

**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, 2021

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

<u>Securities registered pursuant to Section 12(b) of the Act</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 and posted 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 and post 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 10, 2021, Eton Pharmaceuticals, Inc. had outstanding 24,606,175 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, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,709	\$ 21,295
Accounts receivable, net	385	48
Inventories	334	1,242
Prepaid expenses and other current assets	2,435	2,116
Total current assets	25,863	24,701
Property and equipment, net	134	811
Intangible assets, net	463	575
Operating lease right-of-use assets, net	123	192
Other long-term assets, net	23	40
Total assets	\$ 26,606	\$ 26,319
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,273	\$ 2,344
Current portion of long-term debt	1,092	—
PPP loan, current portion	—	280
Accrued liabilities	995	1,170
Total current liabilities	5,360	3,794
Long-term debt, net of discount and including accrued fees	5,550	6,532
Long-term portion of PPP and EIDL loans	—	231
Operating lease liabilities, net of current portion	36	99
Total liabilities	10,946	10,656
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 24,606,175 and 24,312,808 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	25	24
Additional paid-in capital	110,787	107,797
Accumulated deficit	(95,152)	(92,158)
Total stockholders' equity	15,660	15,663
Total liabilities and stockholders' equity	\$ 26,606	\$ 26,319

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)

	For the three months ended		For the nine months ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenues:				
Licensing revenue	\$ —	\$ —	\$ 14,000	\$ —
Product sales and royalties	775	(161)	1,739	(42)
Total net revenues	775	(161)	15,739	(42)
Cost of sales:				
Licensing revenue	—	—	1,500	—
Product sales and royalties	617	(144)	843	(14)
Total cost of sales	617	(144)	2,343	(14)
Gross profit (loss)	158	(17)	13,396	(28)
Operating expenses:				
Research and development	2,678	2,826	5,554	10,703
General and administrative	3,327	3,429	10,651	8,960
Total operating expenses	6,005	6,255	16,205	19,663
Loss from operations	(5,847)	(6,272)	(2,809)	(19,691)
Other (expense) income:				
Interest and other (expense) income, net	(247)	(232)	(731)	(592)
Gain on PPP loan forgiven	—	—	365	—
Gain on equipment sale	—	—	181	—
Loss before income tax expense	(6,094)	(6,504)	(2,994)	(20,283)
Income tax expense	—	—	—	—
Net loss	\$ (6,094)	\$ (6,504)	\$ (2,994)	\$ (20,283)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.31)	\$ (0.12)	\$ (1.01)
Weighted average number of common shares outstanding, basic and diluted	25,276	21,052	25,181	20,070

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, 2021 and 2020
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at June 30, 2021	24,600,175	\$ 25	\$ 109,769	\$ (89,058)	\$ 20,736
Stock-based compensation	—	—	1,009	—	1,009
Stock option exercises	6,000	—	9	—	9
Net loss	—	—	—	(6,094)	(6,094)
Balances at September 30, 2021	24,606,175	\$ 25	\$ 110,787	\$ (95,152)	\$ 15,660
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at June 30, 2020	20,956,033	\$ 21	\$ 84,977	\$ (77,967)	\$ 7,031
Stock-based compensation	—	—	724	—	724
Stock option exercises	32,500	—	43	—	43
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	94	—	94
Net loss	—	—	—	(6,504)	(6,504)
Balances at September 30, 2020	20,988,533	\$ 21	\$ 85,838	\$ (84,471)	\$ 1,388

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, 2021 and 2020
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2020	24,312,808	\$ 24	\$ 107,797	\$ (92,158)	\$ 15,663
Stock-based compensation	—	—	2,518	—	2,518
Stock option exercises	144,233	1	338	—	339
Employee stock purchase plan	29,326	—	134	—	134
Common stock issued related to restricted stock units	25,000	—	—	—	—
Warrant exercises	94,808	—	—	—	—
Net loss	—	—	—	(2,994)	(2,994)
Balances at September 30, 2021	24,606,175	\$ 25	\$ 110,787	\$ (95,152)	\$ 15,660
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2019	17,877,486	\$ 18	\$ 74,720	\$ (64,188)	\$ 10,550
Stock-based compensation	15,190	—	1,803	—	1,803
Stock option exercises	102,378	—	140	—	140
Employee stock purchase plan	14,005	—	64	—	64
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	94	—	94
Proceeds from sales of common stock, net of offering costs	2,600,000	3	7,753	—	7,756
Issuance of common stock for product candidate licensing rights	379,474	—	1,264	—	1,264
Net loss	—	—	—	(20,283)	(20,283)
Balances at September 30, 2020	20,988,533	\$ 21	\$ 85,838	\$ (84,471)	\$ 1,388

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, 2021	Nine months ended September 30, 2020
Cash flows from operating activities		
Net loss	\$ (2,994)	\$ (20,283)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	2,518	1,803
Common stock issued for product candidate licensing rights	—	1,264
Depreciation and amortization	325	490
Debt discount amortization	110	85
Gain on forgiveness of debt	(365)	—
Gain on sale of equipment	(181)	—
Changes in operating assets and liabilities:		
Accounts receivable	(337)	473
Inventories	908	(1,319)
Prepaid expenses and other assets	(283)	1,305
Accounts payable	929	1,633
Accrued liabilities	(234)	(615)
Net cash provided by (used in) operating activities	396	(15,164)
Cash provided by (used in) investing activities		
Proceeds from sale of equipment	700	—
Purchases of property and equipment	(5)	(6)
Net cash provided by (used in) investing activities	695	(6)
Cash flows from financing activities		
Proceeds from sales of common stock, net of offering costs	—	7,756
Proceeds from issuance of long-term debt, net of issuance costs	—	1,965
EIDL loan payoff	(150)	—
Proceeds from PPP and EIDL loans	—	511
Proceeds from employee stock purchase plan and stock option exercises	473	204
Net cash provided by financing activities	323	10,436
Change in cash and cash equivalents	1,414	(4,734)
Cash and cash equivalents at beginning of period	21,295	12,066
Cash and cash equivalents at end of period	\$ 22,709	\$ 7,332
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 603	\$ 545
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosure of non-cash financing activity		
Relative fair value of warrants to purchase common stock issued in connection with debt	\$ —	\$ 94

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 Pharmaceuticals, Inc. (“Eton” or the “Company”) was incorporated as a Delaware “C” corporation on April 27, 2017 and was initially set up as a wholly-owned subsidiary of Harrow Health, Inc. (“Harrow”, fka Imprimis Pharmaceuticals, Inc.). In June 2017, the Company raised \$20,055 in start-up capital through a private sale of preferred stock and a separate management team was then established for Eton with its corporate offices located in Deer Park, Illinois. In November 2018, the Company completed its initial public offering (the “IPO”) and received net proceeds of \$21,960, after deducting underwriting discounts and commissions and offering-related expenses. In November 2019, the Company entered into a credit agreement and received net proceeds of \$4,750 and in August 2020 the Company received net proceeds of \$1,965 under the credit agreement (see Note 5). In March and April 2020, Eton received net proceeds of \$7,756 from the sale of shares of its common stock in a private placement and in October 2020, the Company received net proceeds of \$21,026 from a public offering for its common stock at an offering price of \$7.00 per share.

Eton is an innovative specialty pharmaceutical company focused on developing, acquiring, and commercializing treatments for rare diseases. The Company seeks to improve the formula, delivery system, or safety of existing molecules in order to address unmet patient needs. Eton pursues what it perceives to be low-risk product candidates where existing published literature, historical clinical trials, or physician usage has established safety and/or efficacy of the molecule, thereby reducing the incremental clinical burden required for the Company to bring the product to patients.

The Company’s Biorphen® product was approved by the FDA in October 2019 and sales commenced for this product at the end of 2019. Eton’s EM-100 product was sold to Bausch Health and the product was approved by the FDA in September 2020. Bausch Health launched this product under the name of Alaway® Preservative Free in January 2021 and Eton receives royalties from the sale of the product. In addition, the Company acquired the licensing rights to Alkindi Sprinkle and this product was approved by the FDA in October 2020 and launched in December 2020. In February 2021, the Company sold three pediatric neurology products it had under development to Azurity Pharmaceuticals (“Azurity”) and anticipates additional revenues from Azurity based on various product-related milestones including the commercial launch for these products. One of the three products was approved by the FDA in November 2021 and two are currently under review with the FDA. In June 2021, the Company’s Rezipres product was approved by the FDA and is expected to launch in the coming months. In October 2021, the Company acquired the rights to an FDA-approved generic carglumic acid product indicated for the treatment of hyperammonemia due to N-acetylglutamate Synthase (NAGS) deficiency and it expects to launch this product late in 2021. The Company has three additional product candidates under development, two of which have been submitted to the FDA.

Note 2 — Liquidity Considerations

During the first nine months of 2021, the Company generated net cash provided by operating activities of \$396 primarily from the sale of three neurology products. The Company expects further growth in 2021 and beyond in accordance with additional market penetration from its approved products plus additional revenues from licensing and additional products where it anticipates FDA approval. Prior to 2021, the Company had generated limited revenues and had incurred negative cash flows from operating activities since its inception in 2017.

The Company currently believes its existing cash and cash equivalents of \$22,709 as of September 30, 2021 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 its 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, there can be no assurance that the Company will be able to raise additional capital if needed or under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares 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 sales growth and completing its product development and obtaining regulatory approval for its other product candidates and is unable to obtain such additional financing, operations would need to be scaled back or discontinued.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

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

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)

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, 2021 and the results of its operations and its cash flows for the periods ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine-month periods ended September 30, 2021 and 2020 are also unaudited. The results for the nine-month period ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, 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 as of 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 and sales returns, valuation of inventories, useful lives of assets and the impairment of property and equipment, the accrual of research and development expenses and the valuation of common stock, stock options and warrants. 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 short-term money market accounts. From time to time, amounts deposited with its bank exceed federally insured limits and 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 and returns and allowances. The total for these reserves amounted to \$91 and \$71 as of September 30, 2021 and December 31, 2020, respectively.

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. During the three-month period ended September 30, 2021, the Company recorded a provision of \$432 for excess quantities of its Biorphen product that are approaching expiration. Inventories at September 30, 2021 and December 31, 2020 consist solely of purchased finished goods. At September 30, 2021 and December 31, 2020, inventories are shown net of a slow-moving reserve for its Biorphen product of \$1,414 and \$623, 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.

In March 2021, the Company completed an evaluation of its expected needs for product development and testing activities and determined that it would discontinue its laboratory operation in Lake Zurich, Illinois. The Company completed a sale of the lab equipment in May 2021 at a price of \$700 which was \$181 in excess of the book value for these assets. Accordingly, the \$519 net book value of these assets was removed from the property and equipment accounts and the \$181 gain is reflected in the Company's statements of operations for the nine-month period ended September 30, 2021. In conjunction with the closing of its laboratory operation, the Company scrapped various furniture and equipment which had a net book value of \$31 which has been included in research and development expense in the statements of operations.

Intangible Assets

The Company capitalizes payments it makes for licensed products when the payment is based on FDA approval for the 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. A \$750 payment related to the approval of the Company's Biorphen product in 2019 has been capitalized and that cost is being amortized over five years. The intangible assets, net on the Company's balance sheet reflected \$287 of accumulated amortization as of September 30, 2021. The Company recorded \$37 and \$112 of amortization expense for the three and nine months ended September 30, 2021, respectively. The Company will record amortization expense of \$150 per year for this intangible asset for 2021 through 2023 and then \$125 in 2024 when it will be fully amortized.

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 has been recognized since the Company's inception in 2017.

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 relate to the relative fair value of warrants issued in conjunction with the debt and are also recorded as a reduction to the debt balance and accreted over the expected term of the debt to interest expense using the effective interest method.

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 which 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.

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)

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 and assesses 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.

The Company recognizes as revenue the amount of the transaction price that is 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. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

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 Biorphen 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 Biorphen represent performance obligations under each purchase order. The Company uses a third-party logistics ("3PL") vendor to process and fulfill orders and has 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. The Company has no significant obligations to wholesalers to generate pull-through sales. In addition, the Company sells its Alkindi Sprinkle product to one pharmacy distributor customer which provides order fulfillment and inventory storage/distribution services.

Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell Biorphen at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs. In addition, the Company pays fees to wholesalers for their distribution services, inventory reporting and chargeback processing. The Company pays GPOs fees for administrative services and for access to GPO members and concluded the benefits received in exchange for these fees are not distinct from its sales of Biorphen, and accordingly it applies these amounts to reduce revenues. Wholesalers also have rights to return unsold product nearing or past the expiration date. Because of the shelf life of Biorphen 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. For its Alkindi Sprinkle product, the Company bills at the initial product list price which are subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements which are recorded as a reduction of net revenues at the date of sale/shipment.

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 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 of Biorphen and the impact of the other discounts and fees it pays while Alkindi Sprinkle sales to its distributor 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 recognizes revenue from Biorphen product sales and related cost of sales upon product delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership, and have an enforceable obligation to pay the Company. They also have the ability to direct sales of product 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. The Company stores its Alkindi Sprinkle inventory at its pharmacy distributor customer location and sales are recorded when stock is pulled and shipped to fulfill specific patient orders.

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 of accounts receivable. The Company monitors actual product returns, chargebacks, discounts and fees subsequent to 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 receives revenues from product licensing agreements where it has contracted for milestone payments and royalties from products it has developed or for which it has acquired the rights to a product developed by a third party.

Revenues for the three months ended September 30, 2021 reflected \$734 in product sales and \$41 in royalty revenue. Revenues for the nine months ended September 30, 2021 reflected \$14,000 of licensing milestone fees, \$1,481 in product sales and \$258 in royalty revenue. Revenues for the three and nine months ended September 30, 2020 consisted solely of product sales.

Cost of Sales

Cost of 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, write-downs for excess/obsolete inventory, and freight and handling/storage costs from the Company's 3PL logistics service providers. The cost of sales for profit-sharing and royalty fees and costs for purchased finished products and the associated inbound freight expense is 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. Cost of 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 and 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 technology for 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.

Eton Pharmaceuticals, Inc.
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Note 3 — Summary of Significant Accounting Policies (continued)

Income (Loss) Per Share

Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares, such as unvested restricted stock awards (“RSA”), restricted stock units (“RSU”), stock options and warrants, outstanding during the period. Common stock equivalents (using the treasury stock method) from stock options, unvested RSAs and RSUs, and warrants at September 30, 2021 and 2020 were 4,279,400 and 3,308,152, respectively, and are excluded from the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net loss per share calculation are RSUs awarded to directors that have vested, but the issuance and delivery of the common shares are deferred until the director retires from service as a director.

Basic weighted average shares for the three and nine months ended September 30, 2021 include 600,000 vested warrants to purchase common shares. As the shares underlying these warrants can be purchased for little to no consideration (\$0.01 per share exercise price), they are included in the computation of basic earnings per share.

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 volatilities are based on comparable companies’ historical volatility along with a limited weighting included for the Company’s own volatility subsequent to its IPO, 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.

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.

Eton Pharmaceuticals, Inc.
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Note 3 — Summary of Significant Accounting Policies (continued)

The Company's financial instruments included cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and a long-term debt obligation. Based on borrowing rates currently available to the Company, 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.

Impact of New Accounting Pronouncements

There were no new accounting pronouncements issued by the FASB during the current period that would apply to the Company and have a material impact on its financial position or results of operations.

Note 4 — Property and Equipment

Property and equipment consist of the following:

	September 30, 2021	December 31, 2020
Computer hardware and software	\$ 155	\$ 182
Furniture and fixtures	105	143
Equipment	132	994
Leasehold improvements	71	184
	463	1,503
Less: accumulated depreciation	(329)	(692)
Property and equipment, net	\$ 134	\$ 811

Depreciation expense for the three-month periods ended September 30, 2021 and 2020 was \$24 and \$86, respectively. Depreciation expense for the nine-month periods ended September 30, 2021 and 2020 was \$132 and \$260, respectively. The balances at September 30, 2021 reflect the sale of laboratory equipment in May 2021 which had a net book value of \$519.

Note 5 — Long-Term Debt

SWK Loan

On November 13, 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 was able to borrow an additional \$5,000 upon the FDA approval of a second product developed by the Company, excluding EM-100. In March 2020, in conjunction with the Company's Alkindi Sprinkle product licensing agreement (see Note 12) and the Company's March 2020 sale of additional shares of its common stock, the Company and SWK amended the SWK Credit Agreement. The amendment provided the Company with the option to immediately draw an additional \$2,000 and the ability to borrow an additional \$3,000 based upon the FDA approval of EM-100 and Alkindi Sprinkle which subsequently occurred in September 2020. Accordingly, the Company borrowed an additional \$2,000 on August 11, 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 is required to maintain a minimum cash balance of \$3,000, will only pay interest on the debt until February 14, 2022 and then will 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.

Eton Pharmaceuticals, Inc.
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Note 5 — Long Term Debt (continued)

The SWK Credit Agreement contains customary default provisions and covenants which include limits on 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 will 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 in November 2019, 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 the 51,239 warrants was \$226 and was estimated using the Black-Scholes-Merton option pricing model 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 the Black-Scholes-Merton option pricing model 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%.

These warrants (the "SWK Warrants") are exercisable immediately and have a term of seven years from the date of issuance. The SWK Warrants contain 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.

Interest expense of \$766 was recorded during the nine months ended September 30, 2021, which included \$110 of debt discount amortization. Interest expense of \$617 was recorded during the nine months ended September 30, 2020, which included \$85 of debt discount amortization. As of September 30, 2021, \$107 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, 2021.

	Amount
2021	\$ 212
2022	2,202
2023	1,756
2024	5,300
Total payments	9,470
Less: amount representing interest	(2,470)
Loan payable, gross	7,000
Less: current portion of long-term debt	(1,092)
Less: unamortized discount	(358)
Long-term debt, net of unamortized discount	\$ 5,550

PPP loan

On May 4, 2020, the Company received \$361 in loan proceeds under the Paycheck Protection Program ("PPP") from the Small Business Administration ("SBA") through its banking relationship with Bank of America. On May 20, 2021, the Company received notice that the \$361 loan principal along with cumulative interest of \$4 was forgiven in full as permitted under the applicable SBA guidelines for PPP loans. The \$365 gain on debt extinguishment is reflected in non-operating income for the nine-month period ended September 30, 2021.

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Notes to Condensed Financial Statements
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Note 5 — Long Term Debt (continued)

EIDL loan

On July 21, 2020, the Company received \$150 in loan proceeds under the Economic Injury Disaster Loan program (“EIDL”) from the SBA. The Company paid off the full EIDL loan principal and its cumulative interest of \$6 in July 2021.

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, 2021, the Company issued 144,233 shares of its common stock resulting from stock option exercises under its 2018 Equity Incentive Plan (see Note 8). In April 2021, the Company issued 25,000 shares of common stock to a member of its board of directors upon his retirement from the board in connection with previously vested restricted stock units (“RSUs”).

During the nine months ended September 30, 2021, a holder of the Company’s common stock warrants exercised 135,650 warrants on a cashless basis and the Company issued 94,808 shares of its common stock in connection with the warrant exercise. The intrinsic value of the warrant exercise was \$806.

In June 2021, the Company issued 29,326 shares of its common stock to employees in accordance with its Employee Stock Purchase Plan (“ESPP”).

Note 7 — Common Stock Warrants

The Company’s outstanding warrants to purchase shares of its common stock at September 30, 2021 are summarized in the table below.

Description of Warrants	No. of Shares	Exercise Price	
Business Advisory Warrants	600,000	\$	0.01
Placement Agent Warrants – 2017 Preferred Stock Offering	471,446	\$	3.00
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	1,554,826	\$	3.18(Avg)

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.

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Note 8 — Share-Based Payment Awards

The Company's board of directors and stockholders approved the Eton Pharmaceuticals, Inc. 2017 Equity Incentive Plan in May 2017 (the "2017 Plan"), which authorized the issuance of up to 5,000,000 shares of the Company's common stock. In conjunction with the Company's IPO in November 2018, the Company's stockholders and board of directors approved the 2018 Equity Incentive Plan (as amended in January 2021, 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 481,160 shares available for future issuance under the 2018 Plan as of September 30, 2021.

Shares 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 not 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.

During the third quarter of 2017, the Company issued 25,000 RSU's to each of its four outside directors (100,000 total share units). The RSU's issued to the outside directors were 100% vested at June 30, 2018. The associated 100,000 shares of the Company's common stock are not issued until the individual director retires from service from the Company's board of directors. In April 2021, 25,000 of these vested RSU shares were issued to a director after his retirement from the Company's board. The Company has not issued any additional RSU's.

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 expire within five years if the Company is not able to file certain product submissions to the FDA prior to the five-year expiration date. Furthermore, these option awards to the Company's product consultants do not vest unless certain product submissions are made to the FDA, and accordingly, the Company has not recorded any expense for these contingently vesting option awards to its product consultants.

For the three months ended September 30, 2021 and 2020, the Company's total stock-based compensation expense was \$1,009 and \$724, respectively. Of these amounts, \$838 and \$647, respectively, was recorded in general and administrative expenses, and \$171 and \$77, respectively, was recorded in research and development expenses.

For the nine months ended September 30, 2021 and 2020, the Company's total stock-based compensation expense was \$2,518 and \$1,803, respectively. Of these amounts, \$2,110 and \$1,623, respectively, was recorded in general and administrative expenses, and \$408 and \$180, respectively, was recorded in research and development expenses.

Eton Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
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Note 8 — Share-Based Payment Awards (continued)

A summary of stock option activity is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Yrs)	Aggregate Intrinsic Value
Options outstanding as of December 31, 2020	2,824,500	\$ 4.05	8.3	\$ 11,525
Issued	902,098	\$ 8.61		
Exercised	(144,233)	\$ 2.35		
Forfeited/Cancelled	(12,500)	\$ 7.31		
Options outstanding as of September 30, 2021	3,569,865	\$ 5.26	8.1	\$ 4,167
Options exercisable at September 30, 2021	1,734,652	\$ 4.00	7.4	\$ 2,961
Options vested and expected to vest at September 30, 2021	3,519,865	\$ 5.31	8.1	\$ 3,984

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 for those stock options that had strike prices lower than the fair value of the Company's common stock at period end.

The assumptions used to calculate the fair value of options granted during the nine months ended September 30, 2021 under the BSM were as follows:

Expected dividends	—%
Expected volatility	80%
Risk-free interest rate	0.9 - 1.1%
Expected term	5.3 – 6.3 years
Weighted average fair value	\$ 5.88

Expected Term — The Company has opted to use the “simplified method” for estimating the expected term of options granted to employees and directors, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally ten years). The expected term of options granted to non-employees equals the contractual life of the options.

Expected Volatility — Due to the Company's limited operating history and a lack of Company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The Company has continued this methodology plus given some limited weighting to its own volatility in the periods subsequent to its November 2018 IPO. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options.

Expected Dividend — The Company has not issued any dividends in its history and does not expect to issue dividends over the life of the options and therefore has estimated the dividend yield to be zero.

Fair Value of Common Stock — The Company uses the closing stock price on the date of grant for the fair value of the common stock.

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Notes to Condensed Financial Statements
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Note 8 — Share-Based Payment Awards (continued)

As of September 30, 2021, there was a total of \$7,270 of unrecognized compensation costs related to non-vested stock option and restricted awards. During the nine-month period ended September 30, 2021, there were five stock option exercises which totaled 144,233 shares at an average exercise price of \$2.35 per share with an intrinsic value of \$682. There were six stock option exercises for 102,378 shares during the nine months ended September 30, 2020 at an average exercise price of \$1.37 per share with an intrinsic value of \$436.

In December 2018, the Company's board of directors approved and adopted an initial offering of the Company's common stock under the Company's 2018 ESPP. The Company's 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, 2021, there were 500,009 shares available for issuance under the ESPP.

The initial offering of the ESPP began on December 17, 2018 and ended on December 10, 2019. The annual offerings consist of two stock purchase periods, with the first purchase period ending in June and the second purchase period 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 initial offering period ended, 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.

For the first nine months of 2021 and 2020 there were 29,326 and 14,005 share issuances under the ESPP. The weighted average grant date fair value of share awards in the first nine months of 2021 and 2020 was \$2.83 and \$2.43, respectively. Employees contributed \$192 and \$100 via payroll deductions during the nine months ended September 30, 2021 and 2020, respectively. The Company recorded an expense of \$83 and \$38 related to the ESPP in the nine-month periods ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, the accompanying condensed balance sheets include \$77 and \$19, respectively, in accrued liabilities for remaining employee ESPP contributions.

Note 9 — Earnings (Loss) Per Share

Basic and diluted net income (loss) per share was calculated as follows:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Basic net loss per share:				
Numerator:				
Net loss	\$ (6,094)	\$ (6,504)	\$ (2,994)	\$ (20,283)
Denominator:				
Weighted-average number of common shares outstanding, basic and diluted	25,276,153	21,052,174	25,181,095	20,070,430
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.31)	\$ (0.12)	\$ (1.01)

There was no difference between the Company's net loss and the net loss attributable to common stockholders for all periods presented.

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Note 10 — Related Party Transactions

Harrow

Harrow was issued 3,500,000 shares of the Company's common stock at the formation of the Company at the \$0.001 par value per share price as the paid-in-capital contribution from Harrow. In April 2021, Harrow sold 1,518,000 shares of the Eton common stock it owned in an underwritten public offering. As of September 30, 2021, Harrow owned 1,982,000 shares of Eton's common shares which represents 8.1% of the Company's common shares outstanding. In 2017, the Company and Harrow signed licensing agreements for two products developed by Harrow whereby Harrow assigned the product rights to the Company. In July 2018, the Company determined that one of the products was not viable for its portfolio of product opportunities and cancelled the licensing agreement whereby Harrow retains the product rights.

On May 6, 2019, the Company entered into an Asset Purchase Agreement (the "CT-100 Asset Purchase Agreement") with Harrow. Pursuant to the CT-100 Asset Purchase Agreement, the Company sold all of its right, title and interest in CT-100 to Harrow, including any such product that incorporates or utilizes its intellectual property rights (a "Product" or, collectively, "Products"). Pursuant to the CT-100 Asset Purchase Agreement, Harrow will make certain payments to the Company upon the achievement of certain development and commercial milestones. In addition, Harrow is required to pay the Company a royalty in the low-single digit percentage range worldwide on a country-by-country basis on net sales for a period of the longer of 15 years from the date of the first commercial sale of a product in a particular country or the time that a valid intellectual property claim on such Product remains in force in the applicable country. The CT-100 Asset Purchase Agreement also contains customary representations, warranties, covenants and indemnities by the parties. To date there have not been any sales of the CT-100 product and therefore no earned royalties to the Company for this product.

As part of the early start-up for the Company's pharmaceutical business in 2017, key executives at Harrow received a total of 1,500,000 shares of restricted common stock in the Company for consulting services, and certain Harrow managers also received stock options to purchase a total of 130,000 shares of common stock from the Company (20,000 of these options were forfeited in 2018). The restricted stock and stock options vested in full on April 30, 2018.

Additionally, the Chief Executive Officer of Harrow was a member of the Company's board of directors until March 17, 2021 when he retired from service with the board. The Company issued 25,000 shares to the Harrow CEO in April 2021 after his retirement from the Company's board associated with RSU's that were previously fully vested.

In late March 2021, the Company closed its laboratory operation in Lake Zurich, Illinois and in May 2021 it reached an agreement for Imprimis Pharmaceuticals, a subsidiary of Harrow, to purchase its lab equipment for \$700 which was \$181 above the Company's net book value of the equipment.

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Note 10 — Related Party Transactions (continued)

Chief Executive Officer

The CEO has a partial interest in a company that the Company has partnered with for its EM-100 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 original agreement, the Company would pay Eyemax \$250 upon FDA approval and \$500 upon the first commercial sale of the product and pay Eyemax 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 Eyemax 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 Excelvision SAS dated as of July 11, 2013, as amended (the “Excelvision Agreement”), with respect to certain territories and arising during certain time periods. Pursuant to the Amended Agreement, the Company was obligated to pay 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 which was paid in October 2020 and (ii) one milestone payment for \$500 following the first commercial sale of the first single agent product in the territory which was paid in February 2021. Following payment of the milestones, the Company is entitled to retain all of the non-royalty transaction revenues and royalties up to \$2,000 (the “Recovery Amount”). After the Company has retained the full Recovery Amount, it is entitled to retain half of all royalty and non-royalty transaction revenue. 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 EM-100, which was approved by the FDA in September 2020, will 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 EM-100 U.S market share falls below a specified target percentage. There were no amounts due to Eyemax under the terms of the Amended Agreement as of September 30, 2021 or December 31, 2020.

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Note 11 — 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 in the “Research and Development” and “General and Administrative” captions in the condensed statements of operations was \$0 and \$21, respectively, for the three months ended September 30, 2021 and \$13 and \$21, respectively, for the three months ended September 30, 2020. The Company’s operating lease cost as presented in the “Research and Development” and “General and Administrative” captions in the condensed statements of operations was \$9 and \$64, respectively, for the nine months ended September 30, 2021 and \$41 and \$62, respectively, for the nine months ended September 30, 2020. Cash paid for amounts included in the measurement of operating lease liabilities was \$63 for the nine months ended September 30, 2021. The ROU asset amortization for the three and nine-month periods ended September 30, 2021 was \$20 and \$69, respectively, and is reflected within depreciation and amortization on the Company’s condensed statements of cash flows. The ROU asset amortization for the three and nine-month periods ended September 30, 2020 was \$33 and \$97, respectively, and is reflected within depreciation and amortization on the Company’s condensed statements of cash flows. As of September 30, 2021, the weighted-average remaining lease term was 1.50 years, and the weighted-average incremental borrowing rate was 5.4%.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of September 30, 2021 (in thousands).

Assets	Classification		
Operating lease right-of-use assets	Operating lease right-of-use assets, net	\$	123
Total leased assets		\$	123
Liabilities			
Operating lease liabilities, current	Accrued liabilities	\$	83
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion		36
Total operating lease liabilities		\$	119

The Company’s future lease commitments for its administrative offices in Deer Park, Illinois as of September 30, 2021 are as indicated below:

	<u>Total</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>Thereafter</u>
Undiscounted lease payments	\$ 124	22	88	14	—
Less: Imputed interest	(5)				
Total lease liabilities	\$ 119				

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

Note 12 — 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 may 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 Company acquired the exclusive rights to sell the Cysteine injection product in the United States pursuant to a sales and marketing agreement dated November 17, 2017 with an unaffiliated third party (the “Sales Agreement”). Pursuant to the Sales Agreement, the licensor is responsible for obtaining FDA approval, at its expense, and the Company is responsible for commercializing the product in the United States at its expense. The Company was to pay the third party 50% of the net profit from the sale of the product, however, in February 2020, it executed an amendment to the Sales and Marketing Agreement. Under the revised terms, the Company will be responsible for paragraph IV related litigation and will be entitled to 62.5% of product profit. The initial term is for the first 10 years following the first commercial sale of the product.

On February 8, 2019, the Company entered into an Exclusive Licensing and Supply Agreement (the “ET-202 License Agreement”) with Sintetica SA (“Sintetica”) for marketing rights in the United States to Biorphen® which is used for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. The product was submitted to the FDA for review and subsequently received FDA approval on October 21, 2019. Pursuant to the terms of the ET-202 License Agreement, the Company is responsible for marketing activities and Sintetica is responsible for development, manufacturing, and the regulatory activities related to approval. The Company paid Sintetica a licensing payment of \$2,000 upon execution of the ET-202 License Agreement and \$750 upon the commencement of commercial product shipments. Sintetica supplies Biorphen to the Company at its direct costs and the Company retains 5% of net sales as a marketing fee. Sintetica is entitled to receive the first \$500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-202 License Agreement has a ten-year term from the first commercial sale of Biorphen which occurred in November 2019.

On February 8, 2019, the Company also entered into an Exclusive Licensing and Supply Agreement (the “ET-203 License Agreement”) with Sintetica for marketing rights in the United States to ephedrine (brand name Rezipres®), an injectable product candidate for use in the hospital setting. Pursuant to the terms of the ET-203 License Agreement, the Company will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Sintetica a licensing payment of \$1,000 upon execution of the ET-203 License Agreement which was refunded to Eton in early 2020 due to the FDA not accepting the ET-203 file submission by Sintetica. The refund was reflected as a component of prepaid and other current assets on the Company’s balance sheet at December 31, 2019. The ET-203 product was successfully resubmitted in late 2020 and the Company paid a \$600 milestone fee in October 2021. The product has received FDA approval and the Company will pay \$750 upon the commercial launch of the product candidate which is anticipated in late 2021. Sintetica will supply ET-203 to the Company at its direct costs. The Company will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first \$500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-203 License Agreement has a ten-year term from first commercial sale of product.

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 all its rights and interests in these three products to Azurity Pharmaceuticals, Inc. (“Azurity”) in 2021.

During the years ended December 31, 2020, 2019 and 2018, 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.

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

Note 12 — Commitments and Contingencies (continued)

On January 23, 2019, the Company entered into a Licensing and Supply Agreement (the “Agreement”) with Liqmeds Worldwide Limited (“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. LMW will be responsible for development and manufacturing of ET-104. The Company paid the licensor \$350 upon execution of the Agreement and an additional \$350 after receiving successful bioequivalence study results, and \$325 upon the FDA’s acceptance of the NDA for review and will pay \$325 upon FDA approval of the NDA, \$650 upon issuance of patent covering ET-104 listed in the FDA’s Orange Book and \$500 in the event that product sales in excess of \$10,000 were achieved within a calendar year. In addition, the Company was required to pay the licensor 35% of the net profit from product sales. The Agreement was for an initial term of 10 years from the date of the first commercial sale of the product. The Company was to retain sole ownership of the NDA after expiration of the Agreement.

On June 12, 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 to be responsible for marketing activities and Aucta will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Aucta a licensing payment of \$2,000 in August 2019 upon receiving an acceptance for review letter from the FDA and will pay \$2,450 upon FDA approval and commercial sales of the product candidate and another \$1,000 upon issuance of an Orange-book listed patent. If Aucta successfully completes a Lamotrigine product line extension product, Eton will pay \$1,500 upon FDA acceptance of the product filing and \$1,950 upon FDA approval and commercial sales of the extension product candidate. Aucta will receive a low double-digit royalty on net sales and will be entitled to receive milestone payments of up to \$18,000 based on commercial success of the product, including:

- \$1,000 when net sales exceed \$10 million in a calendar year
- \$2,000 when net sales exceed \$20 million in a calendar year
- \$5,000 when net sales exceed \$50 million in a calendar year
- \$10,000 when net sales exceed \$100 million in a calendar year

Eton will remain responsible for certain licensing fee obligations owed to its development partners and Azurity will assume royalty or profit share obligations owed to development partners.

On March 27, 2020, the Company entered into an Exclusive Licensing and Supply Agreement (the “Alkindi License Agreement”) with Diurnal Limited (“Diurnal”) for marketing Alkindi Sprinkle in the United States. Alkindi Sprinkle’s New Drug Application (NDA) was approved by the FDA on September 29, 2020 as a replacement therapy for pediatric adrenal insufficiency (AI), including congenital adrenal hyperplasia (CAH) in patients from birth to less than 17 years of age.

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 total amount of \$4,764 was recorded as a component of research and development expense in the Company’s statement of operations for the nine months ended September 30, 2020. The Company pays Diurnal a low double-digit royalty on its sales of Alkindi Sprinkle and will also pay Diurnal \$2,500 if the product obtains orphan drug exclusivity status from the FDA.

On June 15, 2021, the Company entered into a Distribution and Promotion License Agreement with Crossject S.A. (“Crossject”) for the U.S. and Canadian rights to Crossject’s ZENEO[®] hydrocortisone needleless autoinjector, which is under development as a rescue treatment for adrenal crisis. The product complements the Company’s Alkindi Sprinkle product which addresses pediatric adrenal insufficiency. The Company paid Crossject \$500 upon execution of the agreement which has been included in research and development expense in the statements of operations and will pay an additional \$500 for technical batches of the product if the technical batches are completed by December 31, 2021 and then another \$500 for registration batches if those are completed by December 31, 2022. The Company will pay Crossject \$1,500 upon FDA acceptance of the product filing and \$2,000 upon FDA approval of the product. The acceptance and approval fees are subject to reduction if other hydrocortisone autoinjector intramuscular products receive FDA approval prior to the Crossject product. In addition, the Company will pay Crossject a ten percent royalty on net sales and one-time net sales milestone fees of up to \$6,000 as indicated in the table below:

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

Note 12 — Commitments and Contingencies (continued)

- \$1,000 when net sales exceed \$10 million in any four consecutive quarters
- \$2,000 when net sales exceed \$20 million in any four consecutive quarters
- \$3,000 when net sales exceed \$30 million in any four consecutive quarters

Indemnifications

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, 2021 or December 31, 2020.

Note 13 — Subsequent Events

On October 27, 2021, the Company entered into a license agreement for a generic carglumic acid product which is used to treat hyperammonemia due to N- acetylglutamate Synthase (NAGS) deficiency. The Company paid \$3,250 at signing for the exclusive U.S. licensing rights for the carglumic acid product and expects to launch this product in late 2021. The Company will also pay its development partners 50% of the net profits for this product.

On November 12, 2021, the Company entered into a multi-year agreement with Tolmar Pharmaceuticals, Inc. ("Tolmar") to co-promote the Company's Alkindi Sprinkle® product. The Company will leverage Tolmar's 62-person sales force and their existing relationships in the pediatric endocrinology specialty. Tolmar will receive a royalty on net sales growth above the Company's current baseline sales for Alkindi Sprinkle.

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, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2021 (the “2020 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 2020 10-K.

Overview

We are an innovative pharmaceutical company focused on developing, acquiring, and commercializing rare disease products and certain hospital injectable products. We seek to improve the formula, delivery system, or safety of existing molecules in order to address unmet patient needs. We pursue what we perceive to be low-risk candidates where existing published literature, historical clinical trials, or physician usage has established safety and/or efficacy of the molecule, thereby reducing the incremental clinical burden required for us to bring the product to patients.

Eton owns or receives profit share or royalty payments on six FDA-approved products:

- **Alkindi Sprinkle® (hydrocortisone granules).** Alkindi Sprinkle is a replacement therapy for adrenalcortical insufficiency in pediatric patients. We commercialize the product with our internal sales force focused on pediatric endocrinologists and we estimate that approximately 10,000 children in the United States suffer from adrenal insufficiency. Eton licensed the product from Diurnal Group plc in March 2020 and the product was approved by the FDA in September 2020 and launched in December 2020.
- **Carglumic acid tablets.** Carglumic acid tablets are a generic version of Carbaglu®, indicated for the treatment of hyperammonemia due to N-acetylglutamate Synthase (NAGS) deficiency. The product was approved by the FDA and licensed by Eton in October 2021. We intend to market the product with our internal sales force and expect the product to be available in the fourth quarter of 2021.
- **Biorphen® (phenylephrine hydrochloride injection).** Biorphen is the first and only FDA-approved formulation of ready-to-use injectable phenylephrine. The product is used for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. We commercialize Biorphen under a co-promotion agreement with Xellia Pharmaceuticals. Biorphen was approved by the FDA in October 2019 and sales commenced at the end of 2019.
- **Rezipres® (ephedrine hydrochloride injection).** Rezipres is a ready-to-use formulation of injectable ephedrine indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. The product was approved by the FDA in June 2021 and we expect to launch the product in the coming months.
- **Alaway Preservative Free® (ketotifen ophthalmic solution).** Alaway Preservative Free (formerly known as EM-100) is the first and only FDA-approved preservative-free ophthalmic product for the treatment of allergic conjunctivitis. Eton sold the product to Bausch Health and the product was approved by the FDA in September 2020. Bausch Health launched the product early in 2021 and currently commercializes the product via the over-the-counter channel and we receive a royalty on sales of the product.
- **Eprontia® (topiramate oral solution).** Eprontia is indicated for the treatment of epilepsy and migraine and is the first and only FDA-approved liquid formulation of topiramate. Eton sold the product to Azurity Pharmaceuticals as part of a multi-product transaction in February 2021. The product was approved by the FDA in November 2021 and we will receive royalties on sales of the product and milestone payments when certain launch and commercial success metrics are met. Azurity Pharmaceuticals is expected to launch the product in the fourth quarter of 2021.

In February 2021, we sold three pediatric neurology products we had under development to Azurity Pharmaceuticals (“Azurity”) and anticipate additional revenues from Azurity based on various product-related milestones including the commercial launch for these products. Of these three products, Eprontia® (topiramate oral solution) was approved by the FDA in November 2021 and two are currently under review with the FDA. We have three additional product candidates under development, two of which have been submitted to the FDA.

We encountered difficulty in creating significant market pull-through demand for Biorphen in 2020 and 2021 as our in-person sales calls to key personnel at hospitals and surgical centers and introductory product presentation seminars were cancelled as a result of the COVID-19 pandemic. We are working on other promotional efforts to drive further adoption in the market, but we expect that our Biorphen sales and marketing efforts will continue to be adversely affected by the pandemic. In September 2020, we reduced the selling price for Biorphen, which we sell through wholesalers, and recognized a \$192 reduction to revenue based on the shelf stock inventory held at our wholesale customers. These same adverse pandemic factors have adversely impacted our Alkindi Sprinkle sales in 2021.

Results of Operations

For the three-month period ended September 30, 2021 we had \$775 in revenues from product sales and royalties which generated a total gross profit of \$158 after recognizing a \$432 cost of sales provision related to writing down slow-moving Biorphen inventories in the period. For the three-month period ended September 30, 2020 we had negative net sales of \$161 for Biorphen due to a \$192 wholesaler price reduction combined with low sales volume primarily as a result of the COVID-19 pandemic marketing and promotion factors discussed above. This unfavorable sales impact was partially offset by a negative cost of sales of \$144 based on the profit/(loss) sharing agreement with our product development partner for Biorphen.

For the nine-month period ended September 30, 2021 we realized \$15,739 in revenues mainly from the \$14,000 of Azurity and Bausch and other milestone revenues discussed above plus \$1,739 of product sales and royalties which generated a total gross profit of \$13,396 for the period. For the nine-month period ended September 30, 2020 we realized a negative \$42 in net sales of Biorphen mainly due to the \$192 wholesaler price reduction noted above combined with low sales volume primarily as a result of the COVID-19 pandemic marketing and promotion factors discussed above.

Research and Development Expenses

For the three-month periods ended September 30, 2021 and 2020, we incurred \$2,678 and \$2,826, respectively, of research and development (“R&D”) expenses. The R&D expense reflects an overall \$148 lower expense level in 2021 mainly due to lower overall spending for product development.

For the nine-month periods ended September 30, 2021 and 2020, we incurred \$5,554 and \$10,703, respectively, of R&D expense. The 2020 period included \$4,764 in expense for the licensing payments for the U.S. rights to Alkindi® Sprinkle. The nine-month R&D expense reflects an overall \$5,149 lower expense level in 2021 mainly as a result of the licensing payments noted for Alkindi Sprinkle in 2020 and discontinuing our laboratory operations at the end of March 2021.

General and Administrative Expenses

General and administrative (“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, 2021 and 2020, we incurred \$3,327 and \$3,429, respectively, of G&A expenses. The \$102 decrease in G&A expense was mainly due to a lower level of promotional expenses related to launching Alkindi Sprinkle and reduced legal expenses from our initiating a Paragraph IV patent challenge against Exela Pharma Science’s Elcys product (cysteine hydrochloride injection) in 2020 partially offset by increased product distribution and selling expenses related to Alkindi Sprinkle commercialization and higher overall administrative expenses.

For the nine-month periods ended September 30, 2021 and 2020, we incurred \$10,651 and \$8,960, respectively, of G&A expenses. The \$1,691 increase in G&A expense was mainly due to increased product marketing/distribution and selling expenses related to Alkindi Sprinkle commercialization partially offset by a lower level of legal expenses from our initiating a Paragraph IV patent challenge against Exela Pharma Science’s Elcys product (cysteine hydrochloride injection) in 2020.

Interest and other (expense) income

We had slightly higher interest expense for the three and nine-month periods ended September 30, 2021 as compared to the same periods in 2020 due to our borrowing an additional \$2,000 under our SWK loan facility in August 2020.

We recognized a \$181 gain from the sale of our laboratory equipment in May 2021 and also recognized a \$365 gain from the forgiveness of our SBA PPP loan in May 2021.

We incurred a net loss of \$6,094 and \$6,504 for the three-month periods ended September 30, 2021 and 2020, respectively. The decreased loss in the 2021 period was mainly a result of increased revenues of \$936 and \$250 in lower operating expenses as discussed above.

We realized a net loss of \$2,994 and a net loss of \$20,283 for the nine-month periods ended September 30, 2021 and 2020, respectively. The improvement in the loss level in the 2021 period was mainly a result of increased revenues of \$15,781 and lower product research and development spending of \$5,149 partially offset by \$1,691 in higher general and administrative expenses for sales/promotion activities to support the launch of Alkindi Sprinkle. In addition, the \$181 gain from the sale of our laboratory equipment and the \$365 gain from the PPP loan forgiveness contributed to the reduced net loss for the period.

Cash Flows

The following table sets forth a summary of our cash flows for the nine-month periods ended September 30, 2021 and 2020:

	Nine months ended September 30, 2021	Nine months ended September 30, 2020
Net cash provided by (used in) operating activities	\$ 396	\$ (15,164)
Cash provided by (used in) investing activities	695	(6)
Cash flows from financing activities	323	10,436
Change in cash and cash equivalents	\$ 1,414	\$ (4,734)

The improvement in cash provided by operating activities was mainly due to the reduced loss level in 2021 which was partially offset by working capital changes when compared to the same period in 2020. Investing activities reflected the \$700 sale of lab equipment in May 2021 and only nominal equipment spending requirements in 2021 and 2020. The change in financing activity cash flows was primarily the result of the sales of our common stock for \$7,756 in March and April 2020 along with \$1,965 in additional loan proceeds from our borrowing with SWK Holdings in August 2020.

Critical Accounting Policies

Our condensed financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (“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 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 Accounting Standards Codification (“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 which 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 and assesses 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 that is 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 Biorphen 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 Biorphen represent 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. In addition, we sell our Alkindi Sprinkle product to one pharmacy distributor customer which provides order fulfillment and inventory storage/distribution services.

Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell Biorphen at negotiated discounted prices to members of certain group purchasing organizations (“GPOs”) and government programs. In addition, we pay fees to wholesalers for their distribution services, inventory reporting and chargeback processing. We pay GPOs fees for administrative services and for access to GPO members and concluded the benefits received in exchange for these fees are not distinct from our sales of Biorphen, and accordingly we apply these amounts to reduce revenues. Wholesalers also have rights to return unsold product nearing or past the expiration date. Because of the shelf life of Biorphen and our lengthy return period, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. For our Alkindi Sprinkle product, we bill at the initial product list prices which are subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements which are recorded as a reduction of net revenues at the date of sale/shipment.

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 arising from all of the above factors. We have developed estimates for future returns and chargebacks of Biorphen and the impact of the other discounts and fees we pay. Our sales of Alkindi Sprinkle to our distributor are not subject to returns. When estimating these adjustments to the transaction price, we reduce 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 recognize revenue from Biorphen product sales and related cost of sales upon product delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership, and have an enforceable obligation to pay us. They also have the ability to direct sales of product 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 to us. We store our Alkindi Sprinkle inventory at our pharmacy distributor customer location and sales are recorded when stock is pulled and shipped to fulfill specific patient orders.

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 of accounts receivable. We monitor actual product returns, chargebacks, discounts and fees subsequent to 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 Accounting Standards Codification (“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. Compensation expense is recognized over the period during which services are rendered by consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model (“BSM”).

We estimate the fair value of stock-based option awards to our using the 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 volatilities are based on comparable companies’ historical volatility along with a limited weighting included for our own volatility subsequent to our IPO, which we believe represents the most accurate basis for estimating expected future volatility under the current conditions. We account for forfeitures as they occur.

Prior to our initial public offering in November 2018, the fair value of the shares of common stock underlying our stock-based awards was determined by our board of directors, with input from management. 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 and 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 technology for 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. Subject to certain conditions, as an emerging growth company, 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 the earlier to occur of (1) the last day of the fiscal year (a) December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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, 2021, all of our cash is in a non-interest bearing account due to the current low-interest rate environment. 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 is also 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 nine-month period ended September 30, 2021, 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, 2021 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 2020 10-K, which could materially affect our business, financial condition, cash flows or future results. The risk factors described in our 2020 10-K, which was filed with the SEC on March 16, 2021, 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

Not applicable.

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	<u>Certification of President and Chief Executive Officer (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1*	<u>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.</u>
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, formatted in Extensible Business Reporting Language (XBRL): (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.

* 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 15, 2021

By: /s/ Sean E. Brynjelsen

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

By: /s/ W. Wilson Troutman

W. Wilson Troutman
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; and

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 15, 2021

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, W. Wilson Troutman, 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; and

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 15, 2021

By: /s/ W. Wilson Troutman

W. Wilson Troutman

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 W. Wilson Troutman, 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, 2021, 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 15th day of November 2021.

/s/ Sean E. Brynjelsen

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

/s/ W. Wilson Troutman

W. Wilson Troutman
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.