

**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

August 8, 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 August 8, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 8, 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: August 8, 2024

By: /s/ James R. Gruber

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

Eton Pharmaceuticals Reports Second Quarter 2024 Financial Results

- Product sales and royalty revenue of \$9.1 million, representing 40% growth over Q2 2023 and the 14th straight quarter of sequential product sales growth
- New drug application (NDA) for ET-400 accepted by the U.S. Food and Drug Administration (FDA) and assigned a February 28, 2025 PDUFA date
- Q2 2024 Cash Flow from Operations of \$1.3 million, including the payment of one-time \$2.0 million NDA filing fee for ET-400
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., August 8, 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 June 30, 2024.

“We are pleased to report another quarter of record product sales as Carglumic Acid and ALKINDI SPRINKLE® continue to deliver impressive growth. During the quarter we also launched PKU GOLIKE under our commercial infrastructure and received a favorable reception from the PKU community. Our five existing commercial products have the potential to deliver strong organic growth for many years to come, and we plan to accelerate that growth with our internal pipeline and business development activities” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“We have made tremendous recent progress advancing our pipeline, which we believe will set us up to deliver even greater growth in 2025 and beyond. Our NDA for ET-400 was recently accepted for review and assigned a target action date in early 2025. Pre-launch commercialization activities for the product are underway and we anticipate launching it shortly after the expected approval. In addition, our ET-600 product candidate is now ready to start its pivotal study in Q3, after passing a pilot study earlier this year. This should allow for an early 2025 NDA submission, which would further boost the Company’s long-term growth prospects” concluded Brynjelsen.

Second quarter and Recent Business Highlights

14th straight quarter of sequential growth in product sales and royalty revenue. Eton reported second quarter 2024 product sales of \$9.1 million, representing 40% growth over the prior year period, and 14% over the first quarter of 2024, driven primarily by the ongoing growth of ALKINDI SPRINKLE and Carglumic Acid. The Company expects to continue to see sequential quarter-over-quarter growth of product sales through the remainder of 2024 and beyond.

NDA for ET-400 submitted and accepted by the FDA. During the second quarter of 2024, Eton submitted an NDA for ET-400, its proprietary patented formulation of hydrocortisone oral solution. The FDA accepted the NDA and assigned it a Prescription Drug User Fee Act (PDUFA) target action date of February 28, 2025. Eton anticipates initiating production of launch quantities in the fourth quarter of 2024, to allow for a commercial launch promptly after the expected approval. Eton believes the introduction of ET-400 will allow the Company to capture a greater percentage of the oral hydrocortisone market and, together with ALKINDI SPRINKLE, can achieve combined peak sales of more than \$50 million annually.

Acceleration of growth for ALKINDI SPRINKLE. ALKINDI SPRINKLE reported 63% year over year revenue growth in Q2 2024. Product sales are benefiting from the Company’s internal sales force, which has now been in place for more than a year and has seen increased production, as well as recent initiatives including the launch of the sampling program and the Company’s strong presence at Endocrinology medical conferences and patient advocacy events in the first half of 2024.

Continued Carglumic Acid outperformance. Sales of Carglumic Acid continue to exceed the Company’s expectations. The product reported strong growth in the second quarter and has already added additional patients in the third quarter of 2024. The recent launches of Betaine Anhydrous, Nitisinone, and now PKU GOLIKE have also helped increase the frequency of the Company’s interactions with potential Carglumic Acid prescribers.

Launched PKU GOLIKE, a medical formula for patients with phenylketonuria (PKU). After acquiring PKU GOLIKE in the first quarter, the Company launched the product under Eton’s commercial infrastructure in April at the Genetic Metabolic Dieticians International Conference. The product has been well received and the Company has already seen an increased number of patient referrals since the initiation of its promotional activities.

Anticipated initiation of ET-600 pivotal study. Eton expects to initiate a pivotal bioequivalence study for ET-600, the Company’s product candidate for diabetes insipidus, in the third quarter. Earlier this year, the product passed its pilot bioequivalence study, and the company anticipates submitting an NDA for the product in early 2025

Second Quarter Financial Results

Net Revenue: Net sales for the second quarter of 2024 were \$9.1 million compared to \$12.0 million in the prior year period. Net sales in the prior year period included \$5.5 million of licensing payments related to the divestment of Eton's neurology product royalties.

Product sales and royalty revenue were \$9.1 million for the second quarter of 2024, an increase of 40% compared to \$6.5 million in the prior year period, and an increase of 14% over the first quarter of 2024. The year-over-year increase in product sales and royalty revenue was primarily driven by growth in ALKINDI SPRINKLE and Carglumic Acid.

Gross Profit: Gross profit for the second quarter of 2024 was \$5.6 million compared to \$9.7 million in the prior year period.

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2024 were \$3.0 million compared to \$1.1 million in the prior year period. The increase was primarily due to the payment of a \$2.0 million NDA filing fee for ET-400.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2024 were \$5.6 million compared to \$4.7 million in the prior year period, mainly due to increased sales and marketing expenses, employee-related expenses, and one-time legal fees related to business development activities.

Net Income: Net loss for the second quarter of 2024 was \$2.9 million or \$0.11 per basic and diluted share, including the \$2.0 million ET-400 filing fee. In the prior year period, net income was \$4.6 million, or \$0.18 per basic and diluted share, and included \$5.5 million from the sale of Eton's royalty interests.

Cash Position: As of June 30, 2024, Eton had cash and cash equivalents of \$17.7 million. The Company generated \$1.3 million of operating cash flow during the quarter, including the \$2.0 million ET-400 filing fee. The company expects to continue to generate positive operating cash flow for the remainder of 2024.

Conference Call and Webcast Information

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

Date August 8, 2024

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

Dial in* (Audio Only) [Click Here](#)

Webcast: [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 also 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:

Lisa M. Wilson, In-Site Communications, Inc.

T: 212-452-2793

E: lwilson@insitecony.com

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, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Revenues:				
Licensing revenue	\$ —	\$ 5,500	\$ —	\$ 5,500
Product sales and royalties	9,074	6,497	17,040	11,801
Total net revenues	9,074	11,997	17,040	17,301
Cost of sales:				
Licensing revenue	—	—	\$ —	\$ —
Product sales and royalties	3,448	2,315	6,407	4,273
Total cost of sales	3,448	2,315	6,407	4,273
Gross profit	5,626	9,682	10,633	13,028
Operating expenses:				
Research and development	2,970	1,125	3,621	1,660
General and administrative	5,591	4,674	10,747	10,019
Total operating expenses	8,561	5,799	14,368	11,679
Income (loss) from operations	(2,935)	3,883	(3,735)	1,349
Other income (expense):				
Other income	—	800	—	800
Interest expense, net	(52)	(124)	(63)	(250)
Total other income (expense)	(52)	676	(63)	550
Income (loss) before income tax expense	(2,987)	4,559	(3,798)	1,899
Income tax expense	54	—	54	—
Net income (loss)	\$ (3,041)	\$ 4,559	\$ (3,852)	\$ 1,899
Net income (loss) per share, basic	\$ (0.12)	\$ 0.18	\$ (0.15)	\$ 0.07
Weighted average number of common shares outstanding, basic	25,778	25,593	25,771	25,560
Net income (loss) per share, diluted	\$ (0.12)	\$ 0.18	\$ (0.15)	\$ 0.07
Weighted average number of common shares outstanding, diluted	25,778	25,983	25,771	25,949

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

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,694	\$ 21,388
Accounts receivable, net	4,873	3,411
Inventories	2,068	911
Prepaid expenses and other current assets	799	1,129
Total current assets	25,434	26,839
Property and equipment, net	45	58
Intangible assets, net	6,122	4,739
Operating lease right-of-use assets, net	210	92
Other long-term assets, net	12	12
Total assets	\$ 31,823	\$ 31,740
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,133	\$ 1,848
Debt, net of unamortized discount	4,658	5,380
Accrued liabilities	11,425	9,013
Total current liabilities	18,216	16,241
Operating lease liabilities, net of current portion	145	22
Total liabilities	18,361	16,263
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,745,802 and 25,688,062 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	26	26
Additional paid-in capital	121,358	119,521
Accumulated deficit	(107,922)	(104,070)
Total stockholders' equity	13,462	15,477
Total liabilities and stockholders' equity	\$ 31,823	\$ 31,740

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

	Six months ended June 30, 2024	Six months ended June 30, 2023
Cash flows from operating activities		
Net loss	\$ (3,852)	\$ 1,899
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	1,661	1,657
Depreciation and amortization	513	385
Non-cash lease expense	36	39
Debt discount amortization	48	61
Changes in operating assets and liabilities:		
Accounts receivable	(1,462)	(1,232)
Inventories	(1,157)	(259)
Prepaid expenses and other assets	330	423
Accounts payable	284	537
Accrued liabilities	2,381	2,045
Net cash (used in) provided by operating activities	(1,218)	5,555
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	(770)	(385)
Proceeds from employee stock purchase plan and stock option exercises	176	272
Payment of tax withholding related to net share settlement of stock option exercises	—	(181)
Net cash used in financing activities	(594)	(294)
Change in cash and cash equivalents	(3,694)	5,261
Cash and cash equivalents at beginning of period	21,388	16,305
Cash and cash equivalents at end of period	\$ 17,694	\$ 21,566
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 362	\$ 426
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosures of non-cash transactions in investing and financing activities		
Right-of-use assets and liabilities obtained due to lease renewal	\$ 153	\$ —