

**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, 2020

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 60010-7208
(Address of principal executive offices) (Zip code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, 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 2, 2020, Eton Pharmaceuticals, Inc. had outstanding 24,213,533 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)

	<u>September 30, 2020</u> (Unaudited)	<u>December 31, 2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,332	\$ 12,066
Accounts receivable, net	—	473
Inventory	1,699	380
Prepaid expenses and other current assets	754	2,090
Total current assets	9,785	15,009
Property and equipment, net	854	1,117
Intangible assets, net	612	725
Operating lease right-of-use assets, net	63	160
Other long-term assets, net	81	61
Total assets	\$ 11,395	\$ 17,072
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,208	\$ 575
PPP loan, current portion	219	—
Accrued liabilities	792	1,388
Total current liabilities	3,219	1,963
Long-term debt, net of discount and including accrued fees	6,496	4,540
Long-term portion of PPP and EIDL loans	292	—
Operating lease liabilities, net of current portion	—	19
Total liabilities	10,007	6,522
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, \$0.001 par value; 50,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 20,988,533 and 17,877,486 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	21	18
Additional paid-in capital	85,838	74,720
Accumulated deficit	(84,471)	(64,188)
Total stockholders' equity	1,388	10,550
Total liabilities and stockholders' equity	\$ 11,395	\$ 17,072

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, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Revenues:				
Product sales, net	\$ (161)	\$ —	\$ (42)	\$ —
Licensing revenue	—	—	—	500
Total revenues	(161)	—	(42)	500
Cost of product sales	(144)	—	(14)	—
Gross (loss) profit	(17)	—	(28)	500
Operating expenses:				
Research and development	2,826	3,418	10,703	11,322
General and administrative	3,429	1,624	8,960	5,123
Total operating expenses	6,255	5,042	19,663	16,445
Loss from operations	(6,272)	(5,042)	(19,691)	(15,945)
Other (expense) income:				
Interest and other (expense) income, net	(232)	77	(592)	321
Loss before income tax expense	(6,504)	(4,965)	(20,283)	(15,624)
Income tax expense	—	—	—	—
Net loss	\$ (6,504)	\$ (4,965)	\$ (20,283)	\$ (15,624)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.28)	\$ (1.01)	\$ (0.88)
Weighted average number of common shares outstanding, basic and diluted	21,052	17,878	20,070	17,706

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, 2020 and 2019
(in thousands, except share amounts)
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
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
	<u>Shares</u>	<u>Amount</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
Balances at June 30, 2019	17,763,045	\$ 18	\$ 73,208	\$ (56,527)	\$ 16,699
Stock-based compensation	—	—	537	—	537
Stock option exercises	44,122	—	77	—	77
Net loss	—	—	—	(4,965)	(4,965)
Balances at September 30, 2019	17,807,167	\$ 18	\$ 73,822	\$ (61,492)	\$ 12,348

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, 2020 and 2019
(in thousands, except share amounts)
(Unaudited)

	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
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
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	94	—	94
Net loss	—	—	—	(20,283)	(20,283)
Balances at September 30, 2020	20,988,533	\$ 21	\$ 85,838	\$ (84,471)	\$ 1,388
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2018	17,607,928	\$ 18	\$ 72,153	\$ (45,868)	\$ 26,303
Stock-based compensation	—	—	1,387	—	1,387
Stock option exercises	134,122	—	154	—	154
Employee stock purchase plan	23,083	—	128	—	128
Stock warrant exercises	42,034	—	—	—	—
Net loss	—	—	—	(15,624)	(15,624)
Balances at September 30, 2019	17,807,167	\$ 18	\$ 73,822	\$ (61,492)	\$ 12,348

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, 2020	Nine months ended September 30, 2019
Cash flows from operating activities		
Net loss	\$ (20,283)	\$ (15,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,803	1,387
Common stock issued for product candidate licensing rights	1,264	—
Depreciation and amortization	490	299
Debt discount amortization	85	—
Changes in operating assets and liabilities:		
Accounts receivable	473	—
Inventory	(1,319)	—
Prepaid expenses and other assets	1,305	426
Accounts payable	1,633	(403)
Accrued liabilities	(615)	(263)
Net cash used in operating activities	(15,164)	(14,178)
Cash used in investing activities		
Purchases of property and equipment	(6)	(1,062)
Cash flows from financing activities		
Proceeds from issuance of long-term debt, net of issuance costs	1,965	—
Proceeds from sales of common stock, net of offering costs	7,756	—
Proceeds from PPP and EIDL loans	511	—
Proceeds from employee stock purchase plan and stock option exercises	204	282
Net cash provided by financing activities	10,436	282
Change in cash and cash equivalents	(4,734)	(14,958)
Cash and cash equivalents at beginning of period	12,066	26,735
Cash and cash equivalents at end of period	\$ 7,332	\$ 11,177
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 545	\$ —
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosure of non-cash financing activity		
Relative fair value of common stock warrants 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 corporation on April 27, 2017 and was initially set up as a wholly owned subsidiary of Harrow Health, Inc. or “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 an 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 (see Note 6). In October 2020, the Company received net proceeds of approximately \$21,040 from a public offering for its shares (see Note 12).

Eton is a specialty pharmaceutical company focused on developing, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and pediatric rare disease products. 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.

Note 2 — Liquidity Considerations

As of September 30, 2020, the Company had an accumulated deficit of \$84,471 and for the nine months ended September 30, 2020, the Company had net cash used in operating activities of \$15,164.

To date, the Company has generated limited revenues and has incurred negative cash flows from operating activities since its inception in 2017. The Company received its first product approval from the U.S. Food and Drug Administration (“FDA”), Biorphen®, in October 2019 and currently believes its future revenues and its cash and cash equivalents of \$7,332 as of September 30, 2020 combined with the \$21,040 of net proceeds from its October 2020 public offering discussed in Note 1 above will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of the filing of this Report. This estimate is based on the Company’s current assumptions, including expected sales for Biorphen and Alkindi Sprinkle and its ability to manage its spending. The Company could use its available capital resources sooner than currently expected, and accordingly, could seek to obtain additional capital through equity financings, additional drawdowns under its current credit agreement (see Note 5), the sale of additional debt, or through 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. Issued debt securities may contain covenants and limit the Company’s ability to pay dividends or make other distributions to stockholders. If the Company is not able to achieve significant revenues from product sales and licensing, encounters delays in completing its product development and obtaining regulatory approval for its product candidates, and is unable to obtain such additional financing, its 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”).

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, 2020 and the results of its operations and its cash flows for the periods ended September 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and nine-month periods ended September 30, 2020 and 2019 are also unaudited. The results for the nine-month period ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods or any future year or period.

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)

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed 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.

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 has been capitalized and that cost is being amortized over five years.

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.

Revenue Recognition for Contracts with Customers

The Company intends to generate its future revenues from direct sales of its approved Biorphen and Alkindi Sprinkle products as well as other of its products which are in development. In addition, the Company anticipates it will receive revenues from product licensing agreements for which 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.

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.

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.

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

Note 3 — Summary of Significant Accounting Policies (continued)

The Company recognizes as revenue the amount of the transaction price 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, which 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.

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 GPO 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 the Company issues credits on returned product.

The Company estimates the transaction price when it receives each purchase order, taking into account the expected reductions of the selling price initially billed to the wholesaler arising from all of the above factors. In September 2020, the Company reduced its estimated selling price for Biorphen through wholesalers and recorded a \$192 reduction to revenue based on the shelf stock inventory held at its wholesale customers. The Company has developed estimates for future returns and chargebacks of Biorphen and the impact of the other discounts and fees it pays. 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, 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.

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)

Upon recognition of revenue from product sales of Biorphen, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, 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 the Company's estimates, it will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

In addition, the Company anticipates it will receive revenues from product licensing agreements where it has contracted for milestone payments and royalties from products it has developed or for which it has acquired the rights to a product developed by a third party.

Cost of Product Sales

Cost of product sales consists of the profit-sharing fees with the Company's product licensing and development partners, the purchase costs for finished products from third-party manufacturers and freight and handling/storage costs from the Company's 3PL logistics service provider. The cost of sales for profit-sharing 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. In the case where there is a loss under the profit-sharing arrangement, the Company is able to true-up and recover the loss from its development partners, as occurred with Biorphen in the three-month period ended September 30, 2020.

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 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. 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 on products which are not yet approved by the FDA are expensed as R&D in the period in which they are incurred. Milestone payments for FDA-approved products are capitalized and amortized over the expected economic life of the product. 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.

Earnings (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 and "if converted" method) from stock options, unvested RSAs and RSUs, and warrants at September 30, 2020 and 2019 were 3,308,152 and 3,573,885, 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.

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)

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. Since the IPO in November 2018, the Company has used the closing common stock price on the date of grant for the fair value of the common stock.

Fair Value Measurements

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

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

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

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

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

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

Impact of New Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The new guidance removes, modifies, and adds to certain disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The Company adopted the new guidance on January 1, 2020 which did not have a material impact on its financial position or results of operations.

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Note 3 — Summary of Significant Accounting Policies (continued)

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes. The new guidance removes certain exceptions to the general principles of ASC 740 in order to simplify the complexities of its application. These changes include eliminations to the exceptions for intraperiod tax allocation, recognizing deferred tax liabilities related to outside basis differences, and year-to-date losses in interim periods, among others. The Company adopted the new guidance on January 1, 2020 which did not 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, 2020	December 31, 2019
Computer hardware and software	\$ 175	\$ 174
Furniture and fixtures	134	133
Equipment	994	994
Leasehold improvements	155	152
Construction in progress	1	9
	1,459	1,462
Less: accumulated depreciation	(605)	(345)
Property and equipment, net	\$ 854	\$ 1,117

Depreciation expense for the three-month periods ended September 30, 2020 and 2019 was \$86 and \$86, respectively. Depreciation expense for the nine-month periods ended September 30, 2020 and 2019 was \$260 and \$197, respectively.

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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 11) and the Company’s March 2020 sale of additional shares of its common stock (see Note 6), the Company and SWK amended the SWK Credit Agreement. The amendment provided the Company with the option to immediately draw \$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 is 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 May 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. 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. The Company is currently in the process of negotiating covenant targets for EBITDA and revenue for the SWK Credit Agreement.

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 these 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 are subject to a cashless exercise feature, with the exercise price and number of shares issuable upon exercise subject to change in connection with stock splits, dividends, reclassifications and other conditions.

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Note 5 — Long Term Debt (continued)

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, 2020, \$123 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, 2020.

	Amount
2020	\$ 247
2021	879
2022	2,202
2023	1,756
2024	5,299
Total payments	10,383
Less: amount representing interest	(3,383)
Loan payable, gross	7,000
Less: unamortized discount	(504)
Long-term debt, net of unamortized discount	\$ 6,496

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. The loan bears a 1.0% annual interest rate and is payable in monthly installments commencing on November 4, 2020 until paid in full on May 4, 2022. The Company recorded \$1 in interest expense for the nine-month period ended September 30, 2020. The Company intends to pursue full or partial forgiveness of the loan as permitted under the applicable SBA guidelines for PPP loans.

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 loan bears a 3.75% annual interest rate and is payable in monthly installments commencing on July 21, 2021 until paid in full on July 21, 2050. The Company recorded \$2 in interest expense for the nine-month period ended September 30, 2020.

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.

In March and April 2020, the Company entered into securities purchase agreements with various investors and sold an aggregate of 2,600,000 shares of its common stock at a price of \$3.00 per share and received \$7,756 in net proceeds after deducting issuance costs associated with the sale.

In March 2020, the Company issued 379,474 shares of its common stock to Diurnal Limited (“Diurnal”) as a milestone fee for acquiring the U.S. marketing rights to Alkindi Sprinkle®, an orphan drug product currently under review with the FDA (see Note 11). The shares were valued at \$1,264 based on the Company’s closing stock price on the date of issuance and this amount was recorded as a component of the Company’s research and development expense and an addition to its paid-in-capital.

During the nine months ended September 30, 2020, the Company issued 102,378 shares of its common stock resulting from stock option exercises under its 2018 Equity Incentive Plan (see Note 8). In April 2020, the Company issued 15,190 shares of its common stock as an RSA to a new employee. This RSA vests 25% every three months and will be 100% vested in April 2021. In June 2020, the Company issued 14,005 shares of its common stock to employees in accordance with its Employee Stock Purchase Plan (“ESPP”).

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Note 7 — Common Stock Warrants

The Company's outstanding warrants to purchase shares of its common stock at September 30, 2020 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	607,096	\$	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	1,690,476	\$	3.17 (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.

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 (the "2018 Plan") which succeeded the 2017 Plan. The Company has granted RSAs, stock options and RSUs for its common stock under the 2018 Plan as detailed below. There were 453,246 shares available for future issuance under the 2018 Plan as of September 30, 2020.

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 will not be issued until the individual director retires from service from the Company's board of directors. 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 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, 2020 and 2019, the Company's total stock-based compensation expense was \$724 and \$537, respectively. Of these amounts, \$647 and \$460 was recorded in general and administrative expenses, respectively, and \$77 and \$77 was recorded in research and development expenses, respectively.

For the nine months ended September 30, 2020 and 2019, the Company's total stock-based compensation expense was \$1,803 and \$1,387, respectively. Of these amounts, \$1,623 and \$1,150 was recorded in general and administrative expenses, respectively, and \$180 and \$237 was recorded in research and development expenses, respectively.

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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, 2019	1,829,878	\$ 4.01	8.1	\$ 6,014
Issued	1,372,000	\$ 3.85		
Exercised	(102,378)	\$ 1.37		
Forfeited/Cancelled	(237,500)	\$ 5.72		
Options outstanding as of September 30, 2020	2,862,000	\$ 3.89	8.4	\$ 11,492
Options exercisable at September 30, 2020	1,187,027	\$ 3.71	7.8	\$ 4,971
Options vested and expected to vest at September 30, 2020	2,812,000	\$ 3.93	8.5	\$ 11,166

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.

The assumptions used to calculate the fair value of options granted during the nine months ended September 30, 2020 under the BSM were as follows:

Expected dividends	—%
Expected volatility	95%
Risk-free interest rate	0.4 - 0.7%
Expected term	5.3 – 6.1 years
Weighted average fair value	\$ 2.91

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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Note 8 — Share-Based Payment Awards (continued)

As of September 30, 2020, there was a total of \$4,810 of unrecognized compensation costs related to non-vested stock option and restricted awards. In the nine-month period ended September 30, 2020, there were six stock option exercises which totaled 102,378 shares at an average exercise price of \$1.37 per share with an intrinsic value of \$436. There were seven stock option exercises for 134,122 shares during the nine months ended September 30, 2019 at an average exercise price of \$1.15 per share with an intrinsic value of \$786.

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, 2020, there were 391,110 shares available for issuance under the ESPP.

The annual offerings consist of two stock purchase periods, with the first purchase period ending in June and the second 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 2020 and 2019 there were 14,005 and 23,083 share issuances under the ESPP. The weighted average grant date fair value of share awards in the first nine months of 2020 and 2019 was \$2.43 and \$2.57, respectively. Employees contributed \$100 and \$199 via payroll deductions during the nine months ended September 30, 2020 and 2019, respectively. The Company recorded an expense of \$38 and \$93 related to the ESPP in the nine-month periods ended September 30, 2020 and 2019, respectively. As of September 30, 2020 and December 31, 2019, the accompanying condensed balance sheets include \$32 and \$79, respectively, in accrued liabilities for remaining employee ESPP contributions.

Note 9 — 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. 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 and the product rights were returned to Harrow.

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 is a member of the Company's board of directors.

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Note 9 — Related Party Transactions (continued)

Chief Executive Officer

The Company's CEO has a partial interest in several companies that the Company is working with for product development and potential marketing if the products are approved by the FDA as detailed 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 is responsible for all costs of testing and FDA approval of the product, other than the FDA filing fee which will be paid by Eyemax. The Company was also 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 Sales Agreement (the "Amended Agreement"). Pursuant to the Amended Agreement, Eyemax sold the Company all of its right, title and interest in EM-100, including any such product that incorporates or utilizes Eyemax's intellectual property rights. Under the Amended Agreement, the Company assumed certain liabilities of Eyemax under its Exclusive Development & Supply Agreement with 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 remains obligated to pay Eyemax two milestones payments: (i) one milestone payment for \$250 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for \$500 following the first commercial sale of the first single agent product in the territory. Following payment of the milestones, the Company 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 on February 18, 2019 and future potential royalties of twelve percent of net sales of Bausch sales of EM-100, pending an FDA approval for EM-100, will be split between Eyemax and the Company. The royalty from Bausch 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. In accordance with the FDA approval for EM-100 on September 24, 2020, the Company owed Eyemax \$250 as of September 30, 2020. There were no amounts due at December 31, 2019.

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Note 10 — Leases

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

The Company does not have any lease contracts that contain: (1) an option to extend that the Company is reasonably certain to exercise, (2) an option to terminate that the Company is reasonably certain not to exercise, or (3) an option to extend (or not to terminate) in which exercise of the option is controlled by the lessor. Additionally, the Company does not have any leases with residual value guarantees or material restrictive covenants. Lease liabilities and their corresponding right-of-use assets have been recorded based on the present value of the future lease payments over the expected lease term. One of the Company’s lease agreements contains provisions for escalating rent payments over the term of the lease.

The Company’s leases do not contain readily determinable implicit discount rates, and therefore, the Company was required to use its incremental borrowing rate of 7.8% to discount the future lease payments based on information available at lease commencement. The incremental borrowing rate was estimated by determining the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

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 \$13 and \$21, respectively, for the three months ended September 30, 2020 and \$13 and \$21, respectively, for the three months ended September 30, 2019. 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 \$41 and \$62, respectively, for the nine months ended September 30, 2020 and \$41 and \$64, respectively, for the nine months ended September 30, 2019. Cash paid for amounts included in the measurement of operating lease liabilities was \$99 for the nine months ended September 30, 2020. 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. The ROU asset amortization for the three and nine-month periods ended September 30, 2019 was \$31 and \$90, respectively, and is reflected within depreciation and amortization on the Company’s condensed statements of cash flows. As of September 30, 2020, the weighted-average remaining lease term was 0.5 years, and the weighted-average incremental borrowing rate was 7.8%.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of September 30, 2020 (in thousands).

Assets	Classification		
Operating lease right-of-use assets	Operating lease right-of-use assets, net	\$	63
Total leased assets		\$	63
Liabilities			
Operating lease liabilities, current	Accrued liabilities	\$	53
Total operating lease liabilities		\$	53

The Company’s future lease commitments for its administrative offices in Deer Park, Illinois and its laboratory facility in Lake Zurich, Illinois as of September 30, 2020 are as indicated below:

	Total	2020	2021	2022	Thereafter
Undiscounted lease payments	\$ 54	35	19	—	—
Less: Imputed interest	(1)				
Total lease liabilities	\$ 53				

On October 16, 2020, the Company negotiated a new two-year lease for its administrative offices in Deer Park, Illinois commencing on April 1, 2021 and ending on March 31, 2023.

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Note 11 — Commitments and Contingencies

Legal

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

On May 7, 2020, the Company announced that it has been confirmed as the first filer of a patent challenge against Exela Pharma Science's Elcys product (cysteine hydrochloride injection). This case matter is still pending at this time.

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 DS-300 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 will be responsible for Paragraph IV litigation management and expense for the product and will be entitled to 62.5% of the net profit from the sale of the product. The initial term is for the first 10 years following the first commercial sale of the product.

The Company acquired the exclusive license to develop, manufacture and sell ET-103 in the United States pursuant to an Exclusive License and Supply Agreement dated August 3, 2018 between the Company and Liqmeds Worldwide Limited ("LMW"), an unaffiliated entity. Pursuant to the agreement, the Company will be responsible for, and will own, all regulatory filings and approvals at its expense, provided that it shall have the right to recoup 35% of any regulatory filing fees from the initial profits from the sale of ET-103 and, provided further, the licensor shall be responsible for any bioequivalence study and shall be responsible for 60% of the costs of such study. An affiliate of the licensor shall manufacture the ET-103 and sell it to the Company at its cost. The Company paid the licensor \$350 upon execution of the agreement and will pay the licensor \$1,500 upon the FDA's acceptance of an NDA for review, \$1,000 upon FDA approval, \$1,500 upon issuance of patent covering ET-103 listed in the FDA's Orange Book and \$500 in the event of product sales in excess of \$10,000 in any calendar year. In addition, the Company is required to pay the licensor 35% of the net profit from product sales. The license agreement is for an initial term of 10 years from the date of the first commercial sale of the product, subject to two-year renewals unless either party elects to terminate no less than 12 months prior to the then current term. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

On January 23, 2019, the Company entered into a Licensing and Supply Agreement (the "Agreement") with LMW for ET-104 oral liquid, a development stage product candidate ("ET-104"). Pursuant to the terms of the Agreement, the Company will 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 will pay \$325 based upon the FDA's acceptance of the NDA for review which occurred on September 27, 2020, \$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 are achieved within a calendar year. In addition, the Company is required to pay the licensor 35% of the net profit from product sales. The Agreement is for an initial term of 10 years from the date of the first commercial sale of the product. The Company will retain sole ownership of the NDA after expiration of the Agreement.

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 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 regulatory activities for the product. In 2019, the Company paid Sintetica a licensing payment of \$2,000 upon execution of the ET-202 License Agreement and paid \$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 commencing on November 26, 2019. There was a gross loss for the three-month period ended September 30, 2020 due to a September product price reduction through the Company's wholesaler customers and the Company will true-up this amount due from Sintetica.

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Note 11 — Commitments and Contingencies (continued)

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 ET-203, 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 and will pay \$750 upon FDA approval and the commercial sale of the product candidate. Upon approval, 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.

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 ET-105, a 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 will 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 \$2,000 upon FDA approval and commercial sales of the product candidate and another \$1,000 upon issuance of an Orange-book listed patent. Aucta will receive a 15% 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

On March 27, 2020, the Company entered into an Exclusive Licensing and Supply Agreement (the “Alkindi License Agreement”) with Diurnal for marketing Alkindi Sprinkle in the United States. 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 (see Note 6). The total amount of \$4,764 was recorded as a component of research and development expense in the Company’s condensed statement of operations for the nine-month period ended September 30, 2020. The Company will pay Diurnal \$2,500 after the commercial launch subject to the product also obtaining orphan drug exclusivity status from the FDA.

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, 2020 or December 31, 2019.

Note 12 — Subsequent Events

On October 16, 2020, the Company completed a public offering for 3,220,000 shares of its common stock at a public offering price of \$7.00 per share. The Company received approximately \$21,040 of net proceeds from the offering.

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, 2019 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2020 (the “2019 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 2019 10-K and Part II, Item 1A of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31 and June 30, 2020.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical products and we have particularly targeted hospital injectable and pediatric rare disease 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.

In October 2019, we received FDA approval for Biorphen® which we are marketing in the United States. Biorphen (phenylephrine HCl injection) is an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. In September 2020, the FDA approved our Alkindi Sprinkle product 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. In addition, the FDA approved EM-100, an eye allergy product which we sold to Bausch Health whereby we will receive royalties on sales of EM-100 which is expected to be launched in early 2021.

We have established a diversified pipeline of product candidates in various stages of development, including multiple candidates that have been submitted to the FDA for review. Our product candidates are primarily focused on two core areas: hospital-based products and pediatric oral liquid products. We believe these candidates can address situations where patient needs are not being met by current FDA-approved products.

Results of Operations

We received FDA approval for our Biorphen® product in October 2019 and began commercializing the product in December 2019. We have encountered difficulty in creating significant market pull-through demand for Biorphen in 2020 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 2020. 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. Biorphen sales are currently our only source of revenue, however we expect to receive revenue from Alkindi Sprinkle in the latter part of 2020 as well as royalty/licensing fees and sales for additional products in future periods. (Note: dollar amounts are listed in thousands below).

Revenues

For the three-month period ended September 30, 2020 we had negative net sales of \$161 for Biorphen 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. 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. There were no revenues for the three-month period ended September 30, 2019.

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. Revenues for the nine-month period ended September 30, 2019 of \$500 reflected the sale of our EM-100 product to Bausch Health in February 2019.

Research and Development Expenses

For the three-month periods ended September 30, 2020 and 2019, we incurred \$2,826 and \$3,418, respectively, of research and development (“R&D”) expenses. The full comparative three-month detail of our R&D expense is listed in the table below and reflects an overall \$592 lower expense level in 2020 mainly due to decreased product development spending for Lamotrigine partially offset by higher spending for Zonisamide and lower compensation and laboratory spending expense in the 2020 period.

For the nine-month periods ended September 30, 2020 and 2019, we incurred \$10,703 and \$11,322, respectively, of R&D expense. The 2020 period includes \$4,764 in expense for the licensing payments for the U.S. rights to Alkindi® Sprinkle and the 2019 period includes \$2,000 for licensing payments related to the U.S. rights for Biorphen and \$1,853 for Selenium product development expenses. The full comparative nine-month detail of our R&D expense is listed in the table below and reflects an overall \$619 lower expense level in 2020.

Set forth in the table below is our R&D spending for our current product candidates and general product development expenses for the three and nine-month periods ended September 30, 2020 and 2019. We currently have five employees that support our overall product development and laboratory product testing operations. We do not track internal costs by product for our employees and laboratory expenses and they are listed as indirect expenses in the table below.

	Three months ended September 30, 2020	Three months ended September 30, 2019	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Alkindi Sprinkle	\$ 1	\$ —	\$ 4,775	\$ —
Biorphen	85	—	361	2,000
Lamotrigine	—	2,060	24	2,060
Zonisamide	1,797	367	1,814	762
Dehydrated Alcohol	—	29	12	1,853
Other products	473	321	1,917	2,602
Indirect expenses	470	641	1,800	2,045
TOTAL	\$ 2,826	\$ 3,418	\$ 10,703	\$ 11,322

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, 2020 and 2019, we incurred \$3,429 and \$1,624, respectively, of G&A expenses. The \$1,085 increase in G&A expense was mainly due to increased spending for marketing/promotional activities towards the Alkindi Sprinkle launch, higher marketing/distribution spending for Biorphen commercialization, legal expenses due to our initiating a Paragraph IV patent challenge against Exela Pharma Science’s Elcys product (cysteine hydrochloride injection), and increased compensation expenses.

For the nine-month periods ended September 30, 2020 and 2019, we incurred \$8,960 and \$5,123, respectively, of G&A expenses. The \$3,837 increase in G&A expense was mainly due to increased spending for marketing/promotional activities towards the Alkindi Sprinkle launch, higher marketing/distribution spending for Biorphen commercialization, legal expenses due to our initiating a Paragraph IV patent challenge against Exela Pharma Science’s Elcys product (cysteine hydrochloride injection), and increased compensation expenses.

Interest and other (expense) income

In comparing the three-month periods ended September 30, 2020 and 2019, net interest expense increased by \$309 as a result of \$232 in interest expense mainly associated with borrowings under our SWK Credit Agreement and \$77 in reduced interest income due to lower interest rates and lower levels of cash and cash equivalents in 2020. For the nine-month periods ended September 30, 2020 and 2019, net interest expense increased by \$913 as a result of \$620 in interest expense mainly associated with borrowings under our SWK Credit Agreement and \$293 in reduced interest income due to lower interest rates and lower levels of cash and cash equivalents during 2020.

We incurred a net loss of \$6,504 and \$4,965 for the three-month periods ended September 30, 2020 and 2019, respectively. The increased loss in the 2020 period was mainly a result of increased general and administrative expenses as discussed above.

We incurred a net loss of \$20,283 and \$15,624 for the nine-month periods ended September 30, 2020 and 2019, respectively. The increased loss in the 2020 period was mainly a result of increased general and administrative expenses, the licensing revenue of \$500 that was realized in 2019 and increased net interest expense as discussed above.

Liquidity and Capital Resources

Our primary source of financing has been raising equity capital in the public markets and obtaining loans through SWK to support our product development projects along with marketing/distribution spending and working capital to support approved product launches. We believe our existing cash balances combined with the net proceeds of approximately \$21,040 from our October 2020 stock offering will be sufficient to fund our business operations for at least the next twelve months from the date of the filing of this Report. We could use our available capital resources sooner than currently expected, and accordingly, would seek to obtain additional capital through equity financings, additional drawdowns under our current credit agreement with SWK Holdings, the sale of additional debt, or through other arrangements.

Cash Flows

The following table sets forth a summary of our cash flows for the nine-month periods ended September 30, 2020 and 2019:

	Nine months ended September 30, 2020	Nine months ended September 30, 2019
Net cash used in operating activities	\$ (15,164)	\$ (14,178)
Cash used in investing activities	(6)	(1,062)
Cash flows provided by financing activities	10,436	282
Change in cash and cash equivalents	\$ (4,734)	\$ (14,958)

The increase in cash used in operating activities was mainly due to the higher operating losses in 2020 being partially offset by favorable working capital changes when compared to the same period in 2019. Investing activities consisted primarily of capital expenditures for setting up our new laboratory facility in 2019 and only nominal equipment spending requirements in 2020. The increase in financing activity was primarily the result of the sales of our common stock in March and April 2020 along with additional loan borrowings 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

Our revenues for the first nine months of 2020 a negative \$42 as a result of limited sales volumes for Biorphen and our reducing the selling price for Biorphen, which we sell through wholesalers, and recognizing a \$192 reduction to revenue based on the shelf stock inventory held at our wholesale customers. Sales for the nine months ended September 30, 2019 of \$500 resulted from the sale of our EM-100 product rights to Bausch Health Ireland Limited (“Bausch”) per an Asset Purchase Agreement dated February 18, 2019 (the “Asset Purchase Agreement”). We expect to generate future revenues from direct sales of our FDA-approved Biorphen® and Alkindi® Sprinkle product as well as products we have in development which will typically require advance review and approval by the FDA. Additionally, we anticipate we will receive revenues from product licensing agreements where we have contracted for milestone payments and royalties from products we have developed or for which we have acquired the rights to a product developed by a third party.

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 determine 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 if 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 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 consolidated 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. To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

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.

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.

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. 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.

Upon recognition of revenue from product sales of Biorphen, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, 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.

In addition, we anticipate we will receive revenues from product licensing agreements where we have contracted for milestone payments and royalties from products we have developed or for which we have acquired the rights to a product developed by a third party.

Stock-Based Compensation

We account for stock-based compensation under the provisions of ASC 718 Compensation – Stock Compensation. The guidance under ASC 718 requires companies to estimate the fair value of the stock-based compensation awards on the date of grant and record expense over the related service periods, which are generally the vesting period of the equity awards.

We estimate the fair value of stock-based option awards 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 limited weighting for our volatility experience from the date of our IPO in November 2018, which management believes represents the most accurate basis for estimating expected future volatility under the current conditions. We account for forfeitures as they occur.

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, laboratory operating costs and other expenses 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 on products which are not yet approved by the FDA are expensed as R&D in the period in which they are incurred. Milestone payments for FDA-approved products are capitalized and amortized over the expected economic life of the product. 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 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, 2020, our cash equivalents and investments are invested exclusively in money market funds. We do not believe we have any material exposure to interest rate risk due to the extremely low interest rate environment and the short duration of the invested funds we hold. Declines in interest rates would reduce our investment income but would not have a material effect on our financial condition or results of operations. We do not currently have exposure to foreign currency risk.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

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

With respect to the nine-month period ended September 30, 2020, 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, 2020 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 2019 10-K and Part II, Item 1A of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31 and June 30, 2020 which could materially affect our business, financial condition, cash flows or future results. The risk factors described in our 2019 10-K and 10-Q for the quarterly periods ended March 31 and June 30, 2020 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.

The risk factor below constitutes an update to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 5, 2020 and the risk factor included in our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2020 filed with the SEC on May 14, 2020 and June 30, 2020 filed with the SEC on August 12, 2020.

Our business is adversely affected by the ongoing coronavirus pandemic and the impact could be material.

The global COVID-19 pandemic has resulted in widespread requirements for individuals to stay in their homes and strained medical facilities worldwide, including certain aspects of our business. For example, we began commercializing our Biorphen product in December 2019, however we have encountered difficulty in creating significant market pull-through demand for Biorphen in 2020 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 2020. COVID-19 may also affect our ability to complete recruitment and data analysis for our clinical trials and our ability to conduct research and development of our complement programs in our planned timeframe. The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain COVID-19 or treat its impact. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- delays or difficulties in enrolling patients in our human factor study for Lamotrigine Oral Suspension (ET-105);
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in promoting our products in-person, at conferences and at hospitals due to limitations on travel and in-person gatherings imposed or recommended by federal or state governments

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

See the registrant's current report on Form 8-K filed with the SEC on March 30, 2020.

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, 2020, 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 12, 2020

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 12, 2020

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 12, 2020

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, 2020, 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 12th day of November 2020.

/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.