

**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): November 10, 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 November 10, 2022, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 10, 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: November 10, 2022

/s/ James R. Gruber

James R. Gruber
Chief Financial Officer and Secretary

Eton Pharmaceuticals Reports Third Quarter 2022 Financial Results

DEER PARK, Ill., November 10, 2022 (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 September 30, 2022.

“Our third quarter results reflect the continued momentum we’re seeing across our product portfolio. Product sales and royalties jumped 315% over the prior year period and 37% from the second quarter of 2022, marking the seventh straight quarter of sequential revenue growth. Physicians and patients are responding positively to ALKINDI SPRINKLE and Carglumic Acid, and both products still have long runways for growth ahead of them,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“During the quarter, we added a third FDA-approved rare disease product. Betaine Anhydrous shares the same prescriber base as Carglumic Acid and makes for an ideal fit for our metabolic genetics sales force. With two commercial products in the market, the upcoming launch of Betaine, and the potential for additional product launches in 2023 and 2024, we are very excited about what lies ahead for the Company,” concluded Brynjelsen.

Third Quarter and Recent Business Highlights

Reported seventh straight quarter of sequential growth in product sales and royalty revenue. Eton reported total third quarter 2022 revenue of \$3.2 million, comprised entirely of product sales and royalty revenue, representing growth of 315% over the prior year and 37% over the second quarter of 2022.

Continued strong growth in sales of ALKINDI SPRINKLE. Sales of ALKINDI SPRINKLE grew 183% over the prior year period and 19% over the second quarter of 2022. Growth came from both new and existing prescribers.

Increasing adoption of Carglumic Acid. Now in its third full calendar quarter since launch, the product continues to see a strong reception from prescribers and patients. Carglumic Acid sales grew 40% over the second quarter and the company believes it remains on track to reach its goal of capturing 25-35% market share of the estimated \$50 million market.

Acquisition of a third FDA-approved rare disease product. During the quarter, Eton announced the acquisition of Betaine Anhydrous. The product shares the same metabolic geneticist prescriber base as Carglumic Acid and is expected to be accretive to Eton’s earnings in 2023.

FDA Approval of Zonisade™. The product is part of Eton’s multi-product neurology oral solution agreement with Azurity Pharmaceuticals. Azurity is solely responsible for commercializing the product; Eton is entitled to receive milestone payments and royalties on net sales of the product. Zonisade was launched in October, triggering a \$5 million milestone payment to Eton that will be recognized in the fourth quarter.

Third Quarter Financial Results

Net Sales: Net sales for the third quarter of 2022 were \$3.2 million compared with \$0.8 million in the prior year period. In both periods, revenue was comprised entirely of product sales and royalties, and the increase was primarily driven by growth in ALKINDI SPRINKLE and the launch of Carglumic Acid in late 2021.

Gross Profit: Gross profit for the third quarter of 2022 was \$2.0 million compared with \$0.1 million in the prior year period.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2022 were \$0.7 million compared to \$2.7 million in the prior year period. The decrease was primarily due to a \$1.1 million fee related to Biorphen and Rezipres conversion projects in the prior year period, and decreased development costs for new product candidates.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2022 were \$4.2 million compared to \$3.3 million in the prior year period. Cash G&A expenses for the third quarter of 2022 were \$3.2 million, compared to \$2.4 million in the prior year period. The increase in G&A expenses was mainly due to incremental marketing and compensation to support product sales growth, partially offset by lower legal and consulting expenses.

Net Income/Loss: Net loss for the third quarter of 2022 was \$3.0 million or \$0.12 per basic and diluted share compared to a net loss of \$6.1 million or \$0.24 per diluted share in the prior year period.

Cash Position: As of September 30, 2022, the company had cash and cash equivalents of \$13.4 million. The Company will receive a \$5.0 million milestone payment for the launch of Zonisade during the fourth quarter.

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 register [here](#) (audio only). 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 three late-stage pipeline candidates under development with dehydrated alcohol injection, ZENEO® hydrocortisone autoinjector, and ET-400. 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.

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

	For the three months ended		For the nine months ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Revenues:				
Licensing revenue	\$ —	\$ —	\$ 5,000	\$ 14,000
Product sales and royalties	3,219	775	7,753	1,739
Total net revenues	3,219	775	12,753	15,739
Cost of sales:				
Licensing revenue	—	—	990	1,500
Product sales and royalties	1,201	654	3,805	955
Total cost of sales	1,201	654	4,795	2,455
Gross profit	2,018	121	7,958	13,284
Operating expenses:				
Research and development	744	2,678	3,052	5,554
General and administrative	4,169	3,290	14,228	10,539
Total operating expenses	4,913	5,968	17,280	16,093
(Loss) income from operations	(2,895)	(5,847)	(9,322)	(2,809)
Other (expense) income:				
Interest and other expense, net	(150)	(247)	(611)	(731)
Gain on PPP loan forgiveness	—	—	—	365
Gain on equipment sale	—	—	—	181
(Loss) income before income tax expense	(3,045)	(6,094)	(9,933)	(2,994)
Income tax expense	—	—	—	—
Net (loss) income	\$ (3,045)	\$ (6,094)	\$ (9,933)	\$ (2,994)
Net loss (income) per share, basic	\$ (0.12)	\$ (0.24)	\$ (0.40)	\$ (0.12)
Net loss (income) per share, diluted	\$ (0.12)	\$ (0.24)	\$ (0.40)	\$ (0.12)
Weighted average number of common shares outstanding, basic	25,365	25,276	25,066	25,181
Weighted average number of common shares outstanding, diluted	25,365	25,276	25,066	25,181

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,378	\$ 14,406
Accounts receivable, net	1,498	5,471
Inventories	481	550
Prepaid expenses and other current assets	1,063	3,177
Total current assets	16,420	23,604
Property and equipment, net	73	115
Intangible assets, net	4,973	3,621
Operating lease right-of-use assets, net	42	104
Other long-term assets, net	12	21
Total assets	\$ 21,520	\$ 27,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,054	\$ 1,774
Current portion of long-term debt	708	1,418
Accrued liabilities	2,899	1,366
Total current liabilities	4,661	4,558
Long-term debt, net of discount and including accrued fees	5,678	5,262
Operating lease liabilities, net of current portion	—	15
Total liabilities	10,339	9,835
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,297,037 and 24,626,004 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	25	25
Additional paid-in capital	115,202	111,718
Accumulated deficit	(104,046)	(94,113)
Total stockholders' equity	11,181	17,630
Total liabilities and stockholders' equity	\$ 21,520	\$ 27,465

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

	Nine months ended September 30, 2022	Nine months ended September 30, 2021
Cash flows from operating activities		
Net loss	\$ (9,933)	\$ (2,994)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Stock-based compensation	3,332	2,518
Depreciation and amortization	1,522	325
Debt discount amortization	96	110
Gain on forgiveness of debt	—	(365)
Gain on sale of equipment	—	(181)
Changes in operating assets and liabilities:		
Accounts receivable	3,973	(337)
Inventories	69	908
Prepaid expenses and other assets	2,129	(283)
Accounts payable	(720)	699
Accrued liabilities	1,513	(4)
Net cash provided by operating activities	1,981	396
Cash flows from investing activities		
Proceeds from sale of equipment	—	700
Purchase of product license rights	(2,750)	—
Purchases of property and equipment	(26)	(5)
Net cash (used in) provided by investing activities	(2,776)	695
Cash flows from financing activities		
Repayment of long-term debt	(385)	(150)
Proceeds from employee stock purchase plan and stock option exercises	152	473
Net cash (used in) provided by financing activities	(233)	323
Change in cash and cash equivalents	(1,028)	1,414
Cash and cash equivalents at beginning of period	14,406	21,295
Cash and cash equivalents at end of period	\$ 13,378	\$ 22,709
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 545	\$ 603

Investor Relations:

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