

**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 11, 2023**

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 11, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2023. 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 11, 2023 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: May 11, 2023

/s/ James Gruber

James Gruber

Chief Financial Officer and Secretary

Eton Pharmaceuticals Reports First Quarter 2023 Financial Results

- Product sales and royalty revenue of \$5.3 million up 144% from Q1 2022 and 52% from Q4 2022
 - Launched Betaine Anhydrous
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., May 11, 2023 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (“Eton” or “the Company”) (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today reported financial results for the quarter ended March 31, 2023.

“We are pleased to announce exceptional first quarter results. ALKINDI SPRINKLE® and Carglumic Acid both delivered record revenue and tremendous growth, aided by the onboarding of our newly expanded sales force. Both products are positioned for continued growth through the rest of the year and beyond, plus we are adding the launch of Betaine Anhydrous which should further boost our growth,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “With our strong cash position and expectation to reach profitability in the near future, we are in a prime position to continue opportunistically expanding our rare disease portfolio.”

First Quarter and Recent Business Highlights

Ninth straight quarter of sequential growth in product sales and royalty revenue. Eton reported first quarter 2023 product sales and royalty revenue of \$5.3 million, representing 144% growth over the prior year period and 52% growth over the fourth quarter of 2022.

Record sales of Carglumic Acid. The company continues to see strong demand for the product from patients and prescribers. The first quarter results benefited from key account conversions that the company believes are a direct result of its expanded sales team.

Record sales of ALKINDI SPRINKLE. ALKINDI SPRINKLE also saw strong revenue and patient growth during the first quarter of 2023. During the quarter, Eton launched a new direct to consumer campaign and implemented initiatives to further increase its engagement with the adrenal insufficiency community.

Launch of Betaine Anhydrous. This week, Eton announced the launch of Betaine Anhydrous. Betaine Anhydrous shares a prescriber base with Carglumic Acid, and both products are expected to benefit from the co-promotion and increased interactions with metabolic geneticists.

Acquired rare disease product candidate ET-600. During the quarter, Eton acquired ET-600, an innovative product candidate under development for a rare pediatric endocrinology condition. If approved, ET-600 would address a significant unmet need and have the same prescriber base as ALKINDI SPRINKLE. The Company expects to file a New Drug Application for the product in 2024.

First Quarter Financial Results

Net Revenue: Net revenues for the first quarter of 2023 were \$5.3 million compared with \$2.2 million in the prior year period. In both periods, revenue was comprised entirely of product sales and royalties, and the increase was driven primarily by growth in ALKINDI SPRINKLE and Carglumic Acid.

Gross Profit: Gross profit for the first quarter of 2023 was \$3.3 million compared with \$1.3 million in the prior year period.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2023 were \$0.5 million compared to \$1.6 million in the prior year period. The decrease in R&D expenses was due primarily to a \$0.5 million one-time development milestone payment made in the first quarter of 2022.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2023 were \$5.3 million compared to \$4.8 million in the prior year period. The increase in G&A expenses was due primarily to incremental employee-related expenses associated with our sales force expansion. \$0.9 million of first quarter 2023 G&A expenses were non-cash.

Net Income: Net loss for the first quarter of 2023 was \$2.7 million or \$0.10 per basic and diluted share compared to a net loss of \$5.3 million or \$0.21 per diluted share in the prior year period.

Cash Position: As of March 31, 2023, the Company had cash and cash equivalents of \$14.7 million.

Conference Call and Webcast Information

As previously announced, Eton Pharmaceuticals will host its first quarter 2023 conference call as follows:

Date: Thursday, May 11, 2023
Time: 4:30 p.m. ET (3:30 p.m.CT)
Register (Audio Only): [Click Here](#)

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.

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.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has three FDA approved products in ALKINDI SPRINKLE®, Carglumic Acid tablets, and Betaine Anhydrous for oral solution, and four late-stage pipeline candidates under development with dehydrated alcohol injection, ZENEO® hydrocortisone autoinjector, ET-400, and ET-600. In addition, the Company receives royalties on three FDA-approved products and is entitled to receive milestone payments on other products. For more information, please visit our website at www.etonpharma.com.

Investor Relations:

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

	For the three months ended	
	March 31, 2023	March 31, 2022
Revenues:		
Licensing revenue	\$ —	\$ —
Product sales and royalties	5,304	2,176
Total net revenues	5,304	2,176
Cost of sales:		
Licensing revenue	—	—
Product sales and royalties	1,958	849
Total cost of sales	1,958	849
Gross profit	3,346	1,327
Operating expenses:		
Research and development	535	1,618
General and administrative	5,345	4,796
Total operating expenses	5,880	6,414
(Loss) income from operations	(2,534)	(5,087)
Other (expense) income:		
Interest and other expense, net	(126)	(243)
(Loss) income before income tax expense	(2,660)	(5,330)
Income tax expense	—	—
Net (loss) income	\$ (2,660)	\$ (5,330)
Net (loss) income per share, basic and diluted	\$ (0.10)	\$ (0.21)
Weighted average number of common shares outstanding, basic and diluted	25,525	25,301

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

	March 31, 2023	December 31, 2022
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,708	\$ 16,305
Accounts receivable, net	2,874	1,852
Inventories	437	557
Prepaid expenses and other current assets	1,099	1,290
Total current assets	19,118	20,004
Property and equipment, net	56	72
Intangible assets, net	4,573	4,754
Operating lease right-of-use assets, net	169	188
Other long-term assets, net	12	12
Total assets	\$ 23,928	\$ 25,030
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,233	\$ 1,766
Current portion of long-term debt	1,339	1,033
Accrued liabilities	4,922	3,662
Total current liabilities	7,494	6,461
Long-term debt, net of discount and including accrued fees	5,107	5,384
Operating lease liabilities, net of current portion	86	107
Total liabilities	12,687	11,952
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,504,378 and 25,353,119 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	26	25
Additional paid-in capital	117,009	116,187
Accumulated deficit	(105,794)	(103,134)
Total stockholders' equity	11,241	13,078
Total liabilities and stockholders' equity	\$ 23,928	\$ 25,030

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

	Three months ended March 31, 2023	Three months ended March 31, 2022
Cash flows from operating activities		
Net loss	\$ (2,660)	\$ (5,330)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	872	1,083
Depreciation and amortization	213	181
Debt discount amortization	29	36
Changes in operating assets and liabilities:		
Accounts receivable	(1,022)	4,675
Inventories	120	40
Prepaid expenses and other assets	191	961
Accounts payable	(530)	(393)
Accrued liabilities	1,239	(30)
Net cash (used in) provided by operating activities	(1,548)	1,223
Cash flows from 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 purchase plan and stock option exercises	132	—
Payment of tax withholding related to net share settlement of stock option exercises	(181)	—
Net cash used in financing activities	(49)	(385)
Change in cash and cash equivalents	(1,597)	823
Cash and cash equivalents at beginning of period	16,305	14,406
Cash and cash equivalents at end of period	\$ 14,708	\$ 15,229
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 216	\$ 215
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosures of non-cash investing activities:		
Payable for product license fee	\$ —	\$ 750