

**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 12, 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 November 12, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the third quarter ended September 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 November 12, 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: November 12, 2024

By: /s/ James R. Gruber

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

Eton Pharmaceuticals Reports Third Quarter 2024 Financial Results

- Reported total revenue of \$10.3 million and GAAP Net Income of \$0.6 million or \$0.02 per diluted share
- Entered into an asset purchase agreement to acquire Increlex® (mecasermin injection)
- Q3 2024 product sales increased 40% over Q3 2023, representing 15th straight quarter of sequential product sales growth
- Produced positive quarterly GAAP net income from product sales for first time in company history
- Generated cash from operations of \$2.9 million in Q3 2024
- Granted additional patent for ET-400
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., November 12, 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 September 30, 2024.

“Our strong product revenue growth in the third quarter allowed us to achieve positive GAAP net income from product revenue for the first time in the Company’s history and we’re pleased to reach this important milestone one quarter ahead of our original goal. We are proud of our ability to continue delivering exceptional growth, as demonstrated by our 15th straight quarter of sequential growth in product revenue, while managing the bottom line,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“This milestone is just the beginning of Eton’s growth story. With the upcoming closing of the Increlex acquisition and our ET-400 PDUFA date approaching, 2025 is shaping up to be a transformational year for Eton. We are very excited about what we can achieve in the coming quarters and years,” concluded Brynjelsen.

Third Quarter and Recent Business Highlights

Delivered 15th straight quarter of sequential growth in product sales and reported positive GAAP net income. Eton reported third quarter 2024 product sales of \$9.8 million, representing 40% growth over the prior year period, and 8% over the second quarter of 2024, driven primarily by the ongoing growth of ALKINDI SPRINKLE and Carglumic Acid. During the quarter, Eton produced positive GAAP net income for the first time in Company history from product revenue alone.

Entered into an asset purchase agreement to acquire Increlex® (mecasermin injection) from Ipsen S.A. The transaction, which was announced in October, will add a high-value biologic product to the Company’s commercial portfolio. The product is synergistic with Eton’s existing pediatric endocrinology call point, and the acquisition is expected to be accretive to 2025 earnings. The Company anticipates the transaction closing near year-end 2024.

New Drug Application (NDA) for ET-400 accepted by the U.S. Food and Drug Administration (FDA). In July, the FDA accepted Eton’s NDA for ET-400, its proprietary patented formulation of hydrocortisone oral solution and assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of February 28, 2025. Eton expects to manufacture product inventory in the fourth quarter of 2024 to enable a commercial launch promptly after the expected approval in 2025. The Company believes the introduction of ET-400 will enable it to capture a greater percentage of the oral hydrocortisone market and, together with ALKINDI SPRINKLE, the two products are expected to achieve combined peak sales of more than \$50 million annually.

Granted additional patent for ET-400. On November 5, Eton was granted an additional patent for ET-400 by the United States Patent & Trademark Office (USPTO), further strengthening the IP protection for the product. The patent, which expires in 2043, covers hydrocortisone oral liquid formulations and is expected to be listed in the FDA’s Orange Book upon ET-400’s approval.

Strong growth of ALKINDI SPRINKLE and the Company’s metabolic portfolio. ALKINDI SPRINKLE reported 55% year over year revenue growth in Q3 2024. Carglumic Acid also reported another quarter of strong sequential and year-over-year growth. The commercial availability of Betaine Anhydrous, Nitisinone, and PKU GOLIKE® has helped increase the frequency of the Company’s interactions with potential Carglumic Acid prescribers.

Initiation of ET-600 pivotal study. ET-600’s pivotal bioequivalence study has been initiated. ET-600 is under development for the treatment of the pediatric endocrinology condition diabetes insipidus. If the study results are positive, Eton anticipates submitting an NDA for the product in the first quarter of 2025.

Third Quarter Financial Results

Net Revenue: Net sales for the third quarter of 2024 were \$10.3 million compared to \$7.0 million in the prior year period. Net sales in the current year period included \$0.5 million of licensing payments received from out-licensing of the company's DS-200 product.

Product sales and royalty revenue were \$9.8 million for the third quarter of 2024, an increase of 40% compared to \$7.0 million in the prior year period, and an increase of 8% over the second quarter of 2024. The year-over-year increase in product sales revenue was primarily driven by growth in ALKINDI SPRINKLE and Carglumic Acid.

Gross Profit: Gross profit for the third quarter of 2024 was \$6.3 million compared to \$4.4 million in the prior year period.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2024 were \$0.5 million compared to \$0.6 million in the prior year period as a result of decreased expenses associated with ET-400 project development activities.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2024 were \$5.3 million compared to \$4.3 million in the prior year period, mainly due to increased sales and marketing activities, legal expenses, and employee-related expenses.

Net Income: Net income for the third quarter of 2024 was \$0.6 million or \$0.02 per basic and diluted share. In the prior year period, net loss was \$0.6 million, or \$0.02 per basic and diluted share.

Cash Position: As of September 30, 2024, Eton had cash and cash equivalents of \$20.3 million. The Company generated \$2.9 million of operating cash flow during the quarter. The Company expects to generate positive cash flow in the fourth quarter and to fund its acquisition of Increlex with cash on hand and an expansion of its existing credit facility.

Conference Call and Webcast Information

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

Date	November 12, 2024
Time	4:30 p.m. ET (3:30 p.m. CT)
Dial in* (Audio Only)	Toll-free: 888-596-4144 Non-toll free: 646-968-2525 Access Code: 1144771
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.

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

	For the three months ended		For the nine months ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Revenues:				
Licensing revenue	\$ 500	\$ —	\$ 500	\$ 5,500
Product sales and royalties	9,824	7,028	26,864	18,829
Total net revenues	10,324	7,028	27,364	24,329
Cost of sales:				
Licensing revenue	270	—	270	—
Product sales and royalties	3,752	2,625	10,159	6,898
Total cost of sales	4,022	2,625	10,429	6,898
Gross profit	6,302	4,403	16,935	17,431
Operating expenses:				
Research and development	505	615	4,126	2,275
General and administrative	5,288	4,336	16,035	14,355
Total operating expenses	5,793	4,951	20,161	16,630
Income (loss) from operations	509	(548)	(3,226)	801
Other income (expense):				
Other income	—	—	—	800
Interest expense, net	(8)	(31)	(71)	(281)
Total other income (expense)	(8)	(31)	(71)	519
Income (loss) before income tax expense	501	(579)	(3,297)	1,320
Income tax expense (benefit)	(126)	—	(72)	—
Net income (loss)	\$ 627	\$ (579)	\$ (3,225)	\$ 1,320
Net income (loss) per share, basic	\$ 0.02	\$ (0.02)	\$ (0.12)	\$ 0.05
Weighted average number of common shares outstanding, basic	25,900	25,719	25,814	25,613
Net income (loss) per share, diluted	\$ 0.02	\$ (0.02)	\$ (0.12)	\$ 0.05
Weighted average number of common shares outstanding, diluted	26,550	25,719	25,814	26,002

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

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,261	\$ 21,388
Accounts receivable, net	5,591	3,411
Inventories	1,938	911
Prepaid expenses and other current assets	1,959	1,129
Total current assets	29,749	26,839
Property and equipment, net	33	58
Intangible assets, net	5,854	4,739
Operating lease right-of-use assets, net	193	92
Other long-term assets, net	12	12
Total assets	\$ 35,841	\$ 31,740
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,684	\$ 1,848
Debt, net of unamortized discount	4,125	5,380
Accrued Medicaid rebates	8,047	3,627
Other accrued liabilities	4,878	5,386
Total current liabilities	19,734	16,241
Operating lease liabilities, net of current portion	126	22
Total liabilities	19,860	16,263
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,836,204 and 25,688,062 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	26	26
Additional paid-in capital	123,250	119,521
Accumulated deficit	(107,295)	(104,070)
Total stockholders' equity	15,981	15,477
Total liabilities and stockholders' equity	\$ 35,841	\$ 31,740

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

	Nine months ended September 30, 2024	Nine months ended September 30, 2023
Cash flows from operating activities		
Net Income (loss)	\$ (3,225)	\$ 1,320
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Stock-based compensation	2,383	2,387
Depreciation and amortization	791	576
Non-cash lease expense	53	50
Debt discount amortization	70	90
Changes in operating assets and liabilities:		
Accounts receivable	(2,179)	(1,643)
Inventories	(1,027)	(494)
Prepaid expenses and other assets	171	749
Accounts payable	836	(52)
Accrued Medicaid rebates	4,420	2,342
Other accrued liabilities	(559)	1,103
Net cash from operating activities	1,734	6,428
Cash flows from investing activities		
Purchases of product license rights	(1,868)	—
Purchases of property and equipment	(14)	—
Net cash from investing activities	(1,882)	—
Cash flows from financing activities		
Repayment of long-term debt	(1,155)	(770)
Proceeds from employee stock purchase plan and stock option exercises	176	288
Payment of tax withholding related to net share settlement of stock option exercises	—	(181)
Net cash from financing activities	(979)	(663)
Change in cash and cash equivalents	(1,127)	5,765
Cash and cash equivalents at beginning of period	21,388	16,305
Cash and cash equivalents at end of period	<u>\$ 20,261</u>	<u>\$ 22,070</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 525	\$ 638
Cash paid for income taxes	\$ 181	\$ —
Right-of-use assets and liabilities obtained due to lease renewal	\$ 153	\$ 29
Supplemental disclosures of non-cash transactions in investing and financing activities		
Relative fair value of warrants issued in connection with debt	\$ 1,170	\$ —