

**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**

**November 9, 2023**

**Date of Report (Date of earliest event reported)**

**ETON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware  
(State  
of incorporation)**

**001-38738  
(Commission  
File Number)**

**37-1858472  
(I.R.S. Employer  
Identification Number)**

**21925 W. Field Parkway, Suite 235  
Deer Park, Illinois 60010-7208  
(Address of principal executive offices) (Zip code)  
(847) 787-7361**

**(Registrant's telephone number, including area code)**

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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ETON	NASDAQ Global Market

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.

**Item 2.02 Results of Operations and Financial Condition.**

On November 9, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the third quarter ended September 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**

**Exhibit 99.1**      [Press Release issued by Eton Pharmaceuticals, Inc. on November 9, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 9, 2023

By: /s/ James R. Gruber  
James R. Gruber  
Chief Financial Officer and Secretary  
(Principal Financial Officer)

## Eton Pharmaceuticals Reports Third Quarter 2023 Financial Results

- Product sales and royalty revenue of \$7.0 million up 118% from Q3 2022, representing the eleventh straight quarter of sequential product sales and royalty revenue growth
- Generated \$0.9 million in positive cash flow from operations; ended quarter with \$22.1 million of cash on hand
- Acquired ultra-rare disease product Nitisinone Capsules
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., November 9, 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 September 30, 2023.

“The momentum continues for Eton, and we’re proud to report our eleventh straight quarter of product sales and royalty revenue growth, which has allowed us to reach cash flow break-even ahead of schedule. Sales of ALKINDI SPRINKLE® and Carglumic Acid remain strong, and we recently added a fourth commercial rare disease product to our portfolio, Nitisinone Capsules, which we expect to launch in early 2024,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“Reaching cash flow break-even is an important milestone on our journey to becoming a highly profitable and industry leading rare disease company. I am proud of the hard work and dedication from our employees that made it possible. With strong organic growth prospects for our existing commercial products, the potential near-term launches of Nitisinone and ET-400, plus a strong balance sheet and favorable M&A environment, I couldn’t be more excited about Eton’s outlook for 2024 and beyond,” concluded Brynjelsen.

### Third Quarter and Recent Business Highlights

**Eleventh straight quarter of sequential growth in product sales and royalty revenue.** Eton reported third quarter 2023 product sales and royalty revenue of \$7.0 million, representing 118% growth over the prior year period and 8% growth over the second quarter of 2023.

**Recorded positive cash flow from operations solely from product sales and royalty revenue.** During the quarter, cash on hand increased from \$21.6 million to \$22.1 million.

**Strong growth in product sales driven by ALKINDI SPRINKLE and Carglumic Acid.** Both products posted strong year-over-year and quarter-over-quarter sales growth. The Company expects to launch an ALKINDI SPRINKLE physician sampling program in the coming weeks, which is expected to further accelerate the product’s growth.

**Acquired FDA-approved ultra-rare disease product Nitisinone.** In October, Eton acquired Nitisinone capsules which will be Eton’s fourth commercial product, moving the company closer to its goal of reaching ten commercial products by the end of 2025. Eton expects to launch the product during the first quarter of 2024.

**First full quarter of commercial availability for Betaine Anhydrous.** The launch of Betaine resulted in a significant increase in the company’s interactions with metabolic geneticists, which is expected to help drive Betaine revenue as well as potentially benefit Carglumic Acid and the company’s soon-to-be-launched Nitisinone product.

**Held pre-NDA meeting with FDA regarding product candidate ET-400.** Last week, Eton held a pre-NDA meeting with the FDA regarding ET-400. Based on feedback from the meeting, the company plans to run an additional bioequivalence study and submit the NDA in the middle of 2024. ET-400 is a proprietary liquid formulation of hydrocortisone that, if approved, would complement ALKINDI SPRINKLE by providing patients with an additional treatment option. The Company believes that the combined peak sales of ET-400 and ALKINDI SPRINKLE could exceed \$50 million annually.

### Third Quarter Financial Results

**Net Revenue:** Net sales for the third quarter of 2023 were \$7.0 million compared with \$3.2 million in the prior year period, an increase of 118%. Net sales were comprised entirely of product sales and royalties in both periods. The year-over-year increase was primarily driven by growth in ALKINDI SPRINKLE and Carglumic Acid tablets. Product sales and royalty revenue for the third quarter of 2023 were up 8% over the second quarter of 2023.

**Gross Profit:** Gross profit for the third quarter of 2023 was \$4.4 million compared with \$2.0 million in the prior year period.

**Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2023 were \$0.6 million compared to \$0.7 million in the prior year period. The decrease was primarily due to decreased expenses associated with products sold to Dr. Reddy’s in 2022.

**General and Administrative (G&A) Expenses:** G&A expenses for the third quarter of 2023 were \$4.3 million compared to \$4.2 million in the prior year period. The slight increase in G&A expenses was mainly due to increased employee-related expenses related to sales force expansion offset by decreased sales and marketing expenses associated with third party sales commissions.

**Net Loss:** Net loss for the third quarter of 2023 was \$0.6 million or \$0.02 per basic and diluted share compared to a net loss of \$3.0 million, or \$0.12 per basic and diluted share, in the prior year period.

**Cash Position:** As of September 30, 2023, the Company had cash and cash equivalents of \$22.1 million.

## Conference Call and Webcast Information

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

Date: Thursday, November 9, 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](mailto:investorrelations@etonpharma.com)

The live webcast can be accessed on the Investors section of Eton's website at [ir.etonpharma.com](http://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 products to address unmet needs in patients suffering from rare diseases. The Company currently has four FDA-approved 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, Betaine Anhydrous for the treatment of homocystinuria, and Nitisinone for the treatment of hereditary tyrosinemia type 1. The Company has three additional product candidates in late-stage development: ET-400 for the treatment of adrenocortical insufficiency, ET-600 for the treatment of diabetes insipidus, and ZENEO® hydrocortisone autoinjector for the treatment of adrenal crisis. For more information, please visit our website at [www.etonpharma.com](http://www.etonpharma.com).

## Investor Relations:

Lisa M. Wilson, In-Site Communications, Inc.  
T: 212-452-2793  
E: [lwilson@insitecony.com](mailto:lwilson@insitecony.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 nine months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
<b>Revenues:</b>				
Licensing revenue	\$ —	\$ —	\$ 5,500	\$ 5,000
Product sales and royalties	7,028	3,219	18,829	7,753
Total net revenues	<u>7,028</u>	<u>3,219</u>	<u>24,329</u>	<u>12,753</u>
<b>Cost of sales:</b>				
Licensing revenue	—	—	—	990
Product sales and royalties	2,625	1,201	6,898	3,805
Total cost of sales	<u>2,625</u>	<u>1,201</u>	<u>6,898</u>	<u>4,795</u>
Gross profit	4,403	2,018	17,431	7,958
<b>Operating expenses:</b>				
Research and development	615	744	2,275	3,052
General and administrative	4,336	4,169	14,355	14,228
Total operating expenses	<u>4,951</u>	<u>4,913</u>	<u>16,630</u>	<u>17,280</u>
Income (loss) from operations	(548)	(2,895)	801	(9,322)
<b>Other income (expense):</b>				
Other income	—	—	800	—
Interest and other expense, net	(31)	(150)	(281)	(611)
Total other income (expense)	<u>(31)</u>	<u>(150)</u>	<u>519</u>	<u>(611)</u>
Income (loss) before income tax expense	(579)	(3,045)	1,320	(9,933)
Income tax expense	—	—	—	—
Net income (loss)	<u>\$ (579)</u>	<u>\$ (3,045)</u>	<u>\$ 1,320</u>	<u>\$ (9,933)</u>
Net income (loss) per share, basic	<u>\$ (0.02)</u>	<u>\$ (0.12)</u>	<u>\$ 0.05</u>	<u>\$ (0.40)</u>
Weighted average number of common shares outstanding, basic	<u>25,719</u>	<u>25,365</u>	<u>25,613</u>	<u>25,066</u>
Net income (loss) per share, diluted	<u>\$ (0.02)</u>	<u>\$ (0.12)</u>	<u>\$ 0.05</u>	<u>\$ (0.40)</u>
Weighted average number of common shares outstanding, diluted	<u>25,719</u>	<u>25,365</u>	<u>26,012</u>	<u>25,066</u>

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

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
	(Unaudited)	
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 22,070	\$ 16,305
Accounts receivable, net	3,495	1,852
Inventories	1,051	557
Prepaid expenses and other current assets	541	1,290
<b>Total current assets</b>	<b>27,157</b>	<b>20,004</b>
Property and equipment, net	38	72
Intangible assets, net	4,210	4,754
Operating lease right-of-use assets, net	109	188
Other long-term assets, net	12	12
<b>Total assets</b>	<b>\$ 31,526</b>	<b>\$ 25,030</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,712	\$ 1,766
Current portion of long-term debt	1,540	1,033
Accrued liabilities	7,141	3,662
<b>Total current liabilities</b>	<b>10,393</b>	<b>6,461</b>
Long-term debt, net of discount and including accrued fees	4,197	5,384
Operating lease liabilities, net of current portion	44	107
<b>Total liabilities</b>	<b>14,634</b>	<b>11,952</b>
<b>Commitments and contingencies (Note 11)</b>		
<b>Stockholders' equity</b>		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,658,396 and 25,353,119 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	26	25
Additional paid-in capital	118,680	116,187
Accumulated deficit	(101,814)	(103,134)
<b>Total stockholders' equity</b>	<b>16,892</b>	<b>13,078</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 31,526</b>	<b>\$ 25,030</b>

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

	Nine months ended September 30, 2023	Nine months ended September 30, 2022
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 1,320	\$ (9,933)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	2,387	3,332
Depreciation and amortization	626	1,522
Debt discount amortization	90	96
Changes in operating assets and liabilities:		
Accounts receivable	(1,643)	3,973
Inventories	(494)	69
Prepaid expenses and other assets	749	2,129
Accounts payable	(52)	(720)
Accrued liabilities	3,445	1,513
<b>Net cash provided by operating activities</b>	<b>6,428</b>	<b>1,981</b>
<b>Cash flows from investing activities</b>		
Purchases of product license rights	—	(2,750)
Purchases of property and equipment	—	(26)
<b>Net cash used in investing activities</b>	<b>—</b>	<b>(2,776)</b>
<b>Cash flows from financing activities</b>		
Repayment of long-term debt	(770)	(385)
Proceeds from employee stock purchase plan and stock option exercises	288	152
Payment of tax withholding related to net share settlement of stock option exercises	(181)	—
<b>Net cash used in financing activities</b>	<b>(663)</b>	<b>(233)</b>
Change in cash and cash equivalents	5,765	(1,028)
Cash and cash equivalents at beginning of period	16,305	14,406
Cash and cash equivalents at end of period	\$ 22,070	\$ 13,378
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	\$ 638	\$ 545
Cash paid for income taxes	\$ —	\$ —
<b>Supplemental disclosures of non-cash transactions</b>		
Adjustment of operating lease right-of-use assets and liabilities due to tenant allowance	\$ 29	\$ —