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, 2022

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** (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, 2022, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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

Exhibit No.	Description
99.1	Press release issued by Eton Pharmaceuticals, Inc. on March 16, 2022 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: March 16, 2022

/s/ W. Wilson Troutman

W. Wilson Troutman
Chief Financial Officer and Secretary

Exhibit 99.1

Eton Pharmaceuticals Reports Fourth Quarter 2021 Financial Results

- Fourth Quarter 2021 Revenue of $6.1 million
- Fourth Quarter 2021 Net Income of $1.0 million and EPS of $0.04

DEER PARK, Ill., Mar. 16, 2022 (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 ended December 31, 2021.

"Our business has never been stronger. The carglumic acid launch is tracking ahead of our initial expectations, the recently implemented co-promotion partnership with Tolmar has accelerated growth of ALKINDI SPRINKLE®, and just this week we launched another new product, Rezipres," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "In addition, we continue to make progress with our four additional products that have been submitted to the FDA, which should lead to even more product launches in the coming quarters," added Brynjelsen.

Major Business Updates

- **Launch of Carglumic Acid tablets**. In late December, Eton launched the first and only generic alternative to Carbaglu®. Initial adoption of the product is ahead of Eton's original expectations.

- **Implementation of ALKINDI SPRINKLE® co-promotion partnership with Tolmar Pharmaceuticals.** By the end of January, Tolmar's 62-person commercial sales force was fully trained and promoting ALKINDI SPRINKLE. Eton has already seen an increase in new ALKINDI SPRINKLE prescriptions, and March is on pace to be the company's best month ever for new patient adds.

- **Launch of EPRONTIA™ (topiramate) oral solution.** In December, Azurity Pharmaceuticals launched EPRONTIA™, the first and only liquid formulation of topiramate. The launch of the product triggered a $5 million milestone payment from Azurity to Eton.

- **Launch of Rezipres® (ready-to-use ephedrine injection).** The market for ephedrine injection in the United States was $86 million in 2021 according to IQVIA. Rezipres will be promoted by XGen Pharmaceutical DJB's hospital sales force.

Commercial Update

Eton launched carglumic acid in late December 2021. The product is the first and only generic version of Carbaglu®. Eton's product has been awarded Competitive Generic Therapy (CGT) designation by the U.S. Food and Drug Administration (FDA) which provides additional market exclusivity. The company's sales force is actively promoting the product to physicians and will be exhibiting in the coming weeks at the annual meetings for the American College of Medical Genetics and Genomics (ACMG) and the Society for Inherited Metabolic Disorders. Initial interest in the product has been strong, with patients, physicians, and payers expressing excitement about carglumic acid's lower price and more convenient room temperature storage. Current adoption of the product has exceeded the company's original forecast.

During the fourth quarter, Eton announced that it had entered into a co-promotion agreement with Tolmar Pharmaceuticals, under which Tolmar's 62-person pediatric endocrinology sales force would promote ALKINDI SPRINKLE. Tolmar's sales force became fully trained and started promoting ALKINDI SPRINKLE in the second half of January. Tolmar's sales force has greatly increased the number of in-person physician visits taking place, and Eton has already seen a significant increase in new patient prescriptions for the product. The company expects the month of March to produce the highest number of monthly new patient prescriptions since the launch of ALKINDI SPRINKLE.

Portfolio Update

Eton now has six FDA-approved commercial products in launch phase. The company also has four additional products that have been submitted to the FDA which are expected to be approved and launched in the coming quarters.

Biorphen & Rezipres Vial Conversions. Biorphen and Rezipres registration batches have successfully been manufactured in vials. Eton plans to submit the supplement applications for both products to the FDA in the second quarter of 2022, which should allow for a launch of vial presentations of both products in 2022.

Dehydrated Alcohol Injection. Eton is actively working to prepare a resubmission to the FDA that addresses all of the FDA's questions from the Complete Response Letter and items discussed during its meeting with the FDA that took place in the fourth quarter. Eton is confident that it will be able to fully address all of the FDA's requests and expects to have the response submitted in the coming weeks.

Zonisamide Oral Suspension. The UK-based contract manufacturing site was inspected by the FDA at the end of January. Eton believes the inspection was successful and should allow for the approval of the application, however no decision timeline has been communicated to Eton. Eton will receive a $5 million milestone payment upon the approval and launch of zonisamide.

Lamotrigine for Suspension. Eton's partner submitted results of the product's human factor study to the FDA in the fourth quarter of 2021 and the application has been assigned a target action date in May 2022. Eton will receive a $5 million milestone payment upon the approval and launch of lamotrigine.

Cysteine Hydrochloride Injection. Eton's paragraph IV bench trial is taking place this week in Delaware. While no timeline has been provided for the judge's ruling, Eton expects to have a decision later this year. The 30-month stay for Eton's application expires in August 2022.

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

Financial Results

Revenue: Eton reported revenue of $6.1 million for the fourth quarter of 2021. Revenue in the quarter included a $5.0 million milestone payment from Azurity Pharmaceuticals triggered by the commercial launch of EPRONTIA. Eton reported no material revenue in the fourth quarter of 2020.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2021 were moderate at $0.7 million compared to $3.4 million in the prior-year period. R&D expenses in the fourth quarter of 2020 were elevated due to a $1.4 million FDA filing fee for topiramate oral solution, a milestone fee for the FDA filing acceptance of Rezipres, and expenses related to the Biorphen® vial and other products in development.

Selling, General and Administrative (SG&A): SG&A expenses were $3.8 million in both the fourth quarters of 2021 and 2020. Fourth quarter 2021 expenses were slightly higher for increased compensation expenses and market research consulting along with FDA product fees for Rezipres, offset by lower sales & marketing expenses associated with the fourth quarter 2020 launch of ALKINDI SPRINKLE. SG&A expenses for the fourth quarter of 2021 included $0.8 million of non-cash expenses.

Net Income: Eton reported net income of $1.0 million for the fourth quarter of 2021, compared to a net loss of $7.7 million in the prior-year period. Eton reported diluted earnings per share (EPS) of $0.04 in the fourth quarter of 2021, compared to ($0.32) in the prior year period.

Cash Position: Cash and cash equivalents were $14.4 million as of December 31, 2021. Eton received the $5.0 million EPRONTIA commercial launch milestone payment in early January.

Conference Call and Webcast Information:

Eton Pharmaceuticals will host a conference call and webcast today at 7:00 p.m. ET (6:00 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 1318317. 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 for approval.

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)

	For the three months ended (Unaudited)		For the years ended	
	December 31, 2021	**December 31, 2020**	**December 31, 2021**	**December 31, 2020**
Revenues:				
Licensing revenue	$ 5,000	**$ —**	$ 19,000	**$ —**
Product sales and royalties, net	1,093	81	2,832	39
Total net revenues	**6,093**	**81**	**21,832**	**39**
Cost of sales:				
Licensing revenue	**—**	**—**	1,500	**—**
Product sales and royalties	280	300	1,123	286
Total cost of sales	**280**	**300**	**2,623**	**286**
Gross profit (loss)	**5,813**	**(219)**	**19,209**	**(247)**
Operating expenses:				
Research and development	681	3,401	6,235	14,104
General and administrative	3,818	3,800	14,469	12,760
Total operating expenses	**4,499**	**7,201**	**20,704**	**26,864**
Income (loss) from operations	**1,314**	**(7,420)**	**(1,495)**	**(27,111)**
Other (expense) income:				
Interest and other expense, net	(275)	(267)	(1,006)	(859)
Gain on PPP loan forgiveness	—	—	365	—
Gain on equipment sale	—	—	181	—
Income (loss) before income tax expense	**1,039**	**(7,687)**	**(1,955)**	**(27,970)**
Income tax expense	—	—	—	—
Net income (loss)	**$ 1,039**	**$ (7,687)**	**$ (1,955)**	**$ (27,970)**
Net income (loss) per share, basic	**$ 0.04**	**$ (0.32)**	**$ (0.08)**	**$ (1.33)**
Net income (loss) per share, diluted	**$ 0.04**	**$ (0.32)**	**$ (0.08)**	**$ (1.33)**
Weighted average number of common shares outstanding, basic	25,285	23,809	25,207	21,010
Weighted average number of common shares outstanding, diluted	25,957	23,809	25,207	21,010

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 14,406	$ 21,295
Accounts receivable, net	5,471	48
Inventories	550	1,242
Prepaid expenses and other current assets	3,177	2,116
Total current assets	**23,604**	**24,701**
Property and equipment, net	115	811
Intangible assets, net	3,621	575
Operating lease right-of-use assets, net	104	192
Other long-term assets, net	21	40
Total assets	**$ 27,465**	**$ 26,319**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,774	$ 2,344
Current portion of long-term debt	1,418	—
PPP loan, current portion	—	280
Accrued liabilities	1,366	1,170
Total current liabilities	**4,558**	**3,794**
Long-term debt, net of discount and including accrued fees	5,262	6,532
Long-term portion of PPP and EIDL loans	—	231
Operating lease liabilities, net of current portion	15	99
Total liabilities	**9,835**	**10,656**
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized; 24,626,004 and 24,312,808 shares issued and outstanding at December 31, 2021 and 2020, respectively	25	24
Additional paid-in capital	111,718	107,797
Accumulated deficit	(94,113)	(92,158)
Total stockholders' equity	**17,630**	**15,663**
Total liabilities and stockholders' equity	**$ 27,465**	**$ 26,319**

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

	Year ended December 31, 2021	Year ended December 31, 2020
Cash flows from operating activities		
Net loss	$ (1,955)	$ (27,970)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,381	2,576
Common stock issued for product candidate licensing rights	—	1,264
Depreciation and amortization	462	651
Debt discount amortization	148	121
Gain on forgiveness of PPP loan	(365)	—
Gain on sale of equipment	(181)	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,423)	425
Inventories	692	(862)
Prepaid expenses and other assets	(1,026)	(20)
Accounts payable	(570)	1,769
Accrued liabilities	116	(300)
Net cash used in operating activities	**(4,721)**	**(22,346)**
Cash used in investing activities		
Proceeds from sale of equipment	700	—
Purchases of property and equipment	(9)	(50)
Purchase of product licensing rights	(3,250)	—
Net cash used in financing activities	**(2,559)**	**(50)**
Cash flows from financing activities		
Proceeds from sales of common stock, net of offering costs	—	28,782
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	541	367
Net cash provided by financing activities	**391**	**31,625**
Change in cash and cash equivalents	**(6,889)**	**9,229**
Cash and cash equivalents at beginning of period	21,295	12,066
Cash and cash equivalents at end of period	$ 14,406	$ 21,295
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 815	$ 797
Cash paid for income taxes	$ —	$ —
Supplemental disclosure of non-cash investing and financing activity		
Relative fair value of common stock warrants issued in connection with debt	$ —	$ 94
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 195

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