

**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): May 12, 2022

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 May 12, 2022, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2022. 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 May 12, 2022 relating to financial results
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 12, 2022

/s/ James R. Gruber

James R. Gruber
Chief Financial Officer and Secretary

Eton Pharmaceuticals Reports First Quarter 2022 Financial Results

DEER PARK, Ill., May 12, 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 first quarter ended March 31, 2022.

“We are proud to report our fifth straight quarter of sequential growth in product sales. We expect this growth to continue for the foreseeable future as our commercial products are still in the early stages of launch, and we expect many additional product launches later this year,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “In addition to the strong commercial results, we have recently made significant progress on the development side with the approval of cysteine injection and the FDA submission for our Biorphen vial product candidate,” added Brynjelsen.

Major Business Highlights

- **Reported a fifth straight quarter of sequential growth in product sales and royalty revenue.** For the first quarter of 2022, Eton reported revenue of \$2.2 million from product sales and royalties, representing a 100% increase from the fourth quarter of 2021.
- **Received final approval for cysteine injection.** In April, the U.S. Food and Drug Administration (FDA) approved Eton’s abbreviated new drug application for cysteine injection. The product-related Paragraph IV trial occurred in March 2022, and a judge’s decision is expected by August 2022. If the outcome is successful, Eton plans to launch the product shortly after the judge’s decision.
- **Submitted Prior Approval Supplement for Biorphen® vial.** The supplement to add the vial container system was submitted in April 2022. The FDA has assigned an August 2022 target action date for the submission.
- **Announcing development of Biorphen® (phenylephrine) premix bag.** Eton announced the development of a Biorphen® premix bag. The product offering would address a significant unmet need in the market. Currently, many hospitals purchase premixed phenylephrine from compounding pharmacies. The product’s New Drug Application (NDA) is expected to be submitted in the third quarter of 2022.

Commercial Update

Eton’s carglumic acid product launched in late-December 2021 and has received a favorable reception from patients and physicians. Patients appreciate the product’s room-temperature stability compared to the competing product’s refrigeration requirement. Numerous patients initiated treatment with carglumic acid in the first quarter, and more have initiated since the quarter end. Eton continues to believe it can capture 25-35% market share before the end of the year. The current market is estimated to be more than \$50 million annually.

ALKINDI SPRINKLE® continues to grow and reported record quarterly revenue. More new patients initiated ALKINDI SPRINKLE® in the first quarter than any other quarter since the launch of the product. Eton’s co-promotion agreement with Tolmar Pharmaceuticals was fully implemented in January, which positively impacted product growth in the first quarter.

ALKINDI SPRINKLE® and carglumic acid continue to see strong growth and both posted record monthly revenue in April. The company expects 2022 revenue of at least \$25 million, including \$10 million of milestone payments and \$15 million of product sales and royalties.

Portfolio Update

Eton now has seven FDA-approved products, six of which are being commercialized and are in launch phase. The company also has three additional products that have been submitted to the FDA, which are expected to be approved and launched in the coming quarters.

Biorphen® (phenylephrine) Premix for Injection. Eton announced the development of a premix Biorphen bag product candidate. The company believes this product would address a significant unmet need and large market opportunity. Currently, hospitals frequently purchase premixed bags from compounding pharmacies. Eton expects the NDA for the product candidate to be submitted by the third quarter of 2022.

Zonisamide Oral Suspension. In April, the product's contract manufacturer received notice that the January 2022 FDA site inspection has been officially closed and the facility was deemed ready for commercial manufacturing. As a result, Eton expects the application to be approved on its newly assigned PDUFA date of July 18th.

Lamotrigine for Suspension. Eton's partner submitted the product-related human factors study results to the FDA in the fourth quarter of 2021, and the application has been assigned a PDUFA date of May 30th.

Biorphen® Vial. The Prior Approval Supplement for Biorphen® vials has been submitted to the FDA and the application has been assigned a target action date of August 4, 2022.

Rezipres® Vial. The Prior Approval Supplement for Rezipres® vials is expected to be submitted to the FDA later this month.

Dehydrated Alcohol Injection. Eton continues to work on addressing the FDA's requests regarding the dehydrated alcohol injection product application. Eton had additional communications with the agency earlier this month and remains confident that all requests received from the agency are addressable.

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 product sales and royalty revenue of \$2.2 million for the first quarter of 2022, compared with \$0.4 million in the prior year period. The revenue increase was primarily due to growth in ALKINDI SPRINKLE® and the launch of carglumic acid and Rezipres®. Eton reported no licensing revenue in the first quarter of 2022, compared with \$11.5 million in the prior year period.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2022 were \$1.6 million compared with \$0.9 million in the prior year period. R&D expenses in the first quarter of 2022 included a \$0.5 million milestone related to the Zeneo® hydrocortisone autoinjector.

Selling, General and Administrative (SG&A): SG&A expenses were \$4.9 million in the first quarter of 2022, compared to \$4.1 million in the prior year quarter. The increased expenses were driven by higher compensation expenses to support sales and quality assurance on commercial products as well as legal expenses associated with the cysteine Paragraph IV trial.

Net Income: Eton reported a net loss of \$5.3 million for the first quarter of 2022, compared with a net income of \$5.1 million in the prior year period. Eton reported diluted earnings per share (EPS) of (\$0.21) in the first quarter of 2022, compared with \$0.19 in the first quarter of 2021. The prior year period included the benefit of \$11.5 million in licensing revenue.

Cash Position: Cash and cash equivalents were \$15.2 million as of March 31, 2022.

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 9537298. 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 seven FDA-approved products, including ALKINDI SPRINKLE®, Carglumic Acid, Biorphen®, Alaway® Preservative Free, Rezipres®, Eprontia™, and cysteine injection and has three 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.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended	
	March 31, 2022	March 31, 2021
Revenues:		
Licensing revenue	\$ —	\$ 11,500
Product sales and royalties	2,176	397
Total net revenues	2,176	11,897
Cost of sales		
Licensing revenue	—	1,500
Product sales and royalties	718	90
Total cost of sales	718	1,590
Gross profit	1,458	10,307
Operating expenses:		
Research and development	1,618	886
General and administrative	4,927	4,058
Total operating expenses	6,545	4,944
(Loss) income from operations	(5,087)	5,363
Other expense:		
Interest and other expense, net	(243)	(247)
(Loss) income before income tax expense	(5,330)	5,116
Income tax expense	—	—
Net (loss) income	\$ (5,330)	\$ 5,116
Net (loss) income per share, basic	\$ (0.21)	\$ 0.21
Net (loss) income per share, diluted	\$ (0.21)	\$ 0.19
Weighted average number of common shares outstanding, basic	25,301	24,453
Weighted average number of common shares outstanding, diluted	25,301	26,547

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

	<u>March 31, 2022</u> (Unaudited)	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,229	\$ 14,406
Accounts receivable, net	796	5,471
Inventories	510	550
Prepaid expenses and other current assets	2,216	3,177
Total current assets	18,751	23,604
Property and equipment, net	109	115
Intangible assets, net	4,240	3,621
Operating lease right-of-use assets, net	84	104
Other long-term assets, net	12	21
Total assets	\$ 23,196	\$ 27,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,131	\$ 1,774
Current portion of long-term debt	—	1,418
Accrued liabilities	1,351	1,366
Total current liabilities	3,482	4,558
Long-term debt, net of discount and including accrued fees	6,331	5,262
Operating lease liabilities, net of current portion	—	15
Total liabilities	9,813	9,835
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 24,626,004 shares issued and outstanding at March 31, 2022 and December 31, 2021	25	25
Additional paid-in capital	112,801	111,718
Accumulated deficit	(99,443)	(94,113)
Total stockholders' equity	13,383	17,630
Total liabilities and stockholders' equity	\$ 23,196	\$ 27,465

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

	Three months ended March 31, 2022	Three months ended March 31, 2021
Cash flows from operating activities		
Net (loss) income	\$ (5,330)	\$ 5,116
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	1,083	673
Depreciation and amortization	181	155
Debt discount amortization	36	36
Changes in operating assets and liabilities:		
Accounts receivable	4,675	(252)
Inventories	40	(106)
Prepaid expenses and other assets	961	(846)
Accounts payable	(393)	(583)
Accrued liabilities	(30)	(478)
Net cash provided by operating activities	1,223	3,715
Cash used in investing activities		
Purchases of property and equipment	(15)	—
Net cash used in investing activities	(15)	—
Cash flows from financing activities		
Repayment of long-term debt	(385)	—
Proceeds from employee stock option exercises	—	103
Net cash (used in) provided by financing activities	(385)	103
Change in cash and cash equivalents	823	3,818
Cash and cash equivalents at beginning of period	14,406	21,295
Cash and cash equivalents at end of period	\$ 15,229	\$ 25,113
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 215	\$ 214
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosures of non-cash investing activities:		
Payable for product license fee	\$ 750	\$ —

Investor Contact:

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