

**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

March 14, 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.

Item 2.02 Results of Operations and Financial Condition.

On March 14, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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

Exhibit 99.1 [Press Release issued by Eton Pharmaceuticals, Inc. on March 14, 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: March 14, 2024

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

Eton Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results

- Q4 2023 revenue of \$7.3 million, representing a 109% increase from Q4 2022, marking the twelfth consecutive quarter of sequential product sales growth
- Full year 2023 revenues reached \$31.6 million with product sales and royalty revenues of \$26.1 million, a 132% increase from 2022
- Announced successful results from ET-400's pivotal bioequivalence study, NDA submission planned for Q2 2024
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., MARCH 14, 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 and year ended December 31, 2023.

"We finished 2023 by delivering our twelfth straight quarter of sequential product sales growth and another quarter of positive operating cash flow. The growth trajectory continues for ALKINDI SPRINKLE® and Carglumic Acid, and we are excited for the company's prospects for 2024 and beyond," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

"In addition to the strong performance of our commercial products, we are pleased to report favorable developments in our pipeline. In recent weeks, we received positive study results for both ET-400 and ET-600, which brings both products one step closer to NDA submission. We look forward to submitting our NDA for ET-400 in the second quarter of this year and ET-600 early next year," concluded Brynjelsen.

Fourth Quarter and Recent Business Highlights

Twelfth straight quarter of sequential growth in product sales. Eton reported fourth quarter 2023 product sales and royalty revenue of \$7.3 million, representing a 109% year-over-year increase and 4% growth over the third quarter of 2023, driven primarily by the ongoing momentum of ALKINDI SPRINKLE and Carglumic Acid. The Company anticipates continued growth of product sales in 2024.

Recorded positive cash flow from operations. Eton generated \$0.4 million of operating cash during the fourth quarter of 2023, with total cash and cash equivalents of \$21.4 million as of December 31, 2023.

Passed pivotal bioequivalence study for ET-400. In February, Eton received preliminary data showing that ET-400, its proprietary formulation of oral hydrocortisone, passed its pivotal bioequivalence study. All other major filing pre-requisites have been completed, and the Company expects to submit the NDA to the FDA for ET-400 when the final clinical study report is available in the second quarter of 2024. This would allow for a potential FDA approval as early as the first quarter of 2025.

Awarded U.S. patent for ET-400. The patent, which covers the Company's proprietary formulation, expires in 2043 and is expected to be listed in the FDA's Orange Book upon the product's approval. The Company has additional patent applications related to the product under review with the United States Patent and Trademark Office.

Passed pilot bioequivalence study for ET-600. The Company plans to run the pivotal study in the second half of 2024, which would allow for a potential NDA submission in early 2025.

Initiated ALKINDI SPRINKLE sampling program. The Company's sampling program went live in February 2024, allowing pediatric endocrinology offices to stock ALKINDI SPRINKLE samples so that newly diagnosed or converting patients can immediately start therapy on ALKINDI SPRINKLE in the presence of their physician. Eton has already seen strong demand for samples from physicians and expects the sampling program to have a positive impact on adoption and 2024 revenue growth.

Launched ultra-rare disease product Nitisinone capsules. The product was launched in February 2024 with full patient and provider support services. Eton believes its commercial advantages, existing relationships with prescribers, and experienced sales force will allow the Company to capture a meaningful percentage of the \$50 million market.

Fourth Quarter Financial Results

Net Revenue: Net product sales and royalty revenues for the fourth quarter of 2023 increased by 109% to \$7.3 million compared to \$3.5 million in the prior year period, driven primarily by growth in ALKINDI SPRINKLE and Carglumic Acid. Total net revenues were \$7.3 million for the fourth quarter of 2023, compared to \$8.5 million for the fourth quarter of 2022. The prior year period included \$5.0 million in licensing revenue resulting from a milestone payment received from Azurity Pharmaceuticals.

Gross Profit: Gross profit for the fourth quarter of 2023 was \$3.6 million. Fourth quarter 2023 gross profit was negatively impacted by a \$1.0 million one-time payment to Diurnal PLC as a result of ALKINDI SPRINKLE net sales triggering a commercial success-based milestone under terms of the product's licensing agreement. Gross profit for the fourth quarter of 2022 was \$6.4 million and benefited from a \$5.0 million milestone payment received from Azurity Pharmaceuticals.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2023 were \$1.0 million compared to \$0.9 million in the prior year period.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2023 were \$4.6 million compared to \$4.4 million in the prior year period. The slight increase in G&A expenses was primarily due to personnel additions.

Net Loss: Net loss for the fourth quarter of 2023 was \$2.3 million or \$0.09 per basic and diluted share compared to net income of \$0.9 million or \$0.04 per diluted share in the prior year period.

Cash Position: As of December 31, 2023, the Company had cash and cash equivalents of \$21.4 million.



Conference Call and Webcast Information

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

Date March 14, 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 four FDA-approved rare disease products, ALKINDI SPRINKLE®, 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)

	For the three months ended		For the years ended	
	(Unaudited)		December 31, 2023	December 31, 2022
	December 31, 2023	December 31, 2022		
Revenues:				
Licensing revenue	\$ —	\$ 5,000	\$ 5,500	\$ 10,000
Product sales and royalties, net	7,313	3,498	26,142	11,251
Total net revenues	7,313	8,498	31,642	21,251
Cost of sales:				
Licensing revenue	1,000	650	1,000	1,640
Product sales and royalties	2,683	1,488	9,581	5,293
Total cost of sales	3,683	2,138	10,581	6,933
Gross profit (loss)	3,630	6,360	21,061	14,318
Operating expenses:				
Research and development	1,047	944	3,322	3,996
General and administrative	4,575	4,354	18,931	18,582
Total operating expenses	5,622	5,298	22,253	22,578
Income (loss) from operations	(1,992)	1,062	(1,192)	(8,260)
Other (expense) income:				
Interest and other (expense) income, net	(17)	(150)	503	(761)
Gain on PPP loan forgiveness	—	—	—	—
Gain on equipment sale	—	—	—	—
Income (loss) before income tax expense	(2,008)	912	(689)	(9,021)
Income tax expense	247	—	247	—
Net income (loss)	\$ (2,256)	\$ 912	\$ (936)	\$ (9,021)
Net loss per share, basic	\$ (0.09)	\$ 0.04	\$ (0.04)	\$ (0.36)
Net loss per share, diluted	\$ (0.09)	\$ 0.04	\$ (0.04)	\$ (0.36)
Weighted average number of common shares outstanding, basic	25,741	25,381	25,645	25,146
Weighted average number of common shares outstanding, diluted	25,741	25,691	25,645	25,146

Eton Pharmaceuticals, Inc.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,388	\$ 16,305
Accounts receivable, net	3,411	1,852
Inventories	911	557
Prepaid expenses and other current assets	1,129	1,290
Total current assets	26,839	20,004
Property and equipment, net	58	72
Intangible assets, net	4,739	4,754
Operating lease right-of-use assets, net	92	188
Other long-term assets, net	12	12
Total assets	\$ 31,740	\$ 25,030
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,848	\$ 1,766
Current portion of long-term debt	5,380	1,033
Accrued liabilities	9,013	3,662
Total current liabilities	16,241	6,461
Long-term debt, net of discount and including accrued fees	—	5,384
Operating lease liabilities, net of current portion	22	107
Total liabilities	16,263	11,952
Commitments and contingencies (Note 14)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,688,062 and 25,353,119 shares issued and outstanding at December 31, 2023 and 2022, respectively	26	25
Additional paid-in capital	119,521	116,187
Accumulated deficit	(104,070)	(103,134)
Total stockholders' equity	15,477	13,078
Total liabilities and stockholders' equity	\$ 31,740	\$ 25,030

Eton Pharmaceuticals, Inc.
STATEMENTS OF CASH FLOWS
(In thousands)

	December 31, 2023	December 31, 2022
Cash flows from operating activities		
Net loss	\$ (936)	\$ (9,021)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	3,137	4,218
Common stock issued for product candidate licensing rights	—	—
Depreciation and amortization	901	1,774
Debt discount amortization	117	127
Gain on forgiveness of PPP loan	—	—
Gain on sale of equipment	—	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,559)	3,619
Inventories	(354)	(7)
Prepaid expenses and other assets	161	1,902
Accounts payable	53	(8)
Accrued liabilities	5,295	2,217
Net cash provided by (used in) operating activities	6,815	4,821
Cash used in investing activities		
Proceeds from sale of equipment	—	—
Purchases of property and equipment	—	(38)
Purchase of product licensing rights	(775)	(2,750)
Net cash used in investing activities	(775)	(2,788)
Cash flows from financing activities		
Proceeds from issuance of long-term debt, net of issuance costs	—	—
Proceeds from sales of common stock, net of offering costs	—	—
Proceeds from PPP and EIDL loans	—	—
Debt paydown	(1,155)	(385)
Proceeds from employee stock purchase plan and stock option and stock warrant exercises	198	251
Net cash (used in) provided by financing activities	(957)	(134)
Change in cash and cash equivalents	5,083	1,899
Cash and cash equivalents at beginning of year	16,305	14,406
Cash and cash equivalents at end of year	<u>\$ 21,388</u>	<u>\$ 16,305</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 842	\$ 730
Cash paid for income taxes	\$ 247	\$ —
Supplemental disclosures of non-cash investing and financing activities:		
Adjustment of operating lease right-of-use assets and liabilities due to tenant allowance	\$ 29	\$ —
Right-of-use assets obtained in exchange for lease liabilities	\$ —	\$ 188