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

November 15, 2021
Date of Report (Date of earliest event reported):

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 60010-7278
(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 ☒

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. ☒

Item 2.02. Results of Operations and Financial Condition

On November 15, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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

Exhibit No.	Description
99.1	Press release issued by Eton Pharmaceuticals, Inc. on November 15, 2021 relating to financial results
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 15, 2021

/s/ W. Wilson Troutman

W. Wilson Troutman

Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Reports Third Quarter Financial Results

DEER PARK, Ill., Nov. 15, 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 third quarter ended September 30, 2021.

"Over the last month we have made tremendous advancements to our commercial portfolio. We gained two more FDA-approved products, EPRONTIA and carglumic acid, both of which should launch in the fourth quarter, and we are increasing ALKINDI SPRINKLE's commercial footprint more than ten-fold through an attractive co-promotion arrangement with Tolmar Pharmaceuticals. These events put us in an even stronger position to deliver significant revenue and reach sustained profitability in 2022," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Major Business Updates

- **Acquired marketing rights to FDA-approved carglumic acid tablets.** Eton's product is the first and only generic alternative to Carbaglu® and is indicated for acute and chronic hyperammonemia due to N-acetylglutamine Synthase (NAGS) deficiency. Carbaglu® is widely believed to be one of the most expensive treatments in the world and Eton looks forward to offering a lower-cost alternative to patients and caregivers.

- **FDA Approval of EPRONTIA™ (topiramate) oral solution.** Earlier this month, the U.S. Food and Drug Administration (FDA) approved EPRONTIA™, the first oral liquid formulation of topiramate. EPRONTIA™ is now Eton's sixth approved product. The product will be launched by Azurity Pharmaceuticals and is expected to be available before the end of the year. The product's launch will trigger a $5 million milestone payment to Eton, and Eton will also receive a royalty on sales of the product and potential future commercial milestone payments.

- **Significantly expanded ALKINDI SPRINKLE®'s commercial footprint through a co-promotion partnership with Tolmar Pharmaceuticals.** Tolmar's 62-person commercial sales force is expected to be fully trained and promoting ALKINDI SPRINKLE® in December. The transaction is expected to significantly accelerate product adoption and ALKINDI SPRINKLE® sales growth.

ALKINDI SPRINKLE® Commercial Update

In a separate press release issued this morning, Eton announced that it has entered into a co-promotion arrangement with Tolmar Pharmaceuticals for the promotion of ALKINDI SPRINKLE®.

ALKINDI SPRINKLE® sales continued to grow month-over-month in the third quarter and in October. During the quarter, Eton held an advisory panel with key opinion leaders in the pediatric endocrinology community and product feedback continues to be overwhelmingly positive as doctors appreciate the critical importance of precisely dosing pediatric patients when treating adrenal insufficiency. Eton believes in-person meetings have proven to be effective at driving adoption, and as a result, is drastically increasing ALKINDI SPRINKLE®'s commercial footprint through the co-promotion arrangement.

Portfolio Update

Eton now has six FDA-approved products, three of which (carglumic acid, EPRONTIA®, and Rezipres®) are expected to launch in the fourth quarter of 2021. The company also has four additional products that have been submitted to the FDA and could be approved and launched in 2022.

Biorphen® & Rezipres® Vial Conversions. Biorphen® and Rezipres® registration batches have successfully been manufactured in vials, and Eton will submit the supplement applications to the FDA as soon as the necessary stability data is available. Eton expects the vial format of both products to be approved and launched in 2022.

Dehydrated Alcohol Injection. Eton recently held a meeting with the FDA to discuss the dehydrated alcohol product application's complete response letter and Eton's proposed responses. Based on the positive outcome of the meeting, Eton believes the FDA's requests are fully addressable, and the company expects to submit its response as an amendment in the coming months.

Zonisamide Oral Suspension. Eton continues to believe the only item holding up FDA approval of the zonisamide oral suspension product application is the FDA inspection of the product's European manufacturer. The FDA has assigned the product application a new target action date of January 29, 2022, but the FDA has yet to conduct or schedule the onsite inspection. Eton will receive a $5 million milestone payment upon the approval and launch of zonisamide.

Lamotrigine for Suspension. The product's human factor study was successfully completed during the quarter. Eton's partner intends to submit the results to the FDA later this month. The submission should allow for a potential approval of the product in the first half of 2022. Eton will receive a $5 million milestone payment upon the approval and launch of lamotrigine.

Cysteine Hydrochloride Injection. Eton's paragraph IV litigation and FDA application review remain on going. Eton expects to receive tentative approval from the FDA in advance of the 30-month stay expiration in August 2022.

Zeneo Hydrocortisone Autoinjector. Development activities are ongoing and the product remains on pace for an expected NDA submission in 2023.

Financial Results

Revenue: Eton reported revenue of $0.8 million for the third quarter of 2021. Eton reported no material revenue in the third quarter of 2020.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2021 were $3.3 million compared to $3.4 million in the prior-year period. Decrease was largely due to elevated spending in the prior year period related to launch preparation activities for ALKINDI SPRINKLE®. The third quarter of 2021 included $0.9 million of non-cash expenses.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2021 were $2.7 million compared to $2.8 million in the prior-year period. R&D expenses in the third quarter of 2021 were elevated due to expenses related to the development of Biorphen® and Rezipres® vial container conversion. R&D expenses in the third quarter of 2020 included a one-time $1.5 million NDA filing fee.

Net Income: Eton reported a net loss of $6.1 million for the third quarter of 2021, compared to a net loss of $6.5 million in the prior-year period. Eton reported diluted earnings per share (EPS) of ($0.24) in the third quarter of 2021, compared to ($0.31) in the prior year period.

Cash Position: Cash and cash equivalents were $22.7 million as of September 30, 2021.

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 1875678. 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 six FDA-approved products, including ALKINDI SPRINKLE®, carglumic acid, Biorphen®, Alaway® Preservative Free, Rezipres®, and Eprontia™, and has four 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.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended		For the nine months ended	
	September 30, 2021	**September 30, 2020**	**September 30, 2021**	**September 30, 2020**
Revenues:				
Licensing revenue	**$ —**	**$ —**	$ 14,000	**$ —**
Product sales and royalties	775	(161)	1,739	(42)
Total net revenues	**775**	**(161)**	**15,739**	**(42)**
Cost of sales:				
Licensing revenue	**—**	**—**	1,500	**—**
Product sales and royalties	617	(144)	843	(14)
Total cost of sales	**617**	**(144)**	**2,343**	**(14)**
Gross profit (loss)	**158**	**(17)**	**13,396**	**(28)**
Operating expenses:				
Research and development	2,678	2,826	5,554	10,703
General and administrative	3,327	3,429	10,651	8,960
Total operating expenses	**6,005**	**6,255**	**16,205**	**19,663**
Loss from operations	**(5,847)**	**(6,272)**	**(2,809)**	**(19,691)**
Other (expense) income:				
Interest and other (expense) income, net	(247)	(232)	(731)	(592)
Gain on PPP loan forgiven	—	—	365	—
Gain on equipment sale	—	—	181	—
Loss before income tax expense	**(6,094)**	**(6,504)**	**(2,994)**	**(20,283)**
Income tax expense	—	—	—	—
Net loss	**$ (6,094)**	**$ (6,504)**	**$ (2,994)**	**$ (20,283)**
Net loss per share, basic and diluted	**$ (0.24)**	**$ (0.31)**	**$ (0.12)**	**$ (1.01)**
Weighted average number of common shares outstanding, basic and diluted	25,276	21,052	25,181	20,070

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

	September 30, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 22,709	$ 21,295
Accounts receivable, net	385	48
Inventories	334	1,242
Prepaid expenses and other current assets	2,435	2,116
Total current assets	**25,863**	**24,701**
Property and equipment, net	134	811
Intangible assets, net	463	575
Operating lease right-of-use assets, net	123	192
Other long-term assets, net	23	40
Total assets	**$ 26,606**	**$ 26,319**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,273	$ 2,344
Current portion of long-term debt	1,092	—
PPP loan, current portion	—	280
Accrued liabilities	995	1,170
Total current liabilities	**5,360**	**3,794**
Long-term debt, net of discount and including accrued fees	5,550	6,532
Long-term portion of PPP and EIDL loans	—	231
Operating lease liabilities, net of current portion	36	99
Total liabilities	**10,946**	**10,656**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 24,606,175 and 24,312,808 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	25	24
Additional paid-in capital	110,787	107,797
Accumulated deficit	(95,152)	(92,158)
Total stockholders' equity	**15,660**	**15,663**
Total liabilities and stockholders' equity	**$ 26,606**	**$ 26,319**

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

	Nine months ended September 30, 2021	Nine months ended September 30, 2020
Cash flows from operating activities		
Net loss	$ (2,994)	$ (20,283)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	2,518	1,803
Common stock issued for product candidate licensing rights	—	1,264
Depreciation and amortization	325	490
Debt discount amortization	110	85
Gain on forgiveness of debt	(365)	—
Gain on sale of equipment	(181)	—
Changes in operating assets and liabilities:		
Accounts receivable	(337)	473
Inventories	908	(1,319)
Prepaid expenses and other assets	(283)	1,305
Accounts payable	929	1,633
Accrued liabilities	(234)	(615)
Net cash provided by (used in) operating activities	**396**	**(15,164)**
Cash provided by (used in) investing activities		
Proceeds from sale of equipment	700	—
Purchases of property and equipment	(5)	(6)
Net cash provided by (used in) financing activities	**695**	**(6)**
Cash flows from financing activities		
Proceeds from sales of common stock, net of offering costs	—	7,756
Proceeds from issuance of long-term debt, net of issuance costs	—	1,965
EIDL loan payoff	(150)	—
Proceeds from PPP and EIDL loans	—	511
Proceeds from employee stock purchase plan and stock option exercises	473	204
Net cash provided by financing activities	**323**	**10,436**
Change in cash and cash equivalents	**1,414**	**(4,734)**
Cash and cash equivalents at beginning of period	21,295	12,066
Cash and cash equivalents at end of period	$ 22,709	$ 7,332
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 603	$ 545
Cash paid for income taxes	$ —	$ —
Supplemental disclosure of non-cash financing activity		
Relative fair value of warrants to purchase common stock issued in connection with debt	$ —	$ 94

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