

**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): August 11, 2022

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 August 11, 2022, Eton Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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

Exhibit No.	Description
99.1	Press release issued by Eton Pharmaceuticals, Inc. on August 11, 2022 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, 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: August 11, 2022

/s/ James R. Gruber

James R. Gruber
Chief Financial Officer and Secretary

Eton Pharmaceuticals Reports Second Quarter 2022 Financial Results

DEER PARK, Ill., August 11, 2022 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today reported financial results for the second quarter ended June 30, 2022.

“The second quarter of 2022 was a critical inflection point for the company. With the completion of the hospital products divestiture, we are now 100% focused on our rare disease strategy and are well capitalized to execute on our mission to be a leading rare disease company. Sales of our recently launched ALKINDI SPRINKLE® remain strong, with 293% year-over-year revenue growth, and feedback from the patient and physician communities continues to be overwhelmingly positive. Carglumic Acid also delivered another impressive quarter, with sales growing 100% sequentially. Physicians and patients appreciate the convenience of the room-temperature-stable product as well as the significant financial savings to the healthcare system compared to the competing product. We believe both products have long runways ahead of them and we are excited about the opportunities to add additional rare disease products to our portfolio this year,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Second Quarter and Recent Business Highlights

- **Sold hospital products for up to \$50 million, finalizing Eton’s transition to a dedicated rare disease company.** In June, Eton sold Biorphen®, Rezipres®, and Cysteine Hydrochloride to Dr. Reddy’s Laboratories, allowing Eton to focus solely on its rare disease product portfolio.
- **Reported sixth straight quarter of sequential growth in product sales and royalty revenue.** For the second quarter of 2022, Eton reported total revenue of \$7.4 million, an increase of 139% over the prior year period. Product sales and royalty revenue were \$2.4 million during the quarter, an increase of 316% over the prior year period.
- **Continued growth in ALKINDI SPRINKLE®.** ALKINDI SPRINKLE sales grew 293% over the second quarter of 2021 and 34% over the first quarter of 2022, demonstrating a strong desire for the low-dose treatment options that ALKINDI SPRINKLE offers.
- **Strong adoption of Carglumic Acid tablets.** Carglumic Acid sales in the second quarter of 2022 grew 100% over the first quarter of 2022. Physicians and patients continue to appreciate the convenience of Eton’s room-temperature-stable product and the significant financial savings that the product delivers to the U.S. healthcare system relative to the competing product.
- **FDA Approval of Zonisade™ (zonisamide oral suspension).** In July, Zonisade was approved by the FDA. Azurity Pharmaceuticals will be solely responsible for commercializing the product and Eton will receive a \$5 million milestone payment upon launch and an ongoing royalty on commercial sales.

Progressed R&D pipeline to support additional new product launches in coming years. During the quarter, the company made progress addressing the FDA’s requests on dehydrated alcohol injection and expects to resubmit the application for the product later this year, which could allow for approval and launch of the product in 2023. The company continues to progress development of ZENEO® hydrocortisone autoinjector, which could be filed with the FDA in 2023. In addition, the company has initiated development of two additional high-value rare disease products.

Second Quarter Financial Results

Net Sales: Net sales for the second quarter of 2022 were \$7.4 million compared with \$3.1 million in the prior year period. Net sales included \$5.0 million of licensing payments related to the sale of the hospital products division to Dr Reddy’s Laboratories during the quarter, and \$2.5 million of licensing payments related to the Azurity Pharmaceuticals transaction in the second quarter of 2021.

Product sales and royalty revenue were \$2.4 million for the second quarter of 2022 compared with \$0.6 for the second quarter of 2021. Product sales and royalty revenue in the second quarter of 2022 were negatively impacted by a \$0.2 million inventory allowance adjustment resulting from the divestiture of Rezipres®. Excluding the impact of this adjustment, product sales and royalty revenue would have increased 351% over the prior year period and 18% over the first quarter of 2022. The increase in product sales and royalty revenue was primarily driven by growth in ALKINDI SPRINKLE and the launch of Carglumic Acid tablets.

Gross Profit: Gross profit for the second quarter of 2022 was \$4.6 million compared with \$2.9 million in the prior year period. Gross profit for the second quarter of 2022 included \$1.8 million of non-cash expenses related to the divestment of the hospital products. The growth was primarily due to increased licensing income, growth in ALKINDI SPRINKLE, and the launch of Carglumic Acid tablets.

General, and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2022 were \$5.3 million compared to \$3.2 million in the prior year period. Cash G&A expenses for the second quarter of 2022 were \$3.9 million, compared to \$2.9 million in the prior year period. The increase in cash SG&A expenses was primarily driven by increased employee expenses and increased sales and marketing expenses to support the growth of the company's commercial products.

Research & Development (R&D) Expenses: R&D expenses for the second quarter of 2022 were \$0.7 million compared to \$2.0 million in the prior year period. The prior year period included a \$0.5 million milestone payment related to the company's ZENEO hydrocortisone autoinjector.

Net Income/Loss: Net income for the second quarter of 2022 was a loss of \$1.6 million or \$0.06 per basic and diluted share compared to a loss of \$2.0 million or \$0.08 per basic and diluted share in the prior year period.

Cash Position: As of June 30, 2022, the company had cash of \$17.0 million. The company is entitled to receive an additional \$5.0 million milestone payment upon the launch of the recently approved Zonisade™ product.

Conference Call and Webcast Information:

Eton Pharmaceuticals will host a conference call and webcast today at 4:30 p.m. ET (3:30 p.m. CT). To access the conference call, please dial 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and refer to conference ID 9229889. 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.

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 commercializes ALKINDI SPRINKLE® and Carglumic Acid tablets and has two additional rare disease products under development, dehydrated alcohol injection and the ZENEO® hydrocortisone autoinjector. In addition, the company is entitled to receive milestone payments or royalties on seven different products.

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, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Revenues:				
Licensing revenue	\$ 5,000	\$ 2,500	\$ 5,000	\$ 14,000
Product sales and royalties	2,358	567	4,534	964
Total net revenues	7,358	3,067	9,534	14,964
Cost of sales:				
Licensing revenue	990	—	990	1,500
Product sales and royalties	1,755	174	2,604	301
Total cost of sales	2,745	174	3,594	1,801
Gross profit	4,613	2,893	5,940	13,163
Operating expenses:				
Research and development	690	1,990	2,308	2,876
General and administrative	5,263	3,228	10,059	7,249
Total operating expenses	5,953	5,218	12,367	10,125
(Loss) income from operations	(1,340)	(2,325)	(6,427)	3,038
Other (expense) income:				
Interest and other expense, net	(218)	(237)	(461)	(484)
Gain on PPP loan forgiveness	—	365	—	365
Gain on equipment sale	—	181	—	181
(Loss) income before income tax expense	(1,558)	(2,016)	(6,888)	3,100
Income tax expense	—	—	—	—
Net (loss) income	\$ (1,558)	\$ (2,016)	\$ (6,888)	\$ 3,100
Net loss (income) per share, basic	\$ (0.06)	\$ (0.08)	\$ (0.28)	\$ 0.12
Net loss (income) per share, diluted	\$ (0.06)	\$ (0.08)	\$ (0.28)	\$ 0.12
Weighted average number of common shares outstanding, basic	25,126	25,211	24,915	25,133
Weighted average number of common shares outstanding, diluted	25,126	25,211	24,915	26,486

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

	<u>June 30, 2022</u> (Unaudited)	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,046	\$ 14,406
Accounts receivable, net	834	5,471
Inventories	531	550
Prepaid expenses and other current assets	1,365	3,177
Total current assets	19,776	23,604
Property and equipment, net	87	115
Intangible assets, net	3,108	3,621
Operating lease right-of-use assets, net	63	104
Other long-term assets, net	12	21
Total assets	\$ 23,046	\$ 27,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,299	\$ 1,774
Current portion of long-term debt	364	1,418
Accrued liabilities	2,149	1,366
Total current liabilities	3,812	4,558
Long-term debt, net of discount and including accrued fees	5,992	5,262
Operating lease liabilities, net of current portion	—	15
Total liabilities	9,804	9,835
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,272,037 and 24,626,004 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	25	25
Additional paid-in capital	114,218	111,718
Accumulated deficit	(101,001)	(94,113)
Total stockholders' equity	13,242	17,630
Total liabilities and stockholders' equity	\$ 23,046	\$ 27,465

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

	Six months ended June 30, 2022	Six months ended June 30, 2021
Cash flows from operating activities		
Net (loss) income	\$ (6,888)	\$ 3,100
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	2,383	1,509
Depreciation and amortization	1,352	240
Debt discount amortization	66	73
Gain on forgiveness of debt	—	(365)
Gain on sale of equipment	—	(181)
Changes in operating assets and liabilities:		
Accounts receivable	4,637	(255)
Inventories	19	—
Prepaid expenses and other assets	1,827	419
Accounts payable	(475)	(822)
Accrued liabilities	763	(372)
Net cash provided by operating activities	3,684	3,346
Cash (used in) provided by investing activities		
Proceeds from sale of equipment	—	700
Purchase of product license rights	(750)	—
Purchases of property and equipment	(26)	(3)
Net cash (used in) provided by investing activities	(776)	697
Cash flows from financing activities		
Repayment of long-term debt	(385)	—
Proceeds from employee stock option exercises and ESPP	117	464
Net cash (used in) provided by financing activities	(268)	464
Change in cash and cash equivalents	2,640	4,507
Cash and cash equivalents at beginning of period	14,406	21,295
Cash and cash equivalents at end of period	<u>\$ 17,046</u>	<u>\$ 25,802</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 378	\$ 424

Investor Contact:

David Krempa
dkrempa@etonpharma.com
612-387-3740