

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-38738

ETON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

37-1858472
(I.R.S. Employer Identification Number)

21925 W. Field Parkway, Suite 235
Deer Park, Illinois 60010-7278
(Address of principal executive offices) (Zip code)

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

Securities registered pursuant to Section 12(b) of the Act	Trading Symbol	Name of each exchange on which registered
Common stock, \$0.001 par value per share	ETON	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter time that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 3, 2023, Eton Pharmaceuticals, Inc. had outstanding 25,658,396 shares of common stock, \$0.001 par value.



Eton Pharmaceuticals, Inc.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,070	\$ 16,305
Accounts receivable, net	3,495	1,852
Inventories	1,051	557
Prepaid expenses and other current assets	541	1,290
Total current assets	27,157	20,004
Property and equipment, net	38	72
Intangible assets, net	4,210	4,754
Operating lease right-of-use assets, net	109	188
Other long-term assets, net	12	12
Total assets	\$ 31,526	\$ 25,030
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,712	\$ 1,766
Current portion of long-term debt	1,540	1,033
Accrued liabilities	7,141	3,662
Total current liabilities	10,393	6,461
Long-term debt, net of discount and including accrued fees	4,197	5,384
Operating lease liabilities, net of current portion	44	107
Total liabilities	14,634	11,952
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized; 25,658,396 and 25,353,119 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	26	25
Additional paid-in capital	118,680	116,187
Accumulated deficit	(101,814)	(103,134)
Total stockholders' equity	16,892	13,078
Total liabilities and stockholders' equity	\$ 31,526	\$ 25,030

The accompanying notes are an integral part of these condensed financial statements.

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

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30,</u> <u>2023</u>	<u>September 30,</u> <u>2022</u>	<u>September 30,</u> <u>2023</u>	<u>September 30,</u> <u>2022</u>
Revenues:				
Licensing revenue	\$ —	\$ —	\$ 5,500	\$ 5,000
Product sales and royalties	7,028	3,219	18,829	7,753
Total net revenues	<u>7,028</u>	<u>3,219</u>	<u>24,329</u>	<u>12,753</u>
Cost of sales:				
Licensing revenue	—	—	—	990
Product sales and royalties	2,625	1,201	6,898	3,805
Total cost of sales	<u>2,625</u>	<u>1,201</u>	<u>6,898</u>	<u>4,795</u>
Gross profit	4,403	2,018	17,431	7,958
Operating expenses:				
Research and development	615	744	2,275	3,052
General and administrative	4,336	4,169	14,355	14,228
Total operating expenses	<u>4,951</u>	<u>4,913</u>	<u>16,630</u>	<u>17,280</u>
Income (loss) from operations	(548)	(2,895)	801	(9,322)
Other income (expense):				
Other income	—	—	800	—
Interest and other expense, net	(31)	(150)	(281)	(611)
Total other income (expense)	<u>(31)</u>	<u>(150)</u>	<u>519</u>	<u>(611)</u>
Income (loss) before income tax expense	(579)	(3,045)	1,320	(9,933)
Income tax expense	—	—	—	—
Net income (loss)	<u>\$ (579)</u>	<u>\$ (3,045)</u>	<u>\$ 1,320</u>	<u>\$ (9,933)</u>
Net income (loss) per share, basic	<u>\$ (0.02)</u>	<u>\$ (0.12)</u>	<u>\$ 0.05</u>	<u>\$ (0.40)</u>
Weighted average number of common shares outstanding, basic	<u>25,719</u>	<u>25,365</u>	<u>25,613</u>	<u>25,066</u>
Net income (loss) per share, diluted	<u>\$ (0.02)</u>	<u>\$ (0.12)</u>	<u>\$ 0.05</u>	<u>\$ (0.40)</u>
Weighted average number of common shares outstanding, diluted	<u>25,719</u>	<u>25,365</u>	<u>26,002</u>	<u>25,066</u>

The accompanying notes are an integral part of these condensed financial statements.

Eton Pharmaceuticals, Inc.
Condensed Statements of Stockholders' Equity
For the three months ended September 30, 2023 and 2022
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at June 30, 2023	25,561,994	\$ 26	\$ 117,934	\$ (101,235)	\$ 16,725
Stock-based compensation	—	—	730	—	730
Stock option exercises and vesting of restricted stock units	96,402	—	16	—	16
Net loss	—	—	—	(579)	(579)
Balances at September 30, 2023	25,658,396	\$ 26	\$ 118,680	\$ (101,814)	\$ 16,892
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at June 30, 2022	25,272,037	\$ 25	\$ 114,218	\$ (101,001)	\$ 13,242
Stock-based compensation	—	—	949	—	949
Stock option exercises	25,000	—	35	—	35
Net loss	—	—	—	(3,045)	(3,045)
Balances at September 30, 2022	25,297,037	\$ 25	\$ 115,202	\$ (104,046)	\$ 11,181

The accompanying notes are an integral part of these condensed financial statements.

Eton Pharmaceuticals, Inc.
Condensed Statements of Stockholders' Equity
For the nine months ended September 30, 2023 and 2022
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2022	25,353,119	\$ 25	\$ 116,187	\$ (103,134)	\$ 13,078
Stock-based compensation	—	—	2,387	—	2,387
Employee stock purchase plan	57,616	—	140	—	140
Stock option exercises and vesting of restricted stock units	298,528	1	147	—	148
Shares withheld related to net share settlement of stock option exercises	(50,867)	—	(181)	—	(181)
Net income	—	—	—	1,320	1,320
Balances at September 30, 2023	25,658,396	\$ 26	\$ 118,680	\$ (101,814)	\$ 16,892
	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2021	24,626,004	\$ 25	\$ 111,718	\$ (94,113)	\$ 17,630
Stock-based compensation	—	—	3,088	—	3,088
Employee stock purchase plan	47,585	—	117	—	117
Stock option exercises	25,000	—	35	—	35
Warrant exercises	598,448	—	—	—	—
Warrant extensions	—	—	244	—	244
Net loss	—	—	—	(9,933)	(9,933)
Balances at September 30, 2022	25,297,037	\$ 25	\$ 115,202	\$ (104,046)	\$ 11,181

The accompanying notes are an integral part of these condensed financial statements.

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

	Nine months ended September 30, 2023	Nine months ended September 30, 2022
Cash flows from operating activities		
Net income (loss)	\$ 1,320	\$ (9,933)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	2,387	3,332
Depreciation and amortization	626	1,522
Debt discount amortization	90	96
Changes in operating assets and liabilities:		
Accounts receivable	(1,643)	3,973
Inventories	(494)	69
Prepaid expenses and other assets	749	2,129
Accounts payable	(52)	(720)
Accrued liabilities	3,445	1,513
Net cash provided by operating activities	6,428	1,981
Cash flows from investing activities		
Purchases of product license rights	—	(2,750)
Purchases of property and equipment	—	(26)
Net cash used in investing activities	—	(2,776)
Cash flows from financing activities		
Repayment of long-term debt	(770)	(385)
Proceeds from employee stock purchase plan and stock option exercises	288	152
Payment of tax withholding related to net share settlement of stock option exercises	(181)	—
Net cash used in financing activities	(663)	(233)
Change in cash and cash equivalents	5,765	(1,028)
Cash and cash equivalents at beginning of period	16,305	14,406
Cash and cash equivalents at end of period	\$ 22,070	\$ 13,378
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 638	\$ 545
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosures of non-cash transactions		
Adjustment of operating lease right-of-use assets and liabilities due to tenant allowance	\$ 29	\$ —

The accompanying notes are an integral part of these condensed financial statements.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 1 — Company Overview

Eton is an innovative pharmaceutical company focused on developing, acquiring, and commercializing products to address unmet needs in patients suffering from rare diseases.

The Company currently has three commercial rare disease products, ALKINDI SPRINKLE® for the treatment of pediatric adrenocortical insufficiency, Carglumic Acid for the treatment of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, and Betaine Anhydrous for the treatment of homocystinuria. The Company has three additional product candidates in late-stage development: ZENEO® hydrocortisone autoinjector for the treatment of adrenal crisis, ET-400 for the treatment of adrenocortical insufficiency, and ET-600 for the treatment of diabetes insipidus.

As noted in Note 12, effective October 11, 2023, the Company acquired an FDA-approved ANDA for Nitisinone Capsules from Oakrum Pharma LLC.

Note 2 — Liquidity Considerations

The Company believes its existing cash and cash equivalents of \$22,070 as of September 30, 2023 in addition to revenues from approved products will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of filing of this quarterly report. This estimate is based on the Company's current assumptions, including assumptions relating to estimated sales and its ability to manage spending. The Company could use its available capital resources sooner than currently expected. Accordingly, the Company could seek to obtain additional capital through equity financings, the issuance of debt or other arrangements. However, the Company cannot make assurances that it will be able to raise additional capital if needed or under acceptable terms. The sale of additional equity may dilute existing stockholders and newly issued stock could contain senior rights and preferences compared to currently outstanding common shares. The Company's existing long-term debt obligation contains covenants and limits the Company's ability to pay dividends or make other distributions to stockholders. If the Company experiences delays in product development or sales growth, obtaining regulatory approval for its other product candidates, or is unable to secure such additional financing, it might need to scale back or discontinue operations.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying condensed financial statements in accordance with accounting principles generally accepted in the United States (“GAAP”).

Unaudited Interim Financial Information

The accompanying interim condensed financial statements are unaudited and have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments necessary for the fair presentation of the Company’s financial position as of September 30, 2023, and the results of its operations and its cash flows for the periods ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three-month and nine-month periods ended September 30, 2023 and 2022 are also unaudited. The results for the three-month and nine-month periods ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, provisions for uncollectible receivables, chargebacks and sales returns, Medicaid program rebates, valuation of inventories, useful lives of assets, and the impairment of property and equipment and intangible assets, valuation of deferred tax assets, the accrual of research and development expenses and the valuation of stock options and warrants, and restricted stock units (“RSUs”). Estimates are periodically reviewed in light of changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Segment Information

The Company operates the business on the basis of a single reportable segment, which is the business of developing and commercializing prescription drug products. The Company’s chief operating decision-maker is the Chief Executive Officer (“CEO”), who evaluates the Company as a single operating segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in U.S. financial institutions or invested in short-term U.S. treasury bills or high-grade money market funds. As of September 30, 2023, the Company’s cash is in a non-interest-bearing account and a government money market fund. From time to time, amounts deposited with its bank exceed federally insured limits. The Company believes the associated credit risk to be minimal.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and are non-interest bearing. Accounts receivable are recorded net of allowances for doubtful accounts, cash discounts for prompt payment, distribution fees, chargebacks, returns, and allowances. The total for these reserves amounted to \$136 and \$262 as of September 30, 2023 and December 31, 2022, respectively. The Company considers historical collection rates and the current financial status of its customers, as well as macroeconomic and industry-specific factors when evaluating potential credit losses. Historically, the Company’s accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of specialty pharmacies and large wholesale pharmaceutical distributors. Given the size and creditworthiness of these customers, we have not experienced and do not expect to experience material credit losses.

Inventories

The Company values its inventories at the lower of cost or net realizable value using the first-in, first-out method of valuation. The Company reviews its inventories for potential excess or obsolete issues on an ongoing basis and will record a write-down if an impairment is identified. Inventories at September 30, 2023 and December 31, 2022, consist solely of purchased finished goods. At September 30, 2023 and December 31, 2022, inventories are shown net of reserves for its ALKINDI SPRINKLE® of \$76 and \$62, respectively, due to the risk of expiry before this entire stock of inventories is sold.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 3 — Summary of Significant Accounting Policies (continued)Property and Equipment

Property and equipment are stated at cost. Depreciation of property and equipment is computed utilizing the straight-line method based on the following estimated useful lives: computer hardware and software is depreciated over three years; equipment, furniture and fixtures is depreciated over five years; leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is shorter. Construction in progress is capitalized but not depreciated until it is placed into service.

Maintenance and repairs are charged to expense as incurred, while renewals and improvements are capitalized.

Intangible Assets

The Company capitalizes payments it makes for licensed products when the payment relates to an FDA-approved product, and the cost is recoverable based on expected future cash flows from the product. The cost is amortized on a straight-line basis over the estimated useful life of the product commencing on the approval date in accordance with Accounting Standards Codification (“ASC”) 350, Intangibles — Goodwill and Other. In November 2021, the Company purchased the rights for its Carglumic Acid product for \$3,250, and that cost is being amortized over ten years. A \$750 payment related to the approval of Biorphen had been capitalized in 2019, and that cost was being amortized over five years. As a result of the Biorphen sale to Dr. Reddy’s Laboratories S.A. (“Dr. Reddy’s”) (see Note 11) in June 2022, amortization of that asset was accelerated to record \$275 of expense in June 2022, and the remaining \$75 of expense in the last six months of the year ended December 31, 2022. A \$750 payment related to the approval of Rezipres had been capitalized in Q1 2022, and that cost was being amortized over five years. As a result of the sale to Dr. Reddy’s, amortization of the Rezipres asset was accelerated to record the remaining \$738 in the three-month period ended June 30, 2022. In September 2022, the Company purchased the rights for its Betaine Anhydrous product for \$2,000 and that cost is being amortized over five years. The intangible assets, net on the Company’s balance sheet, reflected \$1,040 of accumulated amortization as of September 30, 2023. The Company recorded \$182 and \$544, respectively, of amortization expense for the three and nine months ended September 30, 2023. The table below shows the estimated remaining amortization for these products for each of the five years from 2023 to 2027 and thereafter.

Year	Amortization Expense
Remainder of 2023	\$ 181
2024	725
2025	725
2026	725
2027	608
Thereafter	1,246
Total estimated amortization expense	\$ 4,210

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the Company’s statements of operations for the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment was recognized during the nine months ended September 30, 2023 and 2022.

Debt Issuance Costs and Debt Discount and Detachable Debt-Related Warrants

Costs incurred to issue debt are deferred and recorded as a reduction to the debt balance in the accompanying balance sheets. The Company amortizes debt issuance costs over the expected term of the related debt using the effective interest method. Debt discounts related to the relative fair value of warrants issued in conjunction with the debt are also recorded as a reduction to the debt balance and accreted over the expected term of the interest expense using the effective interest method.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 3 — Summary of Significant Accounting Policies (continued)Leases

The Company accounts for leases in accordance with ASC Topic 842, Leases. The Company reviews all relevant facts and circumstances of a contract to determine if it is a lease whereby the terms of the agreement convey the right to control the direct use and receive substantially all the economic benefits of an identified asset for a period of time in exchange for consideration. The associated right-of-use assets and lease liabilities are recognized at lease commencement. The Company measures lease liabilities based on the present value of the lease payments over the lease term discounted using the rate it would pay on a loan with the equivalent payments and term for the lease. The Company does not include the impact for lease term options that would extend or terminate the lease unless it is reasonably certain that it will exercise any such options. The Company accounts for the lease components separately from non-lease components for its operating leases.

The Company measures right-of-use assets based on the corresponding lease liabilities adjusted for (i) any prepayments made to the lessor at or before the commencement date, (ii) initial direct costs it incurs, and (iii) any incentives under the lease. In addition, the Company evaluates the recoverability of its right-of-use assets for possible impairment in accordance with its long-lived assets policy.

Operating leases are reflected on the balance sheets as operating lease right-of-use assets, current accrued liabilities, and long-term operating lease liabilities. The Company did not have any finance leases as of September 30, 2023 or December 31, 2022.

The Company commences recognizing operating lease expense when the lessor makes the underlying asset available for use by the Company and the operating lease expense is recognized on a straight-line basis over the term of the lease. Variable lease payments are expensed as incurred.

The Company does not recognize right-of-use assets or lease liabilities for leases with a term of twelve months or less; such lease costs are recorded in the statements of operations on a straight-line basis over the lease term.

Concentrations of Credit Risk, Sources of Supply and Significant Customers

The Company is subject to credit risk for its cash and cash equivalents which are invested in money market funds and U.S. treasury bills from time to time. The Company maintains its cash and cash equivalent balances with one major commercial bank, and the deposits held with the financial institution exceed the amount of insurance provided on such deposits and is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheets. The Company believes the associated credit risk to be minimal.

The Company is dependent on third-party suppliers for its products and product candidates. In particular, the Company relies, and expects to continue to rely, on a small number of suppliers to manufacture key chemicals, approved products and process its product candidates as part of its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process.

The Company is also subject to credit risk from its accounts receivable related to product sales as it extends credit based on an evaluation of the customer's financial condition, and collateral is not required. Management monitors its exposure to accounts receivable by periodically evaluating the collectability of the account receivable based on a variety of factors, including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at September 30, 2023 and December 31, 2022. The accounts receivable balance at September 30, 2023 and product sales revenue recognized during the nine months ended September 30, 2023, primarily consist of sales to and amounts due from AnovoRx for sales of the Company's ALKINDI SPRINKLE® and Carglumic Acid products. The accounts receivable balance at September 30, 2022 and product sales revenue recognized during the nine months ended September 30, 2022, consist of sales to and amounts due from AnovoRx for sales of the Company's ALKINDI SPRINKLE® and Carglumic Acid products as well as sales to and amounts due from AmerisourceBergen Corporation, Cardinal Health Services, and McKesson Corporation for sales of the Company's Biorphen product. AnovoRx sales made up 73% of total net revenues recognized in the nine months ended September 30, 2023 and 98% of net accounts receivable as of September 30, 2023, and 52% of total net revenues recognized in the nine months ended September 30, 2022, and 80% of net accounts receivable as of December 31, 2022.

Revenue Recognition for Contracts with Customers

The Company accounts for contracts with its customers in accordance with ASC 606, Revenue from Contracts with Customers. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations to assess whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses whether these options provide a material right to the customer and, if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 3 — Summary of Significant Accounting Policies (continued)

The Company recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in the Company's balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

Milestone Payments – If a commercial contract arrangement includes development and regulatory milestone payments, the Company will evaluate whether the milestone conditions have been achieved and if it is probable that a significant revenue reversal would not occur before recognizing the associated revenue. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

Significant Financing Component – In determining the transaction price, the Company will adjust consideration for the effects of the time value of money if the expected period between payment by the licensees and the transfer of the promised goods or services to the licensees will be more than one year.

The Company sells its rare disease products to a pharmacy distributor customer which provides order fulfillment and inventory storage/distribution services. The Company has sold products in the U.S. to wholesale pharmaceutical distributors, who then sold the products to hospitals and other end-user customers. Sales to wholesalers were made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments represented performance obligations under each purchase order. The Company used a third-party logistics ("3PL") vendor to process and fulfill orders and concluded that the Company is the principal in the sales to wholesalers because it controlled access to the 3PL vendor services rendered and directed the 3PL vendor activities. The Company had no significant obligations to wholesalers to generate pull-through sales.

For its rare disease products, the Company bills at the initial product list price, which is subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements that are recorded as a reduction of net revenues at the date of sale/shipment. Selling prices initially billed to wholesalers were subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sold products at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs. Because of the shelf life of the product and the Company's lengthy return period, there may be a significant period of time between when the product is shipped and when it issues credits on returned product.

The Company estimates the transaction price when it receives each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler/distributor arising from all of the above factors. The Company has developed estimates for future returns and chargebacks and the impact of other discounts and fees it pays, although rare disease product sales are not subject to returns. When estimating these adjustments to the transaction price, the Company reduces it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

The Company stores its rare disease product inventory at its pharmacy distributor customer location, and records sales when stock is pulled and shipped to fulfill specific patient orders. The Company recognized revenue and cost of sales from products sold to wholesalers upon delivery to the wholesaler location. At that time, the wholesalers take control of the product and take title, bear the risk of loss of ownership and have an enforceable obligation to pay the Company. The wholesalers also have the ability to direct sales of products to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, the Company does not believe they have a significant incentive to return the product.

Upon recognition of revenue from product sales, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, state Medicaid, and GPO fees are included in sales reserves, accrued liabilities and net accounts receivable. The Company monitors actual product returns, chargebacks, discounts, and fees after the sale. If these amounts end up differing from its estimates, it will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

In addition, the Company anticipates it will receive revenues from product licensing agreements where it has contracted for milestone payments and royalties from products it has developed or acquired.

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Note 3 — Summary of Significant Accounting Policies (continued)Cost of Product Sales

Cost of product sales consists of the profit-sharing and royalty fees with the Company's product licensing and development partners, the purchase costs for finished products from third-party manufacturers, freight and handling/storage from the Company's 3PL logistics service providers, and amortization expense of certain intangible assets. The costs of sales for profit-sharing, royalty fees, purchased finished products, and the associated inbound freight expense are recorded when the associated product sale revenue is recognized in accordance with the terms of shipment to customers while outbound freight and handling/storage fees charged by the 3PL service provider are expensed as they are incurred. Intangible assets are amortized on a straight-line basis over the estimated useful life of the product. Cost of product sales also reflects any write-downs or reserve adjustments for the Company's inventories.

Research and Development Expenses

Research and development ("R&D") expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits, stock-based compensation, and other costs to support the Company's R&D operations. External contracted services include product development efforts such as certain product licensor milestone payments, clinical trial activities, manufacturing and control-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. The Company reviews and accrues R&D expenses based on services performed and relies upon estimates of those costs applicable to the stage of completion of each project. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Upfront payments and milestone payments made for the licensing of products that are not yet approved by the FDA are expensed as R&D in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses and are expensed as the related goods are delivered or the services are performed.

Income (Loss) Per Share

Basic net income (loss) per share of common stock is computed by dividing net income (loss) attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as unvested restricted stock, stock options, RSUs and warrants that are outstanding during the period. Common stock equivalents are excluded from the computation when their inclusion would be anti-dilutive. For the three-month period ended September 30, 2023, common stock equivalents excluded 5,618,663 shares that were anti-dilutive. For the nine months ended September 30, 2023, common stock equivalents were 388,832 and excluded 4,821,906 shares that were anti-dilutive. For the three-month and nine-month periods ended September 30, 2022, common stock equivalents of 5,349,891 and 5,118,574, respectively, are excluded from the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net income (loss) per share calculation are RSUs awarded to employees or directors that have vested, but the issuance and delivery of the shares of common stock are deferred until the director retires from service as a director.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718, Compensation — Stock Compensation. The guidance under ASC 718 requires companies to estimate the fair value of the stock-based compensation awards on the date of grant and record expense over the related service periods, which are generally the vesting period of the equity awards. The Company estimates the fair value of stock-based option awards using the Black-Scholes-Merton option-pricing model ("BSM"). The BSM requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures, and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined from the implied yields for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options or warrants. Dividends on common stock are assumed to be zero for the BSM valuation of the stock options. The expected term of stock options granted is based on vesting periods and the contractual life of the options. Expected volatility is based on the Company's own volatility, along with a limited weighting of comparable companies' historical volatilities, which management believes represents the most accurate basis for estimating expected future volatility under the current conditions. The Company accounts for forfeitures as they occur. The Company uses the closing common stock price on the date of grant for the fair value of the common stock.

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Note 3 — Summary of Significant Accounting Policies (continued)**Fair Value Measurements**

We measure certain of our assets and liabilities at fair value. Fair value represents the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value accounting requires characterization of the inputs used to measure fair value into a three-level fair value hierarchy as follows:

Level 1 — Inputs based on quoted prices in active markets for identical assets or liabilities. An active market is a market in which transactions occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 — Observable inputs that reflect the assumptions market participants would use in pricing the asset or liability developed based on market data obtained from sources independent from the entity.

Level 3 — Unobservable inputs that reflect the entity's own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available.

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below take into account the market for the Company's financials, assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The Company's financial instruments included cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and long-term debt obligation. The carrying amounts of these financial instruments, except for the long-term debt obligation, approximate their fair values due to the short-term maturities of these instruments. Based on borrowing rates currently available to the Company, the carrying value of the long-term debt obligation approximates its fair value.

Impact of Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, "Measurement of Credit Losses on Financial Instruments." This ASU replaces the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses, requires consideration of a broader range of reasonable and supportable information for credit loss estimates on certain types of financial instruments, including trade receivables, and new disclosures. The ASU, as subsequently amended, is effective for the Company for fiscal years beginning after December 15, 2022, as the Company was a smaller reporting company as of November 15, 2019, the determination date. We adopted ASU 2016-13 on January 1, 2023. Based on the composition of the Company's accounts receivable, including current market conditions and historical credit loss activity, the adoption of this standard did not have a material impact on the Company's consolidated financial statements or disclosures. Specifically, the Company's estimate of expected credit losses as of September 30, 2023, using its expected credit loss evaluation process described above, resulted in no provision for credit losses and no cumulative-effect adjustment to accumulated deficit on the adoption date of the standard.

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Note 4 – Property and Equipment

Property and equipment consist of the following:

	September 30, 2023	December 31, 2022
Computer hardware and software	\$ 187	\$ 177
Furniture and fixtures	111	112
Equipment	52	52
Leasehold improvements	71	71
Construction in Progress	—	12
	421	424
Less: accumulated depreciation	(383)	(352)
Property and equipment, net	\$ 38	\$ 72

Depreciation expense for the three months ended September 30, 2023 and 2022 was \$9 and \$14, respectively. Depreciation expense for the nine months ended September 30, 2023 and 2022 was \$32 and \$53, respectively.

Note 5 — Long-Term Debt**SWK Loan**

In November 2019, the Company entered into a credit agreement (the “SWK Credit Agreement”) with SWK Holdings Corporation (“SWK”) which provided for up to \$10,000 in financing. The Company received proceeds of \$5,000 at closing and borrowed an additional \$5,000 upon the FDA approval of a second product developed by the Company. In March 2020, the Company and SWK amended the SWK Credit Agreement, and the Company borrowed an additional \$2,000 in August 2020. The term of the SWK Credit Agreement is for five years, and borrowings bear interest at a rate of LIBOR 3-month plus 10.0%, subject to a stated LIBOR floor rate of 2.0%. A 2.0% unused credit limit fee was assessed during the first twelve months after the date of the SWK Credit Agreement and loan fees include a 5.0% exit fee based on the principal amounts drawn which is payable at the end of the term of the SWK Credit Agreement. The Company was required to maintain a minimum cash balance of \$3,000, only pay interest on the debt until February 2022 and then pay 5.5% of the loan principal balance commencing on February 15, 2022 and then every three months thereafter until November 13, 2024 at which time the remaining principal balance is due. Borrowings under the SWK Credit Agreement are secured by the Company’s assets. The SWK Credit Agreement contains customary default provisions and covenants which limit additional indebtedness. In March 2020, SWK provided a waiver for the Company to obtain loans with the Small Business Association. In February 2021, the Company notified SWK that it would not require additional borrowing capacity under the SWK Credit Agreement and terminated the additional borrowing capacity with SWK.

In connection with the initial \$5,000 borrowed under the SWK Credit Agreement, the Company issued warrants to SWK to purchase 51,239 shares of the Company’s common stock with an exercise price of \$5.86 per share. The relative fair value of these warrants was \$226 and was estimated using BSM with the following assumptions: fair value of the Company’s common stock at issuance of \$5.75 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 1.8%.

In connection with the additional \$2,000 borrowed in August 2020, the Company issued warrants for 18,141 shares of its common stock at an exercise price of \$6.62 per share. The relative fair value of the 18,141 warrants was \$94 and was estimated using BSM with the following assumptions: fair value of the Company’s common stock at issuance of \$6.85 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 0.4%.

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Note 5 — Long-Term Debt (continued)

These warrants (the “SWK Warrants”) are exercisable immediately and have a term of seven years from the date of issuance. The SWK Warrants are subject to a cashless exercise feature, with the exercise price and number of shares issuable upon exercise subject to change in connection with stock splits, dividends, reclassifications and other conditions.

In April 2022, the Company and SWK further amended the SWK Credit Agreement to allow for a deferral of loan principal payments until May 2023 and reduce the interest rate to LIBOR 3-month plus 8.0%, subject to a stated LIBOR floor rate of 2.0%. In accordance with the change, the Company has classified \$1,540 as principal due in the next 12 months, and the remainder classified as long-term debt in its balance sheet at September 30, 2023. Because LIBOR was phased out as of June 30, 2023, the Company amended the Credit Agreement in August 2023 to refer to the secured overnight financing rate (“Term SOFR”), with an interest rate of Term SOFR plus 8.26%, subject to a stated Term SOFR floor rate of 5.0%.

Interest expense of \$805 was recorded during the nine months ended September 30, 2023, which included \$90 of debt discount amortization. Interest expense of \$699 was recorded during the nine months ended September 30, 2022, which included \$96 of debt discount amortization. As of September 30, 2023, \$307 of accrued interest is included in accrued liabilities.

The table below reflects the future payments for the SWK loan principal and interest as of September 30, 2023.

	Amount
Remainder of 2023	\$ 589
2024	6,483
Total payments	7,072
Less: amount representing interest	(1,228)
Loan payable, gross	5,844
Less: current portion of long-term debt	(1,540)
Less: unamortized discount	(107)
Long-term debt, net of unamortized discount	\$ 4,197

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Note 6 — Common Stock

The Company has 50,000,000 authorized shares of \$0.001 par value common stock under its Amended and Restated Certificate of Incorporation.

During the nine months ended September 30, 2023, the Company issued 298,528 shares of its common stock resulting from cash and non-cash stock option exercises under its 2018 Equity Incentive Plan as amended December 2020 (see Note 8) and vesting of restricted stock units. The Company withheld 50,867 shares for payroll tax obligations totaling \$181 for the nine months ended September 30, 2023. In June 2023, the Company issued 57,616 shares of its common stock to employees in accordance with its Employee Stock Purchase Plan (“ESPP”). During the nine months ended September 30, 2022, a holder of the Company’s common stock warrants exercised 600,000 warrants on a cashless basis and the Company issued 598,448 shares of its common stock in connection with the warrant exercise. The intrinsic value of the warrant exercise was \$2,268. In June 2022, the Company issued 47,585 shares of its common stock to employees in accordance with its ESPP. In July 2022, the Company issues 25,000 shares of its common stock to an employee for a stock option exercise under its 2018 Equity Incentive Plan as amended December 2020.

Note 7 — Common Stock Warrants

The Company’s outstanding warrants to purchase shares of its common stock at September 30, 2023 are summarized in the table below.

Description of Warrants	No. of Shares	Exercise Price
Placement Agent Warrants - IPO	414,000	\$ 7.50
SWK Warrants – Debt – Tranche #1	51,239	\$ 5.86
SWK Warrants – Debt – Tranche #2	18,141	\$ 6.62
Total (Avg)	483,380	\$ 7.29

The holders of these warrants or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of 1933, as amended (the “Securities Act”) for their shares that are converted to common stock, including demand registration rights and piggyback registration rights. These rights are provided under the terms of a registration rights agreement between the Company and the investors.

On June 26, 2022, 467,242 warrants from the 2017 preferred stock offering with an exercise price of \$3.00 were set to expire. Prior to the expiration, the Company entered into an agreement with warrant holders, whereby it modified the terms of the warrants to extend the expiration date until December 26, 2022 in exchange for the Company retaining the option of a cashless exercise provision. No other terms were modified. Due to this modification, the Company incurred a modification expense of \$244 that is included in general and administrative (“G&A”) expense on the Condensed Statements of Operations for the nine months ended September 30, 2022.

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Note 8 — Share-Based Payment Awards

The Company adopted the Eton Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the “2017 Plan”), which authorized the issuance of up to 5,000,000 shares of the Company’s common stock, and in 2018 it adopted the 2018 Equity Incentive Plan as amended December 2020 (the “2018 Plan”) which succeeded the 2017 Plan. The Company has granted restricted stock awards (“RSAs”), stock options and RSUs for its common stock under the 2017 Plan and 2018 Plan as detailed in the tables below. There were 693,597 shares available for future issuance under the 2018 Plan as of September 30, 2023.

Share awards that are expired, terminated, surrendered, or canceled without having been fully exercised will be available for future awards under the 2018 Plan. In addition, the 2018 Plan provides that commencing January 1, 2019 and through January 1, 2028, the share reserve will be increased annually by 4% of the total number of shares of common stock outstanding as of the preceding December 31, subject to a reduction at the discretion of the Company’s board of directors. The exercise price for stock options granted is no less than the fair value of common stock as determined by the board of directors as of the date of grant. The Company uses the closing stock price on the date of grant as the exercise price.

To date, all stock options issued have been non-qualified stock options, and the exercise prices were set at the fair value for the shares at the dates of grant. Options typically have a ten-year life, except for options to purchase 50,000 shares of the Company’s common stock granted to product consultants in July 2017 that expired, unexercised, in July 2022.

The Company’s previous CFO had 474,295 employee stock options with an exercise price range of \$1.37 to \$8.61 which were set to expire three months after his retirement date of May 31, 2022; however, the Company extended the expiration date to April 10, 2023. Of these options, 365,858 options were exercised in January and March 2023, and the remainder expired in April 2023. No other terms were modified. Due to this modification, the Company incurred a modification expense of approximately \$72 that is included in general and administration expense on the Condensed Statements of Operations for the nine-month period ended September 30, 2023.

For the three months ended September 30, 2023 and 2022, the Company’s total stock-based compensation expense was \$730 and \$949, respectively. Of these amounts, \$657 and \$893 were recorded in G&A expenses, respectively, and \$73 and \$56 were recorded in research and development expenses, respectively.

For the nine months ended September 30, 2023 and 2022, the Company’s total stock-based compensation expense was \$2,387 and \$3,332, respectively. Of these amounts, \$2,191 and \$3,102 were recorded in G&A expenses, respectively, and \$196 and \$230 were recorded in research and development expenses, respectively.

Stock Options

The following table summarizes stock option activity during the nine months ended September 30, 2023:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Yrs)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	4,402,292	\$ 4.71		
Issued	1,078,291	\$ 3.49		
Exercised	(407,308)	\$ 2.23		
Forfeited/Cancelled	(263,549)	\$ 5.94		
Outstanding as of September 30, 2023	4,809,726	\$ 4.58	7.5	\$ 2,725
Exercisable as of September 30, 2023	3,139,749	\$ 4.81	6.9	\$ 1,828
Vested and expected to vest at September 30, 2023	4,809,726	\$ 4.58	7.5	\$ 2,725

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Note 8 — Share-Based Payment Awards (continued)

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock at September 30, 2023 for those stock options that had strike prices lower than the fair value of the Company's common stock.

Stock-based compensation related to stock options was \$639 and \$2,115 for the three and nine months ended September 30, 2023, respectively. Stock-based compensation related to stock options was \$853 and \$2,850 for the three and nine months ended September 30, 2022, respectively. As of September 30, 2023, there was a total of \$4,164 of unrecognized compensation costs related to non-vested stock option awards. The weighted average grant date fair value of stock option awards for the nine months ended September 30, 2023 was \$2.31 per share. In the nine months ended September 30, 2023, there were six stock option exercises which totaled 407,308 shares at a weighted average exercise price of \$2.23 per share with an intrinsic value of \$611. In the nine-month period ended September 30, 2022, there was one stock option exercise which totaled 25,000 shares at an exercise price of \$1.38 per share with an intrinsic value of \$31.

Restricted Stock Units (RSUs)

The following table summarizes restricted stock unit activity during the nine months ended September 30, 2023:

	<u>Number of Units</u>	<u>Weighted Average Grant-Date Fair Value Per Unit</u>
Outstanding and unvested as of December 31, 2022	369,606	\$ 2.63
Granted	—	\$ —
Vested	(91,402)	\$ 2.63
Forfeited	(4,000)	\$ 2.63
Outstanding and unvested as of September 30, 2023	<u>274,204</u>	<u>\$ 2.63</u>

Stock-based compensation related to RSUs was \$61 and \$179 for the three and nine months ended September 30, 2023. As of September 30, 2023, there was \$668 of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted average period of 2.8 years.

Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan ("ESPP") provides for an initial reserve of 150,000 shares, and this reserve is automatically increased on January 1 of each year by the lesser of 1% of the outstanding common shares at December 31 of the preceding year or 150,000 shares, subject to reduction at the discretion of the Company's board of directors. As of September 30, 2023, there were 652,680 shares available for issuance under the ESPP.

The annual offerings consist of two stock purchase periods, with the first purchase period ending in June and the second ending in December. The terms of the ESPP permit employees of the Company to use payroll deductions to purchase stock at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of common stock on the first date of an offering or (2) 85% of the fair market value of a share of common stock on the date of purchase. After the offering period ends, subsequent twelve-month offering periods automatically commence over the term of the ESPP on the day that immediately follows the conclusion of the preceding offering, each consisting of two purchase periods approximately six months in duration. The terms of the ESPP provide a restart feature if the Company's stock price is lower at the end of a six-month period within the twelve-month offering period than it was at the beginning of the twelve-month offering period.

For the nine months ended September 30, 2023 and 2022, there were 57,616 and 47,585 share issuances, respectively, under the ESPP. The weighted average fair value of share awards in the first nine months of 2023 and 2022 was \$1.22 and \$1.32, respectively. Employees contributed \$181 and \$174 via payroll deductions during the nine months ended September 30, 2023 and 2022, respectively. The Company recorded an expense of \$93 and \$97 related to the ESPP in the nine months ended September 30, 2023 and 2022, respectively. The Company recorded an expense of \$30 and \$27 related to the ESPP in the three months ended September 30, 2023 and 2022, respectively. As of September 30, 2023 and December 31, 2022, the accompanying condensed balance sheets include \$63 and \$23, respectively, in accrued liabilities for employee ESPP contributions.

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Note 9 — Related-Party Transactions**Chief Executive Officer**

The CEO has a partial interest in a company that the Company had partnered with for its EM-100/Alaway® Preservative Free eye allergy product as described below.

The Company acquired the exclusive rights to sell the EM-100 product in the United States pursuant to a sales and marketing agreement (the “Eyemax Agreement”) dated August 11, 2017, between the Company and Eyemax LLC (“Eyemax”), an entity affiliated with the Company’s CEO. The Company also held a right of first refusal to obtain the exclusive license rights for geographic areas outside of the United States. Pursuant to the Eyemax Agreement, the Company was responsible for all costs of testing and FDA approval of the product, other than the FDA filing fee which was paid by Eyemax. The Company was also to be responsible for commercializing the product in the United States at its expense. The Company paid Eyemax \$250 upon execution of the Eyemax Agreement, which was recorded as a component of R&D expense. Under the terms of the Eyemax Agreement, the Company would pay Eyemax \$250 upon FDA approval, \$500 upon the first commercial sale of the product, and a royalty of 10% on the net sales of all products. The Eyemax Agreement was for an initial term of 10 years from the date of the Eyemax Agreement, subject to successive two-year renewals unless the Company elected to terminate the Eyemax Agreement.

On February 18, 2019, the Company entered into an Amended and Restated Agreement with Eyemax amending the Sales Agreement (the “Amended Agreement”). Pursuant to the Amended Agreement, Eyemax sold the Company all of its right, title and interest in EM-100, including any such product that incorporates or utilizes Eyemax’s intellectual property rights. Under the Amended Agreement, the Company assumed certain liabilities of Eyemax under its Exclusive Development & Supply Agreement with Excelvisio SAS, dated as of July 11, 2013, as amended (the “Excelvisio Agreement”), with respect to certain territories and arising during certain time periods. Pursuant to the Amended Agreement, the Company paid Eyemax two milestone payments: (i) one milestone payment for \$250 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for \$500 following the first commercial sale of the first single agent product in the territory. Following payment of the milestones, the Company was entitled to retain all of the non-royalty transaction revenues and royalties up to \$2,000 (the “Recovery Amount”). After the Company had retained the full Recovery Amount, it was entitled to retain half of all royalty and non-royalty transaction revenue. The Company has realized \$1,840 of the non-royalty and royalty revenue as of September 30, 2023. The Amended Agreement also contains customary representations, warranties, covenants, and indemnities by the parties. The EM-100 asset and its associated product rights were sold to Bausch Health on February 18, 2019, and future potential royalties of twelve percent on Bausch Health sales of the product, named Alaway® Preservative Free by Bausch, which was approved by the FDA in September 2020, would be split between Eyemax and the Company. The royalty from Bausch Health is subject to reduction if a competitive product with the same active pharmaceutical ingredient is launched in the U.S. or if the product’s U.S market share falls below a specified target percentage. Bausch Health discontinued sales of Alaway® Preservative Free effective March 24, 2023.

There were no amounts due to Eyemax under the terms of the Amended Agreement as of September 30, 2023 or December 31, 2022.

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Note 10 — Leases

The Company recognizes a right-of-use (“ROU”) asset and a lease liability on the balance sheet for substantially all leases, including operating leases, and separates lease components from non-lease components related to its office space lease.

The Company’s operating lease cost as presented as G&A in the condensed statements of operations was \$57 for the nine months ended September 30, 2023, and \$64 for the nine months ended September 30, 2022. Cash paid for amounts included in the measurement of operating lease liabilities was \$66 for the nine months ended September 30, 2023, and \$66 for the nine months ended September 30, 2022. The ROU asset amortization was \$11 and \$50 for the three and nine-month periods ended September 30, 2023, respectively, and \$21 and \$62 for the three and nine-month periods ended September 30, 2022, respectively, and is reflected within depreciation and amortization on the Company’s condensed statements of cash flows. As of September 30, 2023, the weighted-average remaining lease term was 1.50 years, and the weighted-average incremental borrowing rate was 8.6%.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of September 30, 2023 (in thousands).

Assets	Classification	
Operating lease right-of-use assets	Operating lease right-of-use assets, net	\$ 109
Total leased assets		<u>\$ 109</u>
Liabilities		
Operating lease liabilities, current	Accrued liabilities	\$ 50
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion	\$ 44
Total operating lease liabilities		<u>\$ 94</u>

The Company’s future lease commitments for its administrative offices in Deer Park, Illinois as of September 30, 2023, is as indicated below:

	Operating Lease Liabilities
2023	(10)
2024	90
2025	23
Undiscounted lease payments	103
Less: Imputed interest	(9)
Total lease liabilities	<u>\$ 94</u>

* The Company expects to receive a tenant improvement allowance reimbursement of \$32 in November 2023 which results in a negative lease commitment for the remainder of 2023.

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Note 11 — Commitments and Contingencies

Legal

The Company is subject to legal proceedings and claims that may arise in the ordinary course of business. The Company is not aware of any pending or threatened litigation matters at this time that would have a material impact on the operations of the Company.

License and product development agreements

The Company has entered into various agreements in addition to those discussed above which are described below.

The three oral solution pediatric neurology product candidates discussed below, Topiramate, Zonisamide, and Lamotrigine were developed by the Company and its various product candidate development partners, and the Company subsequently sold certain rights and interests in these three products to Azurity in 2021, but retained rights to certain royalties. The Company has recognized \$27,500 in milestone revenues to date from these three products. Azurity assumed the royalty or profit share obligations owed to development partners as well as additional milestone payments based on sales volume targets. In June 2023, the Company amended its asset purchase agreement with Azurity, and sold the royalty interests it received back to Azurity for total consideration of \$5,500 which was recognized as license revenue for the nine months ended September 30, 2023.

During the years ended December 31, 2021 and 2020, the Company worked with Tulex Pharmaceuticals, Inc. (“Tulex”) as a third-party contract manufacturer to develop an oral solution for Topiramate (fka ET-101) which targets a neurological condition. The Company subsequently filed the product with the FDA in October 2020 and paid a \$1,438 filing fee. In November 2021, the product received approval from the FDA, and was launched by Azurity in December 2021. The Company recognized a \$5,000 milestone revenue at launch which was reflected in accounts receivable on the Company’s balance sheet at December 31, 2021 and subsequently collected in January 2022.

In January 2019, the Company entered into a Licensing and Supply Agreement (the “Agreement”) with Liquimeds Worldwide (“LMW”) for Zonisamide oral liquid, a development stage product candidate (“ET-104”). Pursuant to the terms of the Agreement, the Company was to be responsible for regulatory and marketing activities and LMW was responsible for development and manufacturing of ET-104. The Company paid \$650 to Azurity upon issuance of patent covering ET-104 listed in the FDA’s Orange Book in November 2022.

In June 2019, the Company entered into an Exclusive Licensing and Supply Agreement (the “ET-105 License Agreement”) with Aucta Pharmaceuticals, Inc. (“Aucta”) for marketing rights in the United States to Lamotrigine, an oral suspension product candidate for use as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Pursuant to the terms of the ET-105 License Agreement, the Company was responsible for marketing activities and Aucta will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval.

In March 2020, the Company entered into an Exclusive Licensing and Supply Agreement (the “Alkindi License Agreement”) with Diurnal for marketing ALKINDI SPRINKLE® in the United States. In September 2020, ALKINDI SPRINKLE®’s New Drug Application (NDA) was approved by the FDA as a replacement therapy for pediatric patients with adrenocortical insufficiency.

For the initial licensing milestone fee, the Company paid Diurnal \$3,500 in cash and issued 379,474 shares of its common stock to Diurnal, which were valued at \$1,264 based on the Company’s closing stock price of \$3.33 on March 26, 2020. The Company will also pay Diurnal \$2,500 if the product obtains orphan drug exclusivity status from the FDA.

In June 2021, the Company acquired U.S. and Canadian rights to Crossject’s ZENEO® hydrocortisone needleless autoinjector, which is under development as a rescue treatment for adrenal crisis. The Company paid Crossject \$500 upon signing, \$500 in March 2022 upon a completion of a successful technical batch and could pay up to \$3,500 in additional development milestones and up to \$6,000 in commercial milestones, as well as a 10% royalty on net sales.

In October 2021, the Company acquired the U.S. marketing rights to Carglumic Acid Tablets. The product’s Abbreviated New Drug Application (“ANDA”), which is owned by Novitium Pharma, was approved by the FDA on October 12, 2021. The product is an AB-rated, substitutable generic version of Carbaglu®. The Company paid \$3,250 upon signing and retains 50% of the product profits with the balance being distributed to the licensor and manufacturer. The Company launched this product in December 2021.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(in thousands, except share and per share amounts)
(Unaudited)

Note 11 — Commitments and Contingencies (continued)

In June 2022, the Company sold its rights in Cysteine Hydrochloride, Biorphen®, and Rezipres® to Dr. Reddy's. Under the terms of the transaction, Dr. Reddy's assumed immediate ownership of Eton's rights and interest in the products. The Company received \$5,000 at closing, recorded as licensing revenue in the twelve months ended December 31, 2022, and could receive up to \$42,500 of additional payments based on the achievement of certain event-based and sales-based milestones. Of the \$5,000 received at closing, \$250 was held in escrow to address potential indemnity claims during the 12-month period following the effective date of the agreement. In addition, 10% of any additional payments by Dr. Reddy's during the 12-month period following the effective date will be held in escrow and subsequently released to Eton upon expiration of the 12-month period following the effective date. In accordance with the terms of the agreement, \$812 of Sintetica profit share receivables were expensed as cost of goods sold in the twelve months ended December 31, 2022.

In September 2022, the Company acquired an FDA-approved ANDA for Betaine Anhydrous for oral solution. The ANDA was approved by the FDA in January 2022. The Company paid \$2,000 to the seller upon signing and could pay up to \$1,000 in commercial milestones based on future product sales. The Company will retain 65% of the product profits with the balance being distributed to the licensor.

In March 2023, the Company acquired rare disease endocrinology product candidate ET-600 from Tulex. The Company paid \$450 to Tulex in July 2023 as a result of successful manufacturing of registration batches. The Company will pay Tulex \$200 upon acceptance by the FDA of the NDA for the product, \$250 upon first commercial sale of the product, and tiered royalties of 12.5% to 17.0% on net sales.

Indemnification

As permitted under Delaware law and in accordance with the Company's Amended and Restated Bylaws, the Company is required to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors and officers. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of September 30, 2023 or December 31, 2022.

Note 12 — Subsequent Events

Effective October 11, 2023, the Company acquired an FDA-approved ANDA for Nitisinone Capsules from Oakrum Pharma LLC. The Company paid \$150 to the seller for the acquired product and \$500 to the manufacturer. Eton will retain 80% of product profit and will pay 20% of product profit to the manufacturer.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with (i) our unaudited interim condensed financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 16, 2023 (the "2022 10-K").

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," "may," "plan," "seek" or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider other matters set forth in our SEC filings, including the Risk Factors set forth in Part I, Item 1A of our 2022 10-K.

Overview

Eton is an innovative pharmaceutical company focused on developing, acquiring, and commercializing products to address unmet needs in patients suffering from rare diseases.

The Company currently has three commercial rare disease products, ALKINDI SPRINKLE® for the treatment of adrenocortical insufficiency, Carglumic Acid for the treatment of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, and Betaine Anhydrous for the treatment of homocystinuria. The Company has three additional product candidates in late-stage development: ZENEO® hydrocortisone autoinjector for the treatment of adrenal crisis, ET-400, an innovative patent, and ET-600 for the treatment of an endocrinology condition.

As noted in Note 12, effective October 11, 2023, the Company acquired an FDA-approved ANDA for Nitisinone Capsules from Oakrum Pharma LLC.

Results of Operations (dollars in thousands)

For the three months ended September 30, 2023, we had \$7,028 in total revenue that generated a gross profit of \$4,403. We had total revenue of \$3,219 for the three-month period ended September 30, 2022 that generated a gross profit of \$2,018 for the period. The increase was primarily due to increased sales volume of the Company's ALKINDI SPRINKLE® and Carglumic Acid products.

For the nine months ended September 30, 2023, we had \$24,329 in total revenue that generated a gross profit of \$17,431. We had total revenue of \$12,753 for nine months ended September 30, 2022 that generated a gross profit of \$7,958 for the period. The increase was primarily due to increased sales volume of the Company's ALKINDI SPRINKLE® and Carglumic Acid products as well as a \$500 increase in licensing revenue.

Research and Development Expenses

For the three months ended September 30, 2023, we incurred \$615 of research and development ("R&D") expenses as compared to the \$744 for the same period in 2022. The decrease was primarily due to decreased expenses associated with products sold to Dr. Reddy's in June 2022.

For the nine months ended September 30, 2023, we incurred \$2,275 of research and development ("R&D") expenses as compared to the \$3,052 for the same period in 2022. The decrease was primarily due to decreased expenses associated with products sold to Dr. Reddy's in June 2022.

General and Administrative Expenses

G&A expenses consist primarily of employee compensation expenses, legal and professional fees, product marketing expenses, distribution expenses, business insurance, travel expenses, and general office expenses.

For the three-month periods ended September 30, 2023 and 2022, we incurred \$4,336 and \$4,169, respectively, of G&A expenses. The slight increase in G&A expenses was mainly due to increased employee-related expenses related to our sales force expansion and was partially offset by decreased sales and marketing expenses associated with third-party sales commissions.

For the nine months ended September 30, 2023 and 2022, we incurred \$14,355 and \$14,228, respectively, of G&A expenses. The slight increase in G&A expenses included incremental employee-related expenses related to our sales force expansion and was partially offset by decreased sales and marketing expenses associated with third-party sales commissions along with decreased FDA fees and legal fees associated with products sold to Dr. Reddy's in June 2022.

Other Income and Expenses

For the nine months ended September 30, 2023, we recorded \$800 of other income in accordance with a break-up fee received as the result of participating in an asset acquisition auction process where the Company was not ultimately named the winning bidder.

Liquidity and Capital Resources

As of September 30, 2023, we had total assets of \$31.5 million, including cash and cash equivalents of \$22.1 million and working capital of \$16.8 million. We had previously capitalized our operations from the June 2017 private placement of approximately \$20.1 million of Series A preferred stock which converted into shares of our common stock concurrent with our IPO in November 2018, which provided us with net proceeds of \$22.0 million. In addition, we entered into a Credit Agreement with SWK Holdings in November 2019, whereby we drew a \$5.0 million loan amount at closing and an additional \$2.0 million in August 2020. In March and April 2020, we received net proceeds of approximately \$7.8 million from the sale of shares of our common stock. In October 2020, we received net proceeds of approximately \$21.0 million from a public offering of our common stock at an offering price of \$7.00 per share. We believe that our existing funding and revenues from our approved products will be sufficient for at least the next twelve months of our operations. However, our projected estimates for our product development spending, administrative expenses, and our working capital requirements could be inaccurate, or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

Cash Flows

The following table sets forth a summary of our cash flows for the nine-month periods ended September 30, 2023 and 2022 (dollars in thousands):

	Nine months ended September 30, 2023	Nine months ended September 30, 2022
Net cash provided by operating activities	\$ 6,428	\$ 1,981
Cash used in investing activities	—	(2,776)
Cash used in financing activities	(663)	(233)
Change in cash and cash equivalents	<u>\$ 5,765</u>	<u>\$ (1,028)</u>

The increase in cash provided by operating activities was primarily due to increased sales and gross profit from sales of our Alkindi Sprinkle and Carglumic Acid products. The decrease in cash used in investing activities was due to a \$2,000 payment related to the acquisition of Betaine Anhydrous in September 2022, and a \$750 payment related to the approval of Rezipres, a product sold to Dr. Reddy's in June 2022. The increase in cash used in financing activities was primarily due to increased repayments of the Company's long-term debt and lower stock option net proceeds in the nine months ended September 30, 2023.

Critical Accounting Policies

Our condensed financial statements are prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of our condensed financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs, and expenses in our condensed financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our condensed financial statements included herein, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We account for contracts with our customers in accordance with ASC 606, Revenue from Contracts with Customers. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations to assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer’s discretion are generally considered options. We assess whether these options provide a material right to the customer, and if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We recognize as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time, this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in our balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

Milestone Payments – If a commercial contract arrangement includes development and regulatory milestone payments, we will evaluate whether the milestone conditions have been achieved and if it is probable that a significant revenue reversal would not occur before recognizing the associated revenue. Milestone payments that are not within our control or the licensee’s control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

Significant Financing Component – In determining the transaction price, we will adjust consideration for the effects of the time value of money if the expected period between payment by the licensees and the transfer of the promised goods or services to the licensees will be more than one year.

We sell our rare disease products to one pharmacy distributor customer, which provides order fulfillment and inventory storage/distribution services. We may sell products in the U.S. to wholesale pharmaceutical distributors, who then sell the product to hospitals and other end-user customers. Sales to wholesalers are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments of products represents performance obligations under each purchase order. We use a third-party logistics (“3PL”) vendor to process and fulfill orders and have concluded it is the principal in the sales to wholesalers because it controls access to the 3PL vendor services rendered and directs the 3PL vendor activities. We have no significant obligations to wholesalers to generate pull-through sales.

For our rare disease products, we bill at the initial product list price, which is subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements that are recorded as a reduction of net revenues at the date of sale/shipment. Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when products are sold at negotiated discounted prices to members of certain group purchasing organizations (“GPOs”) and government programs. Because of the shelf life of the product and the Company’s lengthy return period, there may be a significant period of time between when the product is shipped and when it issues credits on returned product.

In addition, we pay fees to wholesalers for their distribution services, inventory reporting, and chargeback processing. We pay GPOs fees for administrative services and access to GPO members and concluded the benefits received in exchange for these fees are not distinct from our sales. Accordingly we apply these amounts to reduce revenues. Wholesalers also have rights to return eligible, unsold products nearing or past the expiration date.

We estimate the transaction price when we receive each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler/distributor arising from all of the above factors. We have developed estimates for future returns and chargebacks and the impact of the other discounts and fees we pay, although rare disease product sales are not subject to returns. When estimating these adjustments to the transaction price, the Company reduces it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

We store our rare disease product inventory at our pharmacy distributor customer location and record sales when stock is pulled and shipped to fulfill specific patient orders. We may recognize revenue and cost of sales from product sold to wholesalers upon delivery to the wholesaler location. At that time, the wholesalers take control of the product and take title, bear the risk of loss of ownership, and have an enforceable obligation to pay us. The wholesalers also have the ability to direct sales of products to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, we do not believe they have a significant incentive to return the product.

Upon recognition of revenue from product sales, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, state Medicaid, and GPO fees are included in sales reserves, accrued liabilities and net accounts receivable. We monitor actual product returns, chargebacks, discounts, and fees after the sale. If these amounts end up differing from our estimates, we will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

Stock-Based Compensation

We account for stock-based compensation under the provisions of ASC 718, Compensation – Stock Compensation. The guidance under ASC 718 requires companies to estimate the fair value of the stock-based compensation awards on the date of grant and record expense over the related service periods, which are generally the vesting period of the equity awards. We estimate the fair value of stock-based option awards to our using the Black-Scholes-Merton option-pricing model (“BSM”). The BSM requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined from the implied yields for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options or warrants. Dividends on common stock are assumed to be zero for the BSM valuation of the stock options. The expected term of stock options granted is based on vesting periods and the contractual life of the options. Expected volatility is based on the Company’s own volatility, along with a limited weighting of comparable companies’ historical volatilities, which management believes represents the most accurate basis for estimating expected future volatility under the current conditions. We account for forfeitures as they occur. We use the closing common stock price on the date of grant for the fair value of the common stock.

Because there had been no public market for our common stock prior to the IPO, our board of directors had determined the fair value of the common stock on the grant-date of the stock-based award by considering a number of objective and subjective factors, including enterprise valuations of our common stock performed by an unrelated third-party specialist, valuations of comparable companies, sales of our convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of our capital stock, and general and industry-specific economic outlook. Following our IPO, we use the closing stock price on the date of grant for the fair value of the common stock.

Research and Development Expenses

R&D expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits, stock-based compensation, and other costs to support our R&D operations. External contracted services include product development efforts including certain product licensor milestone payments, clinical trial activities, manufacturing and control-related activities, and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our estimates.

Upfront payments and milestone payments made for the licensing of products that are not yet approved by the FDA are expensed as R&D in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses and are expensed as the related goods are delivered or the services are performed.

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

JOBS Act Transition Period

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. As an emerging growth company, subject to certain conditions, we may rely on certain of these exemptions, including without limitation: (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments. We are exposed to certain market risks relating primarily to interest rate risk on our cash and cash equivalents invested during the period and risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing in short-term, liquid, highly rated instruments. As of September 30, 2023, our cash is in a non-interest-bearing account as well as a government money market fund. We do not currently have exposure to foreign currency risk.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the three-month period ended September 30, 2023, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company’s Chief Executive Officer and Chief Financial Officer have concluded that the Company’s disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition, and results of operations, and you should carefully consider them. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

You should carefully consider the factors discussed in Part I, Item 1A. “Risk Factors” in our 2022 10-K, which could materially affect our business, financial condition, cash flows or future results. The risk factors described in our 2022 10-K, which was filed with the SEC on March 16, 2023, are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, or future results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b-5(1) Trading Plans. During the three months ended September 30, 2023, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of President and Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Stockholders' Equity, (iv) the Condensed Statements of Cash Flows and (v) Notes to Condensed Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

ETON PHARMACEUTICALS, INC.

November 9, 2023

By: /s/ Sean E. Brynjelsen
Sean E. Brynjelsen
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ James R. Gruber
James R. Gruber
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sean E. Brynjelsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eton Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

By: /s/ Sean E. Brynjelsen

Sean E. Brynjelsen

Principal Executive Officer

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James R. Gruber, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eton Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

By: /s/ James R. Gruber

James R. Gruber

Principal Financial and Accounting Officer

ETON PHARMACEUTICALS, INC.
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean E. Brynjelsen, President and Chief Executive Officer of Eton Pharmaceuticals, Inc. (the "Company"), and James R. Gruber, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 9th day of November, 2023.

/s/ Sean E. Brynjelsen

Sean E. Brynjelsen
President and Chief Executive Officer
(Principal Executive Officer)

/s/ James R. Gruber

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

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.