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 18, 2025

Date of Report (Date of earliest event reported)

ETON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38738**	**37-1858472**
(State of incorporation)	**(Commission File Number)**	**(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 18, 2025, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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.

Item 9.01 Financial Statements and Exhibits

Exhibit 99.1	Press Release issued by Eton Pharmaceuticals, Inc. on March 18, 2025 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 18, 2025

By: */s/ James R. Gruber*

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

Exhibit 99.1

Eton Pharmaceuticals Reports Fourth Quarter 2024 Financial Results
Management to Hold Investor Day Conference Call Today at 10:00am ET

- Reported record product revenue of $11.6 million in Q4 2024, an increase of 59% over Q4 2023, representing the 16th straight quarter of sequential product sales growth
- Closed the transformational acquisition of pediatric endocrinology biologic Increlex® and relaunched the product in January
- Acquired and relaunched ultra rare disease product Galzin®
- Licensed U.S. rights to late-stage pipeline candidate Amglidia®, further boosting the Company's pediatric endocrinology pipeline
- Announced positive pivotal clinical study results for ET-600; preparing for an April 2025 NDA submission
- Manufactured ET-400 launch inventory in preparation for a potential approval on its PDUFA goal date of May 28
- Management to hold Investor Day conference call today at 10:00am ET to discuss its recent acquisitions and review its product portfolio, market opportunities, and 2025 and long-term financial outlook

DEER PARK, Ill., March 18, 2025 (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 December 31, 2024.

"The fourth quarter of 2024 was the most transformational in Eton's history. We closed the pivotal acquisition of Increlex, acquired another high-value rare disease product in Galzin, and boosted our product pipeline with the license of Amglidia and the initiation of two exciting new internal development projects, ET-700 and ET-800. We completed all this while continuing to execute on our base business, delivering record product sales and our 16th straight quarter of sequential revenue growth," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

"We are poised for an acceleration of growth in 2025. Increlex was relaunched in January with our now fully dedicated pediatric endocrinology sales force and is already adding new patients at a pace well ahead of our expectations. Galzin was relaunched in March with our newly deployed metabolic sales force and has been well received by the Wilson disease community. Launch inventory for ET-400 has been manufactured and our team stands ready to launch the product within days of its PDUFA goal date of May 28, if approved. Finally, ET-600's successful pivotal study results allow us to file an additional high-value NDA in the coming weeks." concluded Brynjelsen.

Fourth Quarter and Recent Business Highlights

Delivered 16th straight quarter of sequential growth in product sales. Eton reported fourth quarter 2024 net sales of $11.6 million, an increase of 59% over the prior year period, driven primarily by strong growth of ALKINDI SPRINKLE® and Carglumic Acid. The company expects sequential growth in quarterly product revenue to continue through 2025 and beyond.

Relaunched Increlex, which is tracking ahead of expectations. Increlex is a highly durable, complex biologic used for the treatment of an ultra-rare pediatric endocrinology condition that is estimated to impact approximately 200 children in the U.S. Eton closed the acquisition in late December and relaunched the product in the United States in January. The Company intends to leverage its existing sales team and relationships in the pediatric endocrinology community to promote the product and increase awareness of this underdiagnosed and undertreated condition. The launch has seen strong initial results, with numerous new patients added in January, February, and the first half of March.

Awarded second patent for ET-400 and preparing for potential launch. During the fourth quarter, Eton was granted an additional patent for ET-400 by the United States Patent & Trademark Office (USPTO). The patent, which expires in 2043, covers hydrocortisone oral liquid formulations and is expected to be listed in the FDA's Orange Book upon approval. The Company has successfully manufactured launch quantities for the product and its sales and promotional campaigns are ready to go live. If approved on its May 28 Prescription Drug User Fee Act (PDUFA) goal date, the Company anticipates being in position to quickly launch the product.

Acquired and re-launched Galzin. In January, Eton added the ultra-rare disease commercial product Galzin to its metabolic portfolio. Seeing the need for improved patient experience, increased awareness, and broader access and affordability, the Company relaunched Galzin on March 3 with its newly deployed metabolic sales force and robust Eton Cares patient support service. The Eton Cares patient support program ensures patients can access Galzin with $0 co-pays, patient assistance, reimbursement support, and overnight shipments.

Announced positive pivotal study results for ET-600 and the issuance of a patent. ET-600 passed its pivotal bioequivalence study, successfully demonstrating pharmacokinetic equivalence to the reference product. In addition, the Company was issued a patent covering the product's proprietary formulation of desmopressin oral solution. The patent expires in 2044 and is expected to be listed in the FDA's Orange Book upon the product's approval. Eton is preparing to submit an NDA for ET-600 in April, which could allow for approval in the first quarter of 2026.

Disclosed two new internal development programs, ET-700 and ET-800. The Company has two new, high-value product candidates under development internally. More details regarding these previously undisclosed programs will be shared during Eton's Investor Day conference call.

Acquired U.S. rights to Amglidia (glyburide oral suspension). Amglidia, which has been approved in the E.U. since 2018, is under development in the U.S. for the treatment of neonatal diabetes mellitus and has been granted Orphan Drug Designation by the FDA. Amglidia is a strong strategic fit with Eton's existing pediatric endocrinology portfolio, and the Company has a meeting scheduled with the FDA in April 2025 to discuss the product's clinical pathway.

Fourth Quarter Financial Results

Net Revenue: Total net revenues for the fourth quarter of 2024 increased 59% to $11.6 million compared to $7.3 million in the prior year period, driven primarily by growth in ALKINDI SPRINKLE and Carglumic Acid. The Increlex and Galzin acquisitions closed in late December and contributed less than $0.2 million of revenue in the quarter.

Gross Profit: Gross profit for the fourth quarter of 2024 was $6.5 million, compared to gross profit of $3.6 million for the fourth quarter of 2023. The increase was primarily due to increased product sales. In addition, fourth quarter 2023 gross profit was negatively impacted by $1.0 million as a result of ALKINDI SPRINKLE net sales triggering a one-time commercial success-based milestone under the terms of the product's licensing agreement.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2024 were $(0.9) million compared to $1.0 million in the prior year period. During the fourth quarter of 2024, Eton's ET-400 product was granted Orphan Drug Designation by the FDA, which resulted in Eton receiving a refund of the NDA filing fee that was paid and expensed in the second quarter of 2024.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2024 were $6.7 million compared to $4.6 million in the prior year period. The increase was primarily due to personnel additions and increased sales and marketing investments that were initiated in the fourth quarter of 2024 to support the 2025 launches of Increlex, Galzin, and ET-400, as well as Increlex related transaction costs.

Net Loss: Net loss for the fourth quarter of 2024 was $0.6 million or $0.02 per basic and diluted share compared to a net loss of $2.3 million or $0.09 per basic and diluted share in the prior year period.

Cash Position: As of December 31, 2024, Eton had cash and cash equivalents of $14.9 million.

Conference Call and Webcast Information

As previously announced, Eton Pharmaceuticals will hold a virtual Investor Day and report fourth quarter 2024 financial results on Tuesday, March 18, 2025, beginning at 10:00 a.m. ET (9:00 a.m. CT).

To participate, please click here to register. An archived webcast will be available on the Investors section of Eton's website approximately two hours after the completion of the event and for 30 days thereafter.

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.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has seven commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has six additional product candidates in late-stage development: ET-400, ET-600, Amglidia®, ET-700, ET-800 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.

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Eton Pharmaceuticals, Inc.
STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	For the three months ended (Unaudited)		For the years ended	
	December 31, 2024	**December 31, 2023**	**December 31, 2024**	**December 31, 2023**
Revenues:				
Licensing revenue	$ —	$ —	$ 500	$ 5,500
Product sales and royalties, net	11,647	7,313	38,511	26,142
Total net revenues	**11,647**	**7,313**	**39,011**	**31,642**
Cost of sales:				
Licensing revenue	—	1,000	270	1,000
Product sales and royalties	5,171	2,683	15,330	9,581
Total cost of sales	**5,171**	**3,683**	**15,600**	**10,581**
Gross profit	**6,476**	**3,630**	**23,411**	**21,061**
Operating expenses:				
Research and development	(871)	1,047	3,255	3,322
General and administrative	6,718	4,575	22,753	18,931
Total operating expenses	**5,847**	**5,622**	**26,008**	**22,253**
Income (loss) from operations	**629**	**(1,992)**	**(2,597)**	**(1,192)**
Other (expense) income:				
Interest and other (expense) income, net	(1,140)	(17)	(1,211)	503
Loss before income tax expense	**(511)**	**(2,009)**	**(3,808)**	**(689)**
Income tax expense	87	247	15	247
Net loss	**$ (598)**	**$ (2,256)**	**$ (3,823)**	**$ (936)**
Net loss per share, basic and diluted	**$ (0.02)**	**$ (0.09)**	**$ (0.15)**	**$ (0.04)**
Weighted average number of common shares outstanding, basic and diluted	26,136	25,741	25,895	25,645

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 14,936	$ 21,388
Accounts receivable, net	5,361	3,411
Inventories, net	15,232	911
Prepaid expenses and other current assets	5,492	1,129
Total current assets	**41,021**	**26,839**
Property and equipment, net	34	58
Intangible assets, net	34,881	4,739
Operating lease right-of-use assets, net	175	92
Other long-term assets, net	12	12
Total assets	$ **76,123**	$ **31,740**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,167	$ 1,848
Current portion of long-term debt, net of discount	—	5,380
Accrued Medicaid rebates	6,866	3,627
Accrued liabilities	8,914	5,386
Total current liabilities	**19,947**	**16,241**
Long-term debt, net of discount and including accrued fees	29,811	—
Operating lease liabilities, net of current portion	107	22
Other long-term liabilities	1,830	—
Total liabilities	**51,695**	**16,263**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized; 26,709,084 and 25,688,062 shares issued and outstanding at December 31, 2024 and 2023, respectively	27	26
Additional paid-in capital	132,294	119,521
Accumulated deficit	(107,893)	(104,070)
Total stockholders' equity	**24,428**	**15,477**
Total liabilities and stockholders' equity	$ **76,123**	$ **31,740**

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

	For the three months ended (Unaudited)		For the years ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
Cash flows from operating activities				
Net loss	$ (598)	$ (2,256)	$ (3,823)	$ (936)
Adjustments to reconcile net loss to net cash from operating activities:				
Stock-based compensation	782	750	3,165	3,137
Depreciation and amortization	355	325	1,146	901
Non-cash lease expense	17	17	70	67
Debt discount amortization	1,039	27	1,109	117
Changes in operating assets and liabilities, net of impact of business acquisition:			—	—
Accounts receivable	(939)	84	(3,118)	(1,559)
Inventories	(283)	140	(1,310)	(354)
Prepaid expenses and other assets	(3,520)	(655)	(3,349)	94
Accounts payable	1,482	105	2,318	53
Accrued Medicaid rebates	(1,181)	476	3,239	2,818
Accrued liabilities	2,043	1,374	1,484	2,477
Other non-current assets and liabilities	38	—	38	—
Net cash from operating activities	**(765)**	**387**	**969**	**6,815**
Cash from investing activities				
Purchases of property and equipment	(12)	—	(26)	—
Acquisition of business	(30,000)	—	(30,000)	—
Purchase of product licensing rights	(8,120)	(775)	(9,988)	(775)
Net cash from investing activities	**(38,132)**	**(775)**	**(40,014)**	**(775)**
Cash flows from financing activities				
Net proceeds from the issuance of long-term debt	25,309	—	25,309	—
Repayment of long-term debt	—	(385)	(1,155)	(1,155)
Common stock issued in private placement offering	7,000	—	7,000	—
Proceeds from stock option exercises	1,015	—	1,191	148
Payment of tax withholding related to net share settlement of stock option exercises	—	—	—	(180)
Employee stock purchase plan	108	91	248	229
Stock warrant exercises	—	—	—	—
Net cash from financing activities	**33,432**	**(294)**	**32,593**	**(958)**
Change in cash and cash equivalents	**(5,465)**	**(682)**	**(6,452)**	**5,082**
Cash and cash equivalents at beginning of period	20,401	22,070	**21,388**	**16,305**
Cash and cash equivalents at end of period	$ 14,936	$ 21,388	$ 14,936	$ 21,388
Supplemental disclosures of cash flow information				
Cash paid for interest	$ 140	$ 204	$ 665	$ 842
Cash paid for income taxes	$ (99)	$ 247	$ 82	$ 247
Supplemental disclosures of non-cash investing and financing activities:				
Debt issuance costs	$ 386	$ —	$ 386	$ —
Fair value of warrants issued in connection with debt agreement	$ —	$ —	$ 1,171	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ 66	$ —	$ 219	$ 29