

**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

May 9, 2024

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:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
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.

2.02: Results of Operations and Financial Condition

On May 9, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2024. 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.

9.01: Financial Statements and Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release issued by Eton Pharmaceuticals, Inc. on May 9, 2024 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: May 9, 2024

By: /s/ James R. Gruber

James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Eton Pharmaceuticals Reports First Quarter 2024 Financial Results

- Q1 2024 revenue of \$8.0 million, representing 50% growth over Q1 2023 and the 13th straight quarter of sequential product sales growth
- Acquired PKU GOLIKE®, launched Nitisinone, and submitted a new drug application (NDA) for product candidate ET-400
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., MAY 9, 2024 (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, 2024.

“We have had a very productive start to 2024. In addition to reporting record product sales and our 13th straight quarter of sequential product sales growth, we acquired PKU GOLIKE which adds a compelling new commercial growth asset to our metabolic portfolio. We also launched Nitisinone and submitted an NDA for our highly anticipated ET-400 product candidate,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“It’s an exciting time for Eton as we continue to execute on our vision. With strong growth expected from our existing products, plus the additions of PKU GOLIKE and Nitisinone, we are positioned for a very strong 2024 as we gear up for the potential launch of ET-400 in early 2025,” concluded Brynjelsen.

First quarter and Recent Business Highlights

13th straight quarter of sequential growth in product sales and royalty revenue. Eton reported first quarter 2024 product sales of \$8.0 million, representing 50% growth over the prior year, driven primarily by the ongoing momentum of ALKINDI SPRINKLE® and Carglumic Acid. The Company expects sequential quarter-over-quarter growth of product sales to continue throughout 2024 and beyond.

Acquired U.S. rights to PKU GOLIKE, a medical formula for patients with phenylketonuria (PKU). An estimated 8,000 PKU patients in the U.S. rely on medical formulas such as PKU GOLIKE. The condition is managed by metabolic geneticists and their support staff, the same healthcare professionals that Eton is actively engaged with on its other metabolic products. The U.S. market for PKU medical formulas is estimated to be approximately \$100 million annually. With GOLIKE’s attractive product benefits and Eton’s commercial infrastructure, the Company’s goal is to capture at least 10% market share, or \$10 million annually, in the coming years.

Submitted NDA to the U.S. Food and Drug Administration (FDA) for ET-400. In April, Eton submitted an NDA for ET-400, its proprietary patented formulation of hydrocortisone oral solution. The anticipated 10-month review would allow for potential approval in the first quarter of 2025. The Company continues to see strong interest in the product candidate and believes that ET-400 and ALKINDI SPRINKLE can combine to achieve peak sales of over \$50 million annually.

Continued growth in ALKINDI SPRINKLE and Carglumic Acid. In the first quarter, the Company launched an ALKINDI SPRINKLE sampling program, which allows physicians to hold product and immediately start a patient on treatment. The Company estimates that Carglumic Acid has now captured over 50% of the patient population and continues to see new patient additions. The launches of Betaine and Nitisinone have further strengthened Eton’s relationships with the metabolic community and have helped increase the frequency of interactions with Carglumic Acid prescribers.

Launched rare disease product Nitisinone. The product was launched in February 2024 with full patient and provider support services. The Nitisinone market is estimated to be \$50 million annually, split across multiple participants. Eton expects to capture a share of the existing market and the Nitisinone launch should provide the Company with additional opportunities to cross-sell Carglumic Acid and PKU GOLIKE.

First Quarter Financial Results

Net Revenue: Net revenues for the first quarter of 2024 were \$8.0 million compared with \$5.3 million in the prior year period, an increase of 50%. The increase was driven primarily by growth in ALKINDI SPRINKLE and Carglumic Acid.

Gross Profit: Gross profit for the first quarter of 2024 was \$5.0 million compared with \$3.3 million in the prior year period, with the increase also driven primarily by growth in ALKINDI SPRINKLE and Carglumic Acid.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2024 were \$0.7 million compared to \$0.5 million in the prior year period due to increased development costs associated with product candidate ET-400 and other products in the Company’s R&D pipeline. While the Company expects an increase in second quarter R&D expenses with a \$2.0 million ET-400 filing fee, R&D spend for 2024 is forecasted to be approximately \$4.0 million excluding the one-time filing fee.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2024 were \$5.2 million compared to \$5.3 million in the prior year period, with the decrease due to a slight reduction in employee related expenses and logistics costs.

Net Income: Net loss for the first quarter of 2024 was \$0.8 million or \$0.03 per basic and diluted share compared to a net loss of \$2.7 million or \$0.10 per diluted share in the prior year period.

Cash Position: As of March 31, 2024, the Company had cash and cash equivalents of \$16.7 million and expects continued sales growth to result in positive operating cash flow throughout the remainder of 2024.

Conference Call and Webcast Information

As previously announced, Eton Pharmaceuticals will host a its first quarter 2024 conference call as follows:

Date May 9, 2024
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.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has five commercial rare disease products: ALKINDI SPRINKLE®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has three additional product candidates in late-stage development: ET-400, ET-600, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at www.etonpharma.com.

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.

Investor Relations:

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

	For the three months ended	
	March 31, 2024	March 31, 2023
Revenues:		
Licensing revenue	\$ —	\$ —
Product sales and royalties	7,966	5,304
Total net revenues	7,966	5,304
Cost of sales:		
Licensing revenue	—	—
Product sales and royalties	2,959	1,958
Total cost of sales	2,959	1,958
Gross profit	5,007	3,346
Operating expenses:		
Research and development	651	535
General and administrative	5,156	5,345
Total operating expenses	5,807	5,880
Loss from operations	(800)	(2,534)
Other income (expense):		
Other income	—	—
Interest expense, net	(11)	(126)
Total other income (expense)	(11)	(126)
Loss before income tax expense	(811)	(2,660)
Income tax expense	—	—
Net loss	\$ (811)	\$ (2,660)
Net loss per share, basic	\$ (0.03)	\$ (0.10)
Weighted average number of common shares outstanding, basic	25,763	25,525
Net loss per share, diluted	\$ (0.03)	\$ (0.10)
Weighted average number of common shares outstanding, diluted	25,763	25,525

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

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,655	\$ 21,388
Accounts receivable, net	4,240	3,411
Inventories	2,318	911
Prepaid expenses and other current assets	1,050	1,129
Total current assets	24,263	26,839
Property and equipment, net	57	58
Intangible assets, net	6,388	4,739
Operating lease right-of-use assets, net	74	92
Other long-term assets, net	12	12
Total assets	\$ 30,794	\$ 31,740
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,263	\$ 1,848
Current portion of debt, net of discount	5,020	5,380
Accrued liabilities	8,017	9,013
Total current liabilities	15,300	16,241
Operating lease liabilities, net of current portion	—	22
Total liabilities	15,300	16,263
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,690,562 and 25,688,062 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	26	26
Additional paid-in capital	120,349	119,521
Accumulated deficit	(104,881)	(104,070)
Total stockholders' equity	15,494	15,477
Total liabilities and stockholders' equity	\$ 30,794	\$ 31,740

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

	Three months ended March 31, 2024	Three months ended March 31, 2023
Cash flows from operating activities		
Net loss	\$ (811)	\$ (2,660)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	821	872
Depreciation and amortization	252	213
Debt discount amortization	25	29
Changes in operating assets and liabilities:		
Accounts receivable	(829)	(1,022)
Inventories	(1,407)	120
Prepaid expenses and other assets	79	191
Accounts payable	414	(530)
Accrued liabilities	(1,017)	1,239
Net cash used in operating activities	(2,473)	(1,548)
Cash flows from investing activities		
Purchases of product license rights	(1,868)	—
Purchases of property and equipment	(14)	—
Net cash used in investing activities	(1,882)	—
Cash flows from financing activities		
Repayment of long-term debt	(385)	—
Proceeds from stock option exercises	7	132
Payment of tax withholding related to net share settlement of stock option exercises	—	(181)
Net cash used in financing activities	(378)	(49)
Change in cash and cash equivalents	(4,733)	(1,597)
Cash and cash equivalents at beginning of period	21,388	16,305
Cash and cash equivalents at end of period	<u>\$ 16,655</u>	<u>\$ 14,708</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 190	\$ 216
Cash paid for income taxes	\$ —	\$ —