

**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**

**Date of Report (Date of earliest event reported): March 16, 2023**

**Eton Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38738**  
(Commission  
File Number)

**37-1858472**  
(IRS Employer  
Identification No.)

**21925 W. Field Parkway, Suite 235**  
**Deer Park, Illinois**  
(Address of Principal Executive Offices)

**60010-7278**  
(Zip Code)

Registrant's telephone number, including area code: **(847) 787-7361**

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))

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.

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class                       | Trading Symbol | Name of each exchange on which registered |
|---|----------------|---|
| Common Stock, \$0.001 par value per share | ETON           | NASDAQ Global Market                      |

**Item 2.02. Results of Operations and Financial Condition**

On March 16, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022. 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.**

(d) Exhibits

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 99.1               | <a href="#">Press release issued by Eton Pharmaceuticals, Inc. on March 16, 2023 relating to financial results</a> |
| 104                | Cover Page Interactive Data File (embedded within the Inline XBRL document)  |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Eton Pharmaceuticals, Inc.**

Date: March 16, 2023

*/s/ James Gruber*

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James Gruber  
Chief Financial Officer and Secretary

## Eton Pharmaceuticals Reports Fourth Quarter 2022 Financial Results

- Q4 2022 revenue of \$8.5 million
- Q4 Product sales and royalty revenue up 220% from prior year and 9% from Q3
  - Q4 positive net income
- Management to hold conference call today at 4:30pm ET

DEER PARK, Ill., MARCH 16, 2023 (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, 2022.

“The fourth quarter was another impressive quarter for Eton, fueled by the continued momentum of ALKINDI SPRINKLE and Carglumic Acid. It was our eighth straight quarter of sequential revenue growth in product and royalty revenue, and we expect that strong growth to continue throughout 2023 and beyond,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“Our excitement level for 2023 could not be higher and we believe we can at least double our product sales and royalty revenue this year. ALKINDI SPRINKLE and Carglumic Acid were already poised to deliver major growth in 2023, and we have now completed our sales force expansion which is expected to accelerate their growth, plus we have the planned launch of Betaine in the coming weeks and the anticipated launch of dehydrated alcohol injection later in the year,” continued Brynjelsen.

### Fourth Quarter and Recent Business Highlights

**Eighth straight quarter of sequential growth in product sales and royalty revenue.** Eton reported fourth quarter 2022 product sales and royalty revenue of \$3.5 million, representing 220% growth over the prior year and 9% growth over the third quarter of 2022. Fourth quarter 2022 product sales were negatively impacted by a slowdown in new patient adds during the holiday season and the timing of ALKINDI SPRINKLE® product orders from the Company’s specialty pharmacy customer. The Company expects the sequential growth rate to increase in the first quarter of 2023 compared to the fourth quarter of 2022.

**Launch of Eton’s expanded rare disease sales force.** In January 2023, Eton exercised its right to exit its ALKINDI SPRINKLE co-promotion agreement. Given the significant growth of ALKINDI SPRINKLE in 2022 and the expected growth in 2023, the sales commission to Eton’s co-promotion partner was expected to be approximately the same cost as internally expanding to a full-sized sales force. Eton’s sales force is now fully staffed with twelve rare disease specialists that have been deployed into the field. The new sales force will be solely focused on Eton’s products and will allow Eton to exercise significantly greater control over sales force strategies, incentive plans, and personnel decisions. In addition to providing greater attention to ALKINDI SPRINKLE, the sales force will increase the promotional presence of Carglumic Acid and support the upcoming launch of Betaine.

**Continued strong growth of Carglumic Acid.** The Company’s Carglumic Acid product, which was FDA-approved in October 2021 for the treatment of hyperammonemia due to N-acetylglutamate synthase deficiency, continued to see increased adoption in the fourth quarter of 2022, and the product is off to a strong start in 2023, with notable new patient adds. The launch of Betaine is expected to help drive additional interactions with key metabolic geneticists and may provide benefits to Carglumic Acid prescriptions.

**Increasing adoption of ALKINDI SPRINKLE.** ALKINDI SPRINKLE, which is FDA-approved for the treatment of pediatric patients with adrenocortical insufficiency, saw strong growth of active patients in the fourth quarter of 2022. The Company expects the product’s future growth rate to benefit from the new dedicated sales force. The Company also launched a new direct-to-consumer marketing campaign in the first quarter of 2023.

**Actively preparing for Betaine Anhydrous launch.** The product, which Eton acquired in late 2022 and is FDA-approved for the treatment of homocystinuria, is expected to be commercially available in the coming weeks. The product’s launch inventory has been manufactured and is now undergoing final packaging and release testing. The Company has already received strong interest in the product from patients, prescribers, and advocacy groups.

**Acquired rare disease product candidate ET-600.** Earlier this week, Eton announced the acquisition of an innovative product candidate targeting a rare pediatric endocrinology condition. Eton expects to file a New Drug Application (NDA) for the product in the second quarter of 2024.

**Completed Dehydrated Alcohol Injection Submission.** In the fourth quarter, the Company submitted a response to the U.S. Food and Drug Administration (FDA) for its dehydrated alcohol injection NDA for the Orphan Drug Designated condition of methanol poisoning. The submission was accepted for review and assigned a target action date of June 27, 2023. Eton is actively working with its commercialization partner on launch preparation activities. Based on IQVIA data, the market for dehydrated alcohol injection is more than \$70 million annually.

**Continued progress on ET-400.** ET-400 is an innovative, patent pending product candidate. If approved, the Company would promote the product alongside ALKINDI SPRINKLE and it would be expected to help the Company more rapidly penetrate the \$100 million market opportunity in pediatric adrenal insufficiency. Eton expects to submit an NDA for the product by the end of 2023, which could allow for an approval and launch of the product in 2024.

#### **Fourth Quarter Financial Results**

**Net Revenue:** Net revenues for the fourth quarter of 2022 were \$8.5 million compared with \$6.1 million in the prior year period, driven by growth in ALKINDI SPRINKLE and the launch of Carglumic Acid in December 2021. Both periods included \$5.0 million in licensing revenue as a result of milestone payments received from Azurity Pharmaceuticals.

**Gross Profit:** Gross profit for the fourth quarter of 2022 was \$6.4 million compared with \$5.7 million in the prior year period.

**Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2022 were \$0.9 million compared to \$0.7 million in the prior year period.

**General and Administrative (G&A) Expenses:** G&A expenses for the fourth quarter of 2022 were \$4.4 million compared to \$3.7 million in the prior year period. Cash G&A expenses for the fourth quarter of 2022 were \$3.5 million, compared to \$3.0 million in the prior year period. The increase in G&A expenses was mainly due to incremental marketing and compensation to support product sales growth, partially offset by lower legal and consulting expenses.

**Net Income:** Net income for the fourth quarter of 2022 was \$0.9 million or \$0.04 per basic and diluted share compared to a net income of \$1.0 million or \$0.04 per diluted share in the prior year period.

**Cash Position:** As of December 31, 2022, the Company had cash and cash equivalents of \$16.3 million.

#### **Conference Call and Webcast Information**

As previously announced, Eton Pharmaceuticals will host its fourth quarter 2022 conference call today at 4:30 p.m. ET (3:30 p.m. CT). The webcast can be accessed under “Events & Presentations” in the Investors section of the Company’s website at <https://ir.etonpharma.com>. The webcast will be archived and made available for replay on the Company’s website approximately two hours after the call and will be available for 30 days.

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## 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.

## About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has three FDA approved products in ALKINDI SPRINKLE®, Carglumic Acid tablets, and Betaine Anhydrous for oral solution, and four late-stage pipeline candidates under development with dehydrated alcohol injection, ZENEO® hydrocortisone autoinjector, ET-400, and ET-600. In addition, the Company receives royalties on three FDA-approved products and is entitled to receive milestone payments on other products. For more information, please visit our website at [www.etonpharma.com](http://www.etonpharma.com).

### 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,<br>2022       | December 31,<br>2021 | December 31,<br>2022 | December 31,<br>2021 |
| <b>Revenues:</b>  |                            |                      |                      |                      |
| Licensing revenue   | \$ 5,000                   | \$ 5,000             | \$ 10,000            | \$ 19,000            |
| Product sales and royalties, net                              | 3,498                      | 1,093                | 11,251               | 2,832                |
| <b>Total net revenues</b>                                     | <b>8,498</b>               | <b>6,093</b>         | <b>21,251</b>        | <b>21,832</b>        |
| <b>Cost of sales:</b>   |                            |                      |                      |                      |
| Licensing revenue   | 650                        | —                    | 1,640                | 1,500                |
| Product sales and royalties                                   | 1,488                      | 371                  | 5,293                | 1,327                |
| <b>Total cost of sales</b>                                    | <b>2,138</b>               | <b>371</b>           | <b>6,933</b>         | <b>2,827</b>         |
| <b>Gross profit (loss)</b>                                    | <b>6,360</b>               | <b>5,722</b>         | <b>14,318</b>        | <b>19,005</b>        |
| <b>Operating expenses:</b>                                    |                            |                      |                      |                      |
| Research and development                                      | 944                        | 681                  | 3,996                | 6,235                |
| General and administrative                                    | 4,354                      | 3,727                | 18,582               | 14,265               |
| <b>Total operating expenses</b>                               | <b>5,298</b>               | <b>4,408</b>         | <b>22,578</b>        | <b>20,500</b>        |
| <b>Income (loss) from operations</b>                          | <b>1,062</b>               | <b>1,314</b>         | <b>(8,260)</b>       | <b>(1,495)</b>       |
| <b>Other (expense) income:</b>                                |                            |                      |                      |                      |
| Interest and other (expense) income, net                      | (150)                      | (275)                | (761)                | (1,006)              |
| Gain on PPP loan forgiveness                                  | —                          | —                    | —                    | 365                  |
| Gain on equipment sale  | —                          | —                    | —                    | 181                  |
| <b>Income (loss) before income tax expense</b>                | <b>912</b>                 | <b>1,039</b>         | <b>(9,021)</b>       | <b>(1,955)</b>       |
| Income tax expense  | —                          | —                    | —                    | —                    |
| <b>Net income (loss)</b>                                      | <b>\$ 912</b>              | <b>\$ 1,039</b>      | <b>\$ (9,021)</b>    | <b>\$ (1,955)</b>    |
| <b>Net loss per share, basic</b>                              | <b>\$ 0.04</b>             | <b>\$ 0.04</b>       | <b>\$ (0.36)</b>     | <b>\$ (0.08)</b>     |
| <b>Net loss per share, diluted</b>                            | <b>\$ 0.04</b>             | <b>\$ 0.04</b>       | <b>\$ (0.36)</b>     | <b>\$ (0.08)</b>     |
| Weighted average number of common shares outstanding, basic   | 25,381                     | 25,285               | 25,146               | 25,207               |
| Weighted average number of common shares outstanding, diluted | 25,691                     | 25,957               | 25,146               | 25,207               |

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

|  | <b>December 31, 2022</b> | <b>December 31, 2021</b> |
|--|--------------------------|--------------------------|
| <b>Assets</b>  |                          |                          |
| <b>Current assets:</b>   |                          |                          |
| Cash and cash equivalents  | \$ 16,305                | \$ 14,406                |
| Accounts receivable, net   | 1,852                    | 5,471                    |
| Inventories  | 557                      | 550                      |
| Prepaid expenses and other current assets  | 1,290                    | 3,177                    |
| <b>Total current assets</b>  | <b>20,004</b>            | <b>23,604</b>            |
| Property and equipment, net  | 72                       | 115                      |
| Intangible assets, net   | 4,754                    | 3,621                    |
| Operating lease right-of-use assets, net   | 188                      | 104                      |
| Other long-term assets, net  | 12                       | 21                       |
| <b>Total assets</b>  | <b>\$ 25,030</b>         | <b>\$ 27,465</b>         |
| <b>Liabilities and stockholders' equity</b>  |                          |                          |
| <b>Current liabilities:</b>  |                          |                          |
| Accounts payable   | \$ 1,766                 | \$ 1,774                 |
| Current portion of long-term debt  | 1,033                    | 1,418                    |
| Accrued liabilities  | 3,662                    | 1,366                    |
| <b>Total current liabilities</b>   | <b>6,461</b>             | <b>4,558</b>             |
| Long-term debt, net of discount and including accrued fees   | 5,384                    | 5,262                    |
| Operating lease liabilities, net of current portion  | 107                      | 15                       |
| <b>Total liabilities</b>   | <b>11,952</b>            | <b>9,835</b>             |
| <b>Commitments and contingencies (Note 14)</b>   |                          |                          |
| <b>Stockholders' equity</b>  |                          |                          |
| Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,353,119 and 24,626,004 shares issued and outstanding at December 31, 2022 and 2021, respectively | 25                       | 25                       |
| Additional paid-in capital   | 116,187                  | 111,718                  |
| Accumulated deficit  | (103,134)                | (94,113)                 |
| <b>Total stockholders' equity</b>  | <b>13,078</b>            | <b>17,630</b>            |
| <b>Total liabilities and stockholders' equity</b>  | <b>\$ 25,030</b>         | <b>\$ 27,465</b>         |



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

|   | <b>Twelve months ended<br/>December 31, 2022</b> | <b>Twelve months ended<br/>December 31, 2021</b> |
|---|--|--|
| <b>Cash flows from operating activities</b>   |  |  |
| Net loss  | \$ (9,021)                                       | \$ (1,955)                                       |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: |  |  |
| Stock-based compensation  | 4,218  | 3,381  |
| Common stock issued for product candidate licensing rights                                | —  | —  |
| Depreciation and amortization   | 1,774  | 462  |
| Debt discount amortization  | 127  | 148  |
| Gain on forgiveness of PPP loan   | —  | (365)  |
| Gain on sale of equipment   | —  | (181)  |
| Changes in operating assets and liabilities:  |  |  |
| Accounts receivable   | 3,619  | (5,423)  |
| Inventories   | (7)  | 692  |
| Prepaid expenses and other assets   | 1,902  | (1,026)  |
| Accounts payable  | (8)  | (570)  |
| Accrued liabilities   | 2,217  | 116  |
| <b>Net cash provided by (used in) operating activities</b>                                | <b>4,821</b>                                     | <b>(4,721)</b>                                   |
| <b>Cash used in investing activities</b>  |  |  |
| Proceeds from sale of equipment   | —  | 700  |
| Purchases of property and equipment   | (38)   | (9)  |
| Purchase of product licensing rights  | (2,750)  | (3,250)  |
| <b>Net cash used in investing activities</b>  | <b>(2,788)</b>                                   | <b>(2,559)</b>                                   |
| <b>Cash flows from financing activities</b>   |  |  |
| Debt paydown  | (385)  | (150)  |
| Proceeds from employee stock purchase plan and stock option and stock warrant exercises   | 251  | 541  |
| <b>Net cash (used in) provided by financing activities</b>                                | <b>(134)</b>                                     | <b>391</b>                                       |
| <b>Change in cash and cash equivalents</b>  | <b>1,899</b>                                     | <b>(6,889)</b>                                   |
| Cash and cash equivalents at beginning of period  | 14,406   | 21,295   |
| Cash and cash equivalents at end of period  | \$ 16,305  | \$ 14,406  |
| <b>Supplemental disclosures of cash flow information</b>                                  |  |  |
| Cash paid for interest  | \$ 730   | \$ 815   |
| Cash paid for income taxes  | \$ —   | \$ —   |
| <b>Supplemental disclosure of non-cash investing and financing activities</b>             |  |  |
| Relative fair value of common stock warrants issued in connection with debt               | \$ —   | \$ —   |
| Right-of-use assets obtained in exchange for lease liabilities                            | \$ 188   | \$ —   |