

**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): August 10, 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 August 10, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 10, 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: August 10, 2023

/s/ James Gruber

James Gruber
Chief Financial Officer and Secretary

Eton Pharmaceuticals Reports Second Quarter 2023 Financial Results

- Total Q2 revenue of \$12.0 million and net income of \$4.6 million
- Product sales and royalty revenue of \$6.5 million up 175% from Q2 2022 and 22% from Q1 2023
 - \$21.6 million of cash on hand
 - Launched Betaine Anhydrous
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., August 10, 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 June 30, 2023.

“With record product sales, the launch of Betaine Anhydrous, and positive cash flow and earnings, Eton’s second quarter was exceptional. It was the company’s tenth straight quarter of sequential product revenue growth, driven by robust demand and record results for ALKINDI SPRINKLE® and Carglumic Acid. Given our strong performance through the first half of the year, we have increased our revenue expectation and now anticipate reaching approximately \$30 million in total revenue this year,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“With attractive growth prospects for our existing commercial products, the targeted 2024 launch of ET-400, and the financial resources to continue adding new products, Eton is very well positioned to deliver long-term growth and achieve our goal of having 10 commercial rare disease products on the market by the end of 2025,” concluded Brynjelsen.

Second Quarter and Recent Business Highlights

Tenth straight quarter of sequential growth in product sales and royalty revenue. Eton reported second quarter 2023 product sales and royalty revenue of \$6.5 million, representing 175% growth over the prior year period and 22% growth over the first quarter of 2023.

Record sales of ALKINDI SPRINKLE. ALKINDI SPRINKLE saw another record revenue quarter. The Company’s goal is to reach 400 active patients by the end of the year.

Record sales of Carglumic Acid. Carglumic Acid also posted another quarter of record revenue. The product is benefiting from the Company’s recently expanded sales force as well as the launch of Betaine Anhydrous, which shares the same prescriber base and has resulted in increased interactions with metabolic geneticists.

Strong launch of Betaine Anhydrous. Betaine Anhydrous was launched in May and has already seen strong adoption by patients. The Company’s Eton Cares patient support program has received favorable reviews from both patients and prescribers.

Product candidate ET-400 on track for an NDA submission in Q4 2023. The Company is preparing for an NDA submission in the fourth quarter, which could result in an approval and commercial launch in 2024. ET-400 is a proprietary liquid formulation of hydrocortisone that, if approved, would be sold alongside ALKINDI SPRINKLE, and would provide patients with an additional treatment option. The Company believes ET-400 will accelerate patient adoption, with total combined peak sales of ALKINDI SPRINKLE and ET-400 expected to exceed \$50 million annually.

Monetized royalty interests and strengthened financial position. During the quarter, Eton sold its remaining milestone and royalty interests in ZONISADE®, EPRONTIA®, and the lamotrigine product candidate. In exchange for its interests, Eton received a payment of \$5.5 million, which it intends to reinvest in the acquisition of rare disease products. In the second quarter, the company also received a \$0.8 million break-up fee associated with its participation as the stalking horse bidder in an auction process. The Company finished the quarter with \$21.6 million of cash and cash equivalents.

Second Quarter Financial Results

Net Revenue: Net sales for the second quarter of 2023 were \$12.0 million compared with \$7.4 million in the prior year period. Net sales included \$5.5 million of licensing payments received during the quarter related to the sale of Eton's neurology product royalties and milestones to Azurity Pharmaceuticals, compared to \$5.0 million of licensing revenue in the prior year period related to the sale of multiple hospital products to Dr. Reddy's.

Product sales and royalty revenue were \$6.5 million for the second quarter of 2023 compared with \$2.4 million in the prior year period, an increase of 175% over the prior year period and 22% over the first quarter of 2023. The year-over-year increase in product sales and royalty revenue was primarily driven by growth in ALKINDI SPRINKLE and Carglumic Acid tablets.

Gross Profit: Gross profit for the second quarter of 2023 was \$9.7 million compared with \$4.6 million in the prior year period. The growth was driven by the sale of the Company's neurology product royalties as well as growth in ALKINDI SPRINKLE and Carglumic Acid. Gross profit for the prior year period included \$1.8 million of non-cash expenses related to the hospital products divestment.

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2023 were \$1.1 million compared to \$0.7 million in the prior year period. The increase was primarily due to a \$0.5 million milestone payment resulting from the successful manufacturing of registration batches of product candidate ET-600.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2023 were \$4.7 million compared to \$5.3 million in the prior year period. The decrease in G&A expenses was mainly due to decreased FDA fees and legal fees associated with products sold to Dr. Reddy's in June 2022.

Net Income: Net income for the second quarter of 2023 was \$4.6 million or \$0.18 per basic and diluted share compared to a net loss of \$1.6 million, or \$0.06 per basic and diluted share in the prior year period.

Cash Position: As of June 30, 2023, the Company had cash and cash equivalents of \$21.6 million.

Conference Call and Webcast Information

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

Date: Thursday, August 10, 2023

Time: 4:30 p.m. ET (3:30 p.m.CT)

Register* (Audio Only) [Click here](#)

In addition to taking live questions from participants on the conference call, management will be answering emailed questions from investors. Investors can email questions to: investorrelations@etonpharma.com.

The live webcast can be accessed on the Investors section of Eton's website at <https://ir.etonpharma.com/>. An archived webcast will be available on Eton's website approximately two hours after the completion of the event and for 30 days thereafter.

* Conference call participants should register to obtain their dial-in and passcode details. Please be sure to register using a valid email address.

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 is an innovative pharmaceutical company focused on developing, acquiring, and commercializing innovative products to address unmet needs in patients suffering from rare diseases. The Company currently has three commercial rare disease products, ALKINDI SPRINKLE® for the treatment of pediatric adrenocortical insufficiency, Carglumic Acid for the treatment of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, and Betaine Anhydrous for the treatment of homocystinuria. The Company has four additional product candidates in late-stage development: dehydrated alcohol injection, which has received Orphan Drug Designation for the treatment of methanol poisoning, ZENEO® hydrocortisone autoinjector for the treatment of adrenal crisis, ET-400 for the treatment of adrenocortical insufficiency, and ET-600 for the treatment of diabetes insipidus. For more information, please visit our website at www.etonpharma.com.

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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, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Revenues:				
Licensing revenue	\$ 5,500	\$ 5,000	\$ 5,500	\$ 5,000
Product sales and royalties	6,497	2,358	11,801	4,534
Total net revenues	<u>11,997</u>	<u>7,358</u>	<u>17,301</u>	<u>9,534</u>
Cost of sales:				
Licensing revenue	—	990	—	990
Product sales and royalties	2,315	1,755	4,273	2,604
Total cost of sales	<u>2,315</u>	<u>2,745</u>	<u>4,273</u>	<u>3,594</u>
Gross profit	9,682	4,613	13,028	5,940
Operating expenses:				
Research and development	1,125	690	1,660	2,308
General and administrative	4,674	5,263	10,019	10,059
Total operating expenses	<u>5,799</u>	<u>5,953</u>	<u>11,679</u>	<u>12,367</u>
Income (loss) from operations	3,883	(1,340)	1,349	(6,427)
Other income (expense):				
Other income	800	—	800	—
Interest and other expense, net	(124)	(218)	(250)	(461)
Total other income (expense)	<u>676</u>	<u>(218)</u>	<u>550</u>	<u>(461)</u>
Income (loss) before income tax expense	4,559	(1,558)	1,899	(6,888)
Income tax expense	—	—	—	—
Net income (loss)	<u>\$ 4,559</u>	<u>\$ (1,558)</u>	<u>\$ 1,899</u>	<u>\$ (6,888)</u>
Net income (loss) per share, basic	<u>\$ 0.18</u>	<u>\$ (0.06)</u>	<u>\$ 0.07</u>	<u>\$ (0.28)</u>
Weighted average number of common shares outstanding, basic	<u>25,593</u>	<u>25,126</u>	<u>25,560</u>	<u>24,915</u>
Net income (loss) per share, diluted	<u>\$ 0.18</u>	<u>\$ (0.06)</u>	<u>\$ 0.07</u>	<u>\$ (0.28)</u>
Weighted average number of common shares outstanding, diluted	<u>25,983</u>	<u>25,126</u>	<u>25,949</u>	<u>24,915</u>

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

	<u>June 30, 2023</u> (Unaudited)	<u>December 31, 2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,566	\$ 16,305
Accounts receivable, net	3,084	1,852
Inventories	816	557
Prepaid expenses and other current assets	867	1,290
Total current assets	26,333	20,004
Property and equipment, net	46	72
Intangible assets, net	4,392	4,754
Operating lease right-of-use assets, net	149	188
Other long-term assets, net	12	12
Total assets	\$ 30,932	\$ 25,030
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,300	\$ 1,766
Current portion of long-term debt	1,540	1,033
Accrued liabilities	5,748	3,662
Total current liabilities	9,588	6,461
Long-term debt, net of discount and including accrued fees	4,553	5,384
Operating lease liabilities, net of current portion	66	107
Total liabilities	14,207	11,952
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,561,994 and 25,353,119 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	26	25
Additional paid-in capital	117,934	116,187
Accumulated deficit	(101,235)	(103,134)
Total stockholders' equity	16,725	13,078
Total liabilities and stockholders' equity	\$ 30,932	\$ 25,030

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

	Six months ended June 30, 2023	Six months ended June 30, 2022
Cash flows from operating activities		
Net income (loss)	\$ 1,899	\$ (6,888)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	1,657	2,383
Depreciation and amortization	424	1,352
Debt discount amortization	61	66
Changes in operating assets and liabilities:		
Accounts receivable	(1,232)	4,637
Inventories	(259)	19
Prepaid expenses and other assets	423	1,827
Accounts payable	537	(475)
Accrued liabilities	2,045	763
Net cash provided by operating activities	5,555	3,684
Cash flows from investing activities		
Purchases of product license rights	—	(750)
Purchases of property and equipment	—	(26)
Net cash used in investing activities	—	(776)
Cash flows from financing activities		
Repayment of long-term debt	(385)	(385)
Proceeds from employee stock purchase plan and stock option exercises	272	117
Payment of tax withholding related to net share settlement of stock option exercises	(181)	—
Net cash used in financing activities	(294)	(268)
Change in cash and cash equivalents	5,261	2,640
Cash and cash equivalents at beginning of period	16,305	14,406
Cash and cash equivalents at end of period	\$ 21,566	\$ 17,046
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 426	\$ 378
Cash paid for income taxes	\$ —	\$ —