest and other expense, net	(247)	(168)
<b>Income (loss) before income tax expense</b>	<b>5,116</b>	<b>(9,049)</b>
Income tax expense	—	—
<b>Net income (loss)</b>	<b>\$ 5,116</b>	<b>\$ (9,049)</b>
<b>Net income (loss) per share, basic</b>	<b>\$ 0.21</b>	<b>\$ (0.50)</b>
<b>Net income (loss) per share, diluted</b>	<b>\$ 0.19</b>	<b>\$ (0.50)</b>
Weighted average number of common shares outstanding, basic	24,453	18,143
Weighted average number of common shares outstanding, diluted	26,547	18,143

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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
	(Unaudited)	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 25,113	\$ 21,295
Accounts receivable, net	300	48
Inventories	1,348	1,242
Equipment held-for-sale	551	—
Prepaid expenses and other current assets	2,962	2,116
<b>Total current assets</b>	<b>30,274</b>	<b>24,701</b>
Property and equipment, net	176	811
Intangible assets, net	537	575
Operating lease right-of-use assets, net	163	192
Other long-term assets, net	36	40
<b>Total assets</b>	<b>\$ 31,186</b>	<b>\$ 26,319</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,761	\$ 2,344
Current portion of long-term debt	385	—
PPP loan, current portion	341	280
Accrued liabilities	712	1,170
<b>Total current liabilities</b>	<b>3,199</b>	<b>3,794</b>
Long-term debt, net of discount and including accrued fees	6,183	6,532
Long-term portion of PPP and EIDL loans	170	231
Operating lease liabilities, net of current portion	79	99
<b>Total liabilities</b>	<b>9,631</b>	<b>10,656</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.001 par value; 50,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 24,482,616 and 24,312,808 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	24	24
Additional paid-in capital	108,573	107,797
Accumulated deficit	(87,042)	(92,158)
<b>Total stockholders' equity</b>	<b>21,555</b>	<b>15,663</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 31,186</b>	<b>\$ 26,319</b>



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

	<b>Three months ended March 31, 2021</b>	<b>Three months ended March 31, 2020</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 5,116	\$ (9,049)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	673	365
Common stock issued for product candidate licensing rights	—	1,264
Depreciation and amortization	155	162
Debt discount amortization	36	27
Changes in operating assets and liabilities:		
Accounts receivable	(252)	268
Inventories	(106)	(1,346)
Prepaid expenses and other assets	(846)	1,020
Accounts payable	(583)	608
Accrued liabilities	(478)	(536)
<b>Net cash provided by (used in) operating activities</b>	<b>3,715</b>	<b>(7,217)</b>
<b>Cash used in investing activities</b>		
Purchases of property and equipment	—	(4)
<b>Cash flows from financing activities</b>		
Proceeds from sales of common stock, net of offering costs	—	7,459
Proceeds from employee stock option exercises	103	31
<b>Net cash provided by financing activities</b>	<b>103</b>	<b>7,490</b>
<b>Change in cash and cash equivalents</b>	<b>3,818</b>	<b>269</b>
Cash and cash equivalents at beginning of period	21,295	12,066
Cash and cash equivalents at end of period	<u>\$ 25,113</u>	<u>\$ 12,335</u>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	\$ 214	\$ 189
Cash paid for income taxes	\$ —	\$ —

**Investor Contact:**

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