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

August 16, 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 August 16, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 16, 2021 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 16, 2021

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Reports Second Quarter Financial Results

DEER PARK, Ill., Aug 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 second quarter ended June 30, 2021.

“During the second quarter we received FDA-approval for Rezipres®, which is now the fourth FDA-approved product in our portfolio,” said Sean Brynjelsen CEO of Eton Pharmaceuticals. “We look forward to launching Rezipres® in the coming months. We also expanded our pediatric endocrinology portfolio with the acquisition of U.S. and Canadian rights to the ZENEO® Hydrocortisone autoinjector. ZENEO Hydrocortisone is a terrific strategic fit with ALKINDI SPRINKLE, and we look forward to working with Crossject to bring it to market as quickly as possible.”

Second Quarter Business Highlights

- **Received U.S. Food and Drug Administration (FDA) approval of Rezipres®, a ready-to-use formulation of ephedrine injection.** Eton expects the product to be commercially available in the coming months.

- **Acquired U.S. and Canadian rights to ZENEO® Hydrocortisone autoinjector.** The product candidate is expected to be the first needle-free autoinjector for the treatment of adrenal crisis. Eton expects the product to be submitted to the FDA in 2023.

- **Progressed ALKINDI SPRINKLE commercial launch.** ALKINDI SPRINKE launch activities expanded in the quarter as the company was able to shift from virtual meetings to in-person meetings with physicians and industry leaders. The product continues to receive a favorable reception from physicians, patients, and payers.

Commercial Update

The second quarter of 2021 was ALKINDI SPRINKLE’s second full quarter of commercial launch. Eton continues to see increasing adoption of the product, and the number of patients on treatment has grown month over month. As a result of fewer COVID-19 restrictions during the quarter, the ALKINDI SPRINKLE sales force was able to prioritize in-person meetings for the first time since the product’s launch. In-person meetings are now the primary method of engagement, surpassing telephone and video calls in the quarter. As a result of favorable feedback from the in-person meetings, Eton expects to expand its sales force to drive more frequent engagement with physicians and potentially faster patient conversion.

ALKINDI SPRINKLE has received favorable support from payers that recognize the importance of precision dosing in the treatment of adrenal insufficiency. The company has seen a very high rate of new patients converting from initial quick starts to commercial reimbursement. Currently more than 90% of patients on treatment are being reimbursed.

During the quarter Eton expanded its active engagement with the adrenal insufficiency community. The company sponsored continuing medical education programs for healthcare professionals to raise awareness of the significant risks and lifelong side effects associated with over or under-dosing when treating adrenal insufficiency in pediatric patients. Eton continues to work with key advocacy partners to help raise awareness of adrenal insufficiency and is hosting an advisory panel with key opinion leaders in the adrenal insufficiency community in late August.

Pipeline Update

Current Product Portfolio & Pipeline

Product	Status
ALKINDI SPRINKLE®	Commercial
Alaway® Preservative Free	Commercial
Biorphen®	Commercial
Rezipres®	Approved
Topiramate Oral Solution	Filed
Dehydrated Alcohol Injection	Filed
Zonisamide Oral Solution	Filed
Lamotrigine for Suspension	Filed
Cysteine Injection	Filed
ALKINDI® (Canada)	Under Development
ZENEO® Hydrocortisone Autoinjector	Under Development

Topiramate Oral Solution. The topiramate product candidate was sold to Azurity Pharmaceuticals in February 2021. Azurity is now responsible for all regulatory activities. During the quarter, Azurity submitted responses to the FDA's review questions which the FDA deemed to be an amendment to the application and resulted in the FDA extending the application's PDUFA date to November 6, 2021. Eton believes all FDA requests have been responded to and expects the application to be approved on or before the new PDUFA date. The product's U.S. manufacturing site was successfully inspected by the FDA in August 2020, so Eton does not expect a pre-approval inspection to be required for the application review.

Dehydrated Alcohol Injection. Eton expects to submit an application amendment to the FDA in the coming months that fully addresses the agency's complete response letter and could allow for FDA approval in early 2022.

Zonisamide Oral Solution. The zonisamide product candidate was sold to Azurity Pharmaceuticals in February 2021. Azurity is now responsible for all regulatory activities. Azurity has submitted a formal response to the FDA's complete response letter; however, the potential timing of an inspection of the product's foreign manufacturing site remains unknown.

Lamotrigine for Suspension. The lamotrigine product candidate was sold to Azurity Pharmaceuticals in February 2021. Azurity is now responsible for all regulatory activities. The third and final arm of the human factor study has now been enrolled. The study is expected to be completed and submitted to the FDA before the end of 2021.

Cysteine Injection. The product's paragraph IV litigation remains ongoing and the company remains confident in a successful outcome.

Financial Results

Revenue: Eton reported revenue of $3.1 million for the second quarter of 2021. Revenue included $2.5 million of licensing revenue related to the company's previously announced transaction with Azurity. In the prior-year period, the company did not have any material revenue.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2021 were $3.3 million compared to $2.9 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 second quarter of 2021 included $0.7 million of non-cash expenses.

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2021 were $2.0 million compared to $1.6 million in the prior-year period. R&D expenses included $0.5 million related to the acquisition of U.S. and Canadian rights to ZENEO® Hydrocortisone in the quarter.

Net Income: Eton reported a net loss of $2.0 million for the second quarter of 2021, compared to a net loss of $4.7 million in the prior-year period. Eton reported diluted earnings per share (EPS) of ($0.08) in the second quarter of 2021, compared to ($0.23) in the prior year period.

Cash Position: Cash and cash equivalents were $25.8 million as of June 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 2454465. 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 four FDA-approved products, including ALKINDI® SPRINKLE, Biorphen®, Alaway® Preservative Free, and Rezipres® and has five 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 six months ended	
	June 30, 2021	**June 30, 2020**	**June 30, 2021**	**June 30, 2020**
Revenues:				
Licensing revenue	$ 2,500	**$ —**	$ 14,000	**$ —**
Product sales and royalties	567	20	964	119
Total net revenues	**3,067**	**20**	**14,964**	**119**
Cost of sales:				
Licensing revenue	**—**	**—**	1,500	**—**
Product sales and royalties	136	28	226	130
Total cost of sales	**136**	**28**	**1,726**	**130**
Gross profit (loss)	**2,931**	**(8)**	**13,238**	**(11)**
Operating expenses:				
Research and development	1,990	1,609	2,876	7,877
General and administrative	3,266	2,921	7,324	5,531
Total operating expenses	**5,256**	**4,530**	**10,200**	**13,408**
(Loss) income from operations	**(2,325)**	**(4,538)**	**3,038**	**(13,419)**
Other (expense) income:				
Interest and other expense, net	(237)	(192)	(484)	(360)
Gain on PPP loan forgiveness	365	—	365	—
Gain on equipment sale	181	—	181	—
(Loss) income before income tax expense	**(2,016)**	**(4,730)**	**3,100**	**(13,779)**
Income tax expense	—	—	—	—
Net (loss) income	**$ (2,016)**	**$ (4,730)**	**$ 3,100**	**$ (13,779)**
Net loss (income) per share, basic	**$ (0.08)**	**$ (0.23)**	**$ 0.12**	**$ (0.70)**
Net loss (income) per share, diluted	**$ (0.08)**	**$ (0.23)**	**$ 0.12**	**$ (0.70)**
Weighted average number of common shares outstanding, basic	25,211	21,005	25,133	19,574
Weighted average number of common shares outstanding, diluted	25,211	21,005	26,486	19,574

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

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 25,802	$ 21,295
Accounts receivable, net	303	48
Inventories	1,242	1,242
Prepaid expenses and other current assets	1,728	2,116
Total current assets	**29,075**	**24,701**
Property and equipment, net	156	811
Intangible assets, net	500	575
Operating lease right-of-use assets, net	143	192
Other long-term assets, net	32	40
Total assets	**$ 29,906**	**$ 26,319**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,522	$ 2,344
Current portion of long-term debt	749	—
PPP loan, current portion	—	280
Accrued liabilities	835	1,170
Total current liabilities	**3,106**	**3,794**
Long-term debt, net of discount and including accrued fees	5,856	6,532
Long-term portion of PPP and EIDL loans	150	231
Operating lease liabilities, net of current portion	58	99
Total liabilities	**9,170**	**10,656**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 24,600,175 and 24,312,808 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	25	24
Additional paid-in capital	109,769	107,797
Accumulated deficit	(89,058)	(92,158)
Total stockholders' equity	**20,736**	**15,663**
Total liabilities and stockholders' equity	**$ 29,906**	**$ 26,319**

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

	Six months ended June 30, 2021	Six months ended June 30, 2020
Cash flows from operating activities		
Net income (loss)	$ 3,100	$ (13,779)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	1,509	1,079
Common stock issued for product candidate licensing rights	—	1,264
Depreciation and amortization	240	326
Debt discount amortization	73	50
Gain on forgiveness of debt	(365)	—
Gain on sale of equipment	(181)	—
Changes in operating assets and liabilities:		
Accounts receivable	(255)	473
Inventories	—	(1,329)
Prepaid expenses and other assets	419	1,251
Accounts payable	(822)	1,378
Accrued liabilities	(372)	(783)
Net cash provided by (used in) operating activities	**3,346**	**(10,070)**
Cash provided by (used in) investing activities		
Proceeds from sale of equipment	700	—
Purchases of property and equipment	(3)	(4)
Net cash provided by (used in) financing activities	**697**	**(4)**
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	464	161
Net cash provided by financing activities	**464**	**8,278**
Change in cash and cash equivalents	**4,507**	**(1,796)**
Cash and cash equivalents at beginning of period	21,295	12,066
Cash and cash equivalents at end of period	$ 25,802	$ 10,270
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 424	$ 358
Cash paid for income taxes	$ —	$ —

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