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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: 001-33678

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

Delaware	**68-0454536**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2000 Powell Street, Suite 1150, Emeryville, CA 94608
(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (510) 899-8800

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange On Which Registered**
Common Stock, par value $0.01 per share	NBY	NYSE American

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

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

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

Large accelerated filer	☐	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Smaller reporting company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 10, 2020, there were 41,782,584 shares of the registrant's common stock outstanding.

NOVABAY PHARMACEUTICALS, INC.

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Unless the context requires otherwise, all references in this report to "we," "our," "us," the "Company" and "NovaBay" refer to NovaBay Pharmaceuticals, Inc.

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVABAY PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	September 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,413	$ 6,937
Accounts receivable, net of allowance for doubtful accounts ($0 and $51 at September 30, 2020 and December 31, 2019, respectively)	1,119	1,066
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments ($194 and $247 at September 30, 2020 and December 31, 2019, respectively)	785	492
Prepaid expenses and other current assets	695	886
Total current assets	16,012	9,381
Operating lease right-of-use assets	518	1,252
Property and equipment, net	76	110
Other assets	476	477
TOTAL ASSETS	$ 17,082	$ 11,220
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 796	$ 331
Accrued liabilities	1,655	1,778
Operating lease liabilities	400	930
Note payable, related party	104	1,202
Convertible note	—	1,409
Other current liabilities	48	37
Total current liabilities	3,003	5,687
Operating lease liabilities-non-current	197	505
Warrant liability	—	4,055
Total liabilities	3,200	10,247
Stockholders' equity:		
Preferred stock: 5,000 shares authorized; none issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 75,000 shares and 50,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 41,760 and 27,938 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	417	279
Additional paid-in capital	147,774	125,718
Accumulated deficit	(134,309)	(125,024)
Total stockholders' equity	13,882	973
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,082	$ 11,220

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

NOVABAY PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Sales:				
Product revenue, net	$ 2,167	$ 1,615	$ 8,038	$ 4,854
Other revenue, net	3	—	8	41
Total sales, net	2,170	1,615	8,046	4,895
Product cost of goods sold	536	401	3,157	1,145
Gross profit	1,634	1,214	4,889	3,750
Research and development	125	49	249	166
Sales and marketing	1,692	1,544	4,675	6,610
General and administrative	1,879	1,333	4,633	4,136
Total operating expenses	3,696	2,926	9,557	10,912
Operating loss	(2,062)	(1,712)	(4,668)	(7,162)
Non-cash (loss) gain on changes in fair value of warrant liability	(1,589)	1,480	(5,224)	936
Non-cash gain on changes in fair value of embedded derivative liability	1	669	3	423
Other income (expense), net	429	(719)	605	(1,166)
Loss before provision for income taxes	(3,221)	(282)	(9,284)	(6,969)
Provision for income taxes	—	—	(1)	(3)
Net loss and comprehensive loss	$ (3,221)	$ (282)	$ (9,285)	$ (6,972)
Net loss per share attributable to common stockholders (basic)	$ (0.08)	$ (0.01)	$ (0.28)	$ (0.36)
Net loss per share attributable to common stockholders (diluted)	$ (0.08)	$ (0.02)	$ (0.28)	$ (0.36)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic)	40,037	23,096	32,614	19,623
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (diluted)	40,067	23,213	32,642	19,623

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

NOVABAY PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (9,285)	$ (6,972)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	40	50
Impairment of operating lease right-of-use assets	—	125
Gain on early termination of lease	(54)	—
(Gain) loss on disposal of property and equipment	(1)	32
Stock-based compensation expense for options and stock issued to employees and directors	279	270
Stock-based compensation expense for options and stock issued to non-employees	27	28
Stock option modification expense	53	45
Issuance of RSUs to employees	2	8
Issuance of RSUs related to employee separation agreement	—	220
Issuance of RSUs to non-employees for services	220	—
Issuance of warrants for service	—	59
Non-cash loss (gain) on changes in fair value of warrant liability	5,224	(936)
Non-cash gain on changes in fair value of embedded derivative liability	(3)	(423)
Interest expense related to amortization of debt issuance and debt discount	141	498
Interest expense related to amortization of debt issuance related to related party note payable	2	16
Changes in operating assets and liabilities:		
Accounts receivable	(226)	1,880
Inventory	(293)	(558)
Prepaid expenses and other current assets	191	573
Operating lease right-of-use assets	734	679
Other assets - long term	1	10
Accounts payable and accrued liabilities	355	(1,551)
Operating lease liabilities	(784)	(788)
Related party note payable	73	159
Other current liabilities	28	(41)
Long-term obligations	—	117
Net cash used in operating activities	(3,276)	(6,500)
Investing activities:		
Purchases of property and equipment	(5)	(19)
Net cash used in investing activities	(5)	(19)
Financing activities:		
Proceeds from preferred stock issuance, net	—	2,598
Proceeds from common stock issuances, net	5,220	6,700
Proceeds from issuance of note payable, related party	—	1,000
Proceeds from exercise of options, net	6	189
Proceeds from stock options & RSUs sold to cover taxes	—	4
Proceeds from exercise of warrants, net	7,094	67
Proceeds from convertible note, net of discount	—	2,000
Payment on the convertible note	(1,563)	—
Payment on the note payable, related party	(1,000)	—
Debt issuance cost	—	(202)
Net cash provided by financing activities	9,757	12,356
Net increase in cash, cash equivalents, and restricted cash	6,476	5,837
Cash, cash equivalents and restricted cash, beginning of period	7,412	3,658
Cash, cash equivalents and restricted cash, end of period	$ 13,888	$ 9,495

	Nine Months Ended September 30,	
	2020	**2019**
Supplemental disclosure of cash flow information:		
Interest paid	$ 61	$ —
Supplemental disclosure of non-cash information:		
Warrant liability transferred to equity	$ 9,293	$ 553
Non-cash payment of related party loan accrued interest by offsetting related party accounts receivables - see Note 9	$ 173	$ —
Cumulative effect of adoption of ASU 2017-11	$ —	$ 56
Addition of operating lease, right-of-use asset	$ —	$ 2,473
Fixed asset purchases, included in accounts payable and accrued liabilities	$ —	$ 10
Fair value of warrants issued in connection with financings	$ —	$ 5,269

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

NOVABAY PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(in thousands)

	Common Stock		Additional		Total
2020	**Shares**	**Amount**	**Paid-In Capital**	**Accumulated Deficit**	**Stockholders' Equity (Deficit)**
Balance at December 31, 2019	27,938	$ 279	$ 125,718	$ (125,024)	$ 973
Net loss	—	—	—	(1,582)	(1,582)
Issuance of common stock in connection with exercise of warrants	299	3	198	—	201
Vesting of employee restricted stock awards	2	—	2	—	2
Stock-based compensation expense related to employee and director stock options	—	—	45	—	45
Stock-based compensation expense related to non-employee stock options	—	—	12	—	12
Balance at March 31, 2020	28,239	$ 282	$ 125,975	$ (126,606)	$ (349)
Net loss	—	—	—	(4,482)	(4,482)
Issuance of common stock, net of offering costs	5,838	58	5,162	—	5,220
Issuance of common stock in connection with exercise of warrants	571	6	462	—	468
Stock-based compensation expense related to employee and director stock options	—	—	92	—	92
Stock-based compensation expense related to non-employee stock options	—	—	(2)	—	(2)
Stock option modification	—	—	36	—	36
Balance at June 30, 2020	34,648	$ 346	$ 131,725	$ (131,088)	983
Net loss	—	—	—	(3,221)	(3,221)
Reclassification of warrant liability to equity – see Note 11	—	—	9,293	—	9,293
Issuance of common stock in connection with exercise of warrants, net	6,899	69	6,356	—	6,425
Issuance of RSUs to non-employees for services	193	2	218	—	220
Issuance of stock for option exercises	20	—	6	—	6
Stock-based compensation expense related to employee and director stock options	—	—	142	—	142
Stock-based compensation expense related to non-employee stock options	—	—	17	—	17
Stock option modification	—	—	17	—	17
Balance at September 30, 2020	41,760	$ 417	$ 147,774	$ (134,309)	$ 13,882

	Preferred Stock		Common Stock		Additional Paid-		Total
2019	**Shares**	**Amount**	**Shares**	**Amount**	**In Capital**	**Accumulated Deficit**	**Stockholders' Equity**
Balance at December 31, 2018	—	$ —	17,089	$ 171	$ 119,764	$ (114,981)	$ 4,954
Net loss	—	—	—	—	—	(4,189)	(4,189)
Reclassification of warrant liability to equity – see Note 2	—	—	—	—	412	(356)	56
Vesting of employee restricted stock awards	—	—	6	—	10	—	10
Stock-based compensation expense related to employee and director stock options	—	—	—	—	107	—	107
Stock-based compensation expense related to non-employee stock options	—	—	—	—	7	—	7
Debt discount associated with convertible note – beneficial conversion feature	—	—	—	—	184	—	184
Balance at March 31, 2019	—	$ —	17,095	$ 171	$ 120,484	$ (119,526)	$ 1,129
Net loss	—	—	—	—	—	(2,501)	(2,501)
Down round feature adjustment related to warrants	—	—	—	—	29	(29)	—
Issuance of common stock in connection with offering, net of offering costs	—	—	3,269	33	2,434	—	2,467
Issuance of common stock in connection with exercise of warrants	—	—	286	3	443	—	446
Issuance of common stock for option exercises	—	—	83	—	189	—	189
Stock-based compensation expense related to employee and director stock options	—	—	—	—	95	—	95
Stock-based compensation expense related to non-employee stock options	—	—	—	—	7	—	7
Stock option modification	—	—	—	—	21	—	21
Debt discount associated with convertible note – beneficial conversion feature	—	—	—	—	(184)	—	(184)
Balance at June 30, 2019	—	$ —	20,733	$ 207	$ 123,518	$ (122,056)	$ 1,669
Net loss	—	—	—	—	—	(282)	(282)
Issuance of Series A Preferred Stock and common stock warrants, net of offering costs	2,700	584	—	—	—	—	—
Issuance of common stock in connection with offering, net of offering costs	—	—	4,198	42	994	—	1,036
Issuance of common stock in connection with exercise of warrants	—	—	103	1	173	—	174
Issuance of RSUs related to employee separation agreement	—	—	168	2	218	—	220
Stock-based compensation expense related to employee and director stock options	—	—	—	—	68	—	68
Stock-based compensation expense related to non-employee stock options	—	—	—	—	14	—	14
Stock option modification	—	—	—	—	24	—	24
Balance at September 30, 2019	2,700	$ 584	25,202	$ 252	$ 125,009	$ (122,338)	$ 2,923

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

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the "Company") is a medical device company predominantly focused on eye care. Our main product is Avenova®, an FDA cleared product sold in the United States that has proven in laboratory testing to have broad antimicrobial properties as it removes foreign material including microorganisms and debris from skin around the eye, including the eyelid. Avenova is formulated with our proprietary, stable and pure form of hypochlorous acid and is available direct to consumers through on-line distribution channels and is also often prescribed and dispensed by eyecare professionals for blepharitis and dry-eye disease. During the second quarter of 2020, our primary source of revenue was from third-party manufactured disposable KN95 facial coverings ("KN95 Masks") which we offered in response to the consumer demand created by the COVID-19 pandemic. Sales of our KN95 Masks continued in the third quarter of 2020 but were not our primary source of revenue during that quarter. We do not anticipate that KN95 Masks will provide a significant future source of revenue.

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. It had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, it changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In June 2010, the Company changed the state in which it was incorporated (the "Reincorporation") and is now incorporated under the laws of the State of Delaware. All references to "the Company" herein refer to the California corporation prior to the date of the Reincorporation and to the Delaware corporation on and after the date of the Reincorporation. The Company is managed as a single segment focused on commercializing Avenova in the United States.

Liquidity

Based primarily on the funds available at September 30, 2020, management believes that the Company's existing cash and cash equivalents and cash flows generated from product sales will be sufficient to enable the Company to meet its planned operating expenses at least through November 12, 2021. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. Additionally, our future results, cash expenditures and ability to obtain additional external financing could be adversely affected by the COVID-19 pandemic and general adverse economic conditions.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, assumptions for valuing options and warrants, income taxes, and other contingencies. Actual results could differ from those estimates.

Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements and related disclosures have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosure made are adequate to make the information not misleading. It is suggested that these condensed financial statements be read in conjunction with the Company's financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2019. The year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly-liquid instruments with a stated maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value. As of September 30, 2020 and December 31, 2019, the Company's cash and cash equivalents were held in a highly-rated, major financial institution in the United States.

The following table provides a reconciliation of the cash and cash equivalents reported in the condensed consolidated balance sheets to cash, cash equivalents and restricted cash reported in the statement of cash flows:

(in thousands)	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 13,413	$ 6,937
Restricted cash included in other assets	475	475
Total cash, cash equivalents, and restricted cash in the statements of cash flows	$ 13,888	$ 7,412

The restricted cash amount included in other assets on the condensed consolidated balance sheets represents amounts held as certificates of deposit for long-term financing and lease arrangements as contractually required by our financial institution and landlord.

Concentrations of Credit Risk and Major Partners

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. The Company maintains deposits of cash, cash equivalents and restricted cash with a highly-rated, major financial institution in the United States.

Deposits in this bank may exceed the amount of federal insurance provided on such deposits. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institution in which the deposits are held.

During the three and nine months ended September 30, 2020, revenues were derived primarily from sales of Avenova. Avenova is sold directly to consumers through Amazon.com and Avenova.com. Avenova is also sold with a prescription through local pharmacies via three major distribution partners, at eye care specialist offices and through a limited number of partner pharmacies. During the nine months ended September 30, 2020, primarily during the second quarter, the Company also generated revenue from the sale of KN95 Masks through the Company's webstore and offline bulk orders. The Company does not expect KN95 Masks to provide a significant future source of revenue.

During the three and nine months ended September 30, 2020 and 2019, revenues from each product were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Avenova	$ 1,835	$ 1,615	$ 4,509	$ 4,645
KN95 Masks	69	—	3,081	—
Other products	263	—	448	209
Total product revenue, net	2,167	1,615	8,038	4,854
Other revenue, net	3	—	8	41
Total sales, net	$ 2,170	$ 1,615	$ 8,046	$ 4,895

During the three and nine months ended September 30, 2020 and 2019, Avenova revenues from our major distribution partners greater than 10% were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Major distribution partner	2020	2019	2020	2019
Avenova Direct via Amazon	40%	21%	26%	*%
Avenova distributor A	*%	15%	*%	17%
Avenova distributor B	*%	13%	*%	17%
Avenova distributor C	*%	19%	*%	16%

***Not greater than 10%**

As of September 30, 2020 and December 31, 2019, accounts receivable from our customers and distribution partners greater than 10% were as follows:

Major distribution partner or customer	September 30, 2020	December 31, 2019
Customer A from sales of KN95 Masks	21%	—%
Avenova distributor A	17%	28%
Avenova Direct via Amazon	14%	20%
Avenova distributor B	14%	19%
Avenova distributor C	12%	13%

The Company relies on two contract manufacturers to produce Avenova. The Company does not own any manufacturing facilities and intends to continue to rely on third parties for the supply of finished goods. Contract manufacturers may or may not be able to meet the Company's needs with respect to timing, quantity or quality. In particular, it is possible that we may suffer from unexpected supply chain delays in light of the worldwide COVID-19 pandemic.

Fair Value of Financial Assets and Liabilities

The Company's financial instruments include cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, related party note payable, and warrants liabilities. The fair value of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and related party note payable is carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

A liability for warrants that are expected to be issued upon the achievement of future milestones by TLF Bio Innovation (See Note 8, "Commitments and Contingencies") is carried at fair value and included in accrued liabilities in the Company's condensed consolidated balance sheet.

The Company follows Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*, with respect to assets and liabilities that are measured at fair value on a recurring basis and nonrecurring basis. Under this standard, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The standard also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. There are three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities;
Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable; and
Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

Categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Allowance for Doubtful Accounts

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identifies amounts due that are in dispute and it believes are unlikely to be collected. Management did not record any reserves for accounts receivable at September 30, 2020. At December 31, 2019, management reserved $51 thousand based on specific amounts that were in dispute or were over 120 days past due as of those dates.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method. At September 30, 2020 and December 31, 2019, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $194 thousand and $247 thousand, respectively.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets of five to seven years for office and laboratory equipment, three years for computer equipment and software and seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of seven years or the lease term.

The costs of normal maintenance, repairs, and minor replacements are expensed as incurred.

Impairment of Long-Lived Assets and Operating Lease Right-of-Use Assets

The Company accounts for long-lived assets and operating lease right-of-use assets in accordance with ASC 360, *Property, Plant and Equipment*, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use or right-of-use assets is present. Management periodically evaluates the carrying value of long-lived assets and right-of-use assets. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the condensed consolidated statements of operations and comprehensive loss. During the first quarter of 2019, in connection with the restructuring of its U.S. sales force, the Company reviewed its fleet leases for impairment and recorded an impairment charge of $125 thousand. There was no such impairment charge during the three and nine months ended September 30, 2020.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)*, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019. Using the optional transition method, prior period financial statements have not been recast to reflect the new lease standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use assets may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component for all leases in which it is a lessee or a lessor. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. As a result, as of the effective date, the Company no longer recognizes deferred rent on the condensed consolidated balance sheet.

Comprehensive Income (Loss)

ASC 220*, Comprehensive Income,* requires that an entity's change in equity or net assets during a period from transactions and other events from non-owner sources be reported.

Revenue Recognition

Revenue generated through the Company's webstore for Avenova and KN95 Masks is recognized upon receipt by the customer through multiple third-party carriers. Shipping and handling costs are expensed as fulfillment costs are incurred and included in cost of goods sold in the condensed consolidated statements of operations and comprehensive loss. We present revenue net of sales taxes and refunds.

Revenue generated through Amazon.com for Avenova and other products is recognized upon fulfillment, which generally occurs upon delivery of the related products to a third-party carrier or, in the case of an Amazon delivery, to the customer. We present revenue net of commissions and any related fulfillment and shipping fees charged by these partners. Fees paid to partners for promoting our product are expensed as incurred and are included in sales and marketing expenses within the operating expenses in the condensed consolidated statements of operations and comprehensive loss.

The Company also generates Avenova product revenue through product sales to its major distribution partners. Product supply of Avenova is the only performance obligation contained in these arrangements, and the Company recognizes product revenue upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to, generally upon shipment to the distributor on a "sell-in" basis. Upon recognition of product sales, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because the Company does not have sufficient historical data to compute its own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. The Company updates the return rate assumption quarterly and applies it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the distributor. At any point in time there is generally one month of inventory in the sales channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved one month from when control is transferred.

Revenue generated through the Company's partner pharmacies is recognized when control of the product transfers to the end customer.

Bulk orders of KN95 Masks are shipped directly to the customer from a manufacturer in China. Revenue is recognized when control of the product passes to the customer, which is upon delivery of the KN95 Masks to the customer. As such, customer orders are recorded as deferred revenue prior to product delivery.

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping and handling costs, and other costs associated with products sold. Cost of goods sold also includes any necessary allowance for excess and obsolete inventory along with lower of cost and estimated net realizable value.

Research and Development Costs

The Company charges research and development costs to expense as incurred. These costs include all costs associated with research, development and regulatory activities, including Emergency Use Authorization ("EUA") submissions to the Food and Drug Administration ("FDA"). Research and development costs may vary depending on the type of item or service incurred, location of performance or production, level of availability of the item or service, and specificity required in production for certain compounds.

Patent Costs

Patent costs, including legal expenses, are expensed in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units ("RSUs") to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's condensed consolidated statements of stockholders' equity (deficit) based on their fair values as they are earned under the applicable vesting terms. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes option pricing model. See Note 13, "Equity-Based Compensation" for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. The Company accounts for RSUs issued to employees and non-employees (consultants and advisory board members) based on the fair market value of the Company's common stock as of the date of issuance.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized.

Common Stock Warrant Liability

The Company accounts for common stock purchase warrants issued in connection with its equity offerings in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*.

The Company accounts for common stock purchase warrants issued in connection with share-based compensation agreements in accordance with the provisions of ASC 718, *Stock Compensation,* which encompasses the provisions of ASC 480, *Distinguishing Liabilities from Equity*.

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). Additionally, for common stock purchase warrants accounted for in accordance with ASC 718, *Stock Compensation,* the Company classifies as liabilities any contracts where it believes the warrants are deemed to be probable of issuance.

For warrants that are classified as liabilities, the Company records the fair value of the warrants at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the condensed consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Black-Scholes option pricing model, the Binomial Lattice ("Lattice") valuation model, or the Monte Carlo simulation model where deemed appropriate. These values are subject to a significant degree of management's judgment.

On January 1, 2019, the Company adopted ASU 2017-11, "*Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*" on a modified retrospective basis. Upon adoption of ASU 2017-11, the Company changed its method of accounting for warrants by reclassifying warrant liabilities related to outstanding warrants that have a down round feature to additional paid in capital on its March 31, 2019 consolidated balance sheet, which increased additional paid-in capital by $56 thousand and decreased warrant liability by $56 thousand. In addition, because of the modified retrospective adoption, the Company recorded a cumulative-effect adjustment of $356 thousand to the Company's beginning accumulated deficit as of January 1, 2019, with an offset that increased additional paid-in capital by $356 thousand.

Net Loss per Share

The Company computes net loss per share by presenting both basic and diluted earnings (loss) per share ("EPS").

Basic EPS is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method. In computing diluted EPS, the average stock price for the period is used to determine the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods because their effect would be anti-dilutive.

During the three months ended September 30, 2020, both basic and diluted EPS was a net loss of $0.08 per share. The gain on changes in fair value of the October 2015 warrant liability had a nominal impact on the diluted EPS. During the three months ended September 30, 2019, the basic EPS was a net loss of $0.01 per share, and the diluted EPS was a net loss of $0.02 per share, due to the gain on changes in fair value of warrant liability. During the nine months ended September 30, 2020 and 2019, both basic and diluted EPS was a net loss of $0.28 and $0.36, per share, respectively. The gain on changes in fair value of the October 2015 warrant liability had a nominal impact on the diluted EPS.

The following table sets forth the calculation of basic and diluted EPS:

(In thousands, except par value amounts)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Numerator				
Net loss	$ (3,221)	$ (282)	$ (9,285)	$ (6,972)
Less retained earning reduction related to down round feature triggered	—	—	—	(29)
Net loss, basic	$ (3,221)	$ (282)	$ (9,285)	$ (7,001)
Less gain on changes in fair value of warrant liability	(19)	(75)	(14)	—
Net loss, diluted	$ (3,240)	$ (357)	$ (9,299)	$ (7,001)
Denominator				
Weighted average shares outstanding, basic	40,037	23,096	32,614	19,623
Net loss per share, basic	$ (0.08)	$ (0.01)	$ (0.28)	$ (0.36)
Weighted average shares outstanding, basic	40,037	23,096	32,614	19,623
Effect of dilutive warrants	30	117	28	—
Weighted average shares outstanding, diluted	40,067	23,213	32,642	19,623
Net loss per share, diluted	$ (0.08)	$ (0.02)	$ (0.28)	$ (0.36)

The following outstanding stock options and stock warrants were excluded from the diluted net loss per share computation, as their effect would have been anti-dilutive:

(in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Period end stock options to purchase common stock	3,328	2,240	3,328	2,240
Period end common stock warrants	7,067	8,438	7,067	8,588
Period end Series A Preferred Stock	—	2,700	—	2,700
	10,395	13,378	10,395	13,528

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 improved the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements. The Company adopted the new standard effective January 1, 2020 and the adoption of this guidance did not have a material impact on our condensed consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. ASU 2016-13 is effective for the Company for annual and interim reporting periods beginning January 1, 2023. The Company will adopt the new standard effective January 1, 2023. We are currently evaluating the impact of the new guidance on our condensed consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12)*, which simplifies the accounting for income taxes. This guidance will be effective for us in the first quarter of 2021 on a prospective basis. We are currently evaluating the impact of the new guidance on our condensed consolidated financial statements.

NOTE 3. FAIR VALUE MEASUREMENTS

The Company follows ASC 820, *Fair Value Measurements and Disclosures*, with respect to assets and liabilities that are measured at fair value on a recurring basis and nonrecurring basis. Under this standard, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date.

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities and certificates of deposit.

The Company's warrant liability for outstanding warrants is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions using the Black-Scholes valuation method or the Lattice valuation model as appropriate. As of September 30, 2020, the Company's warrant liability consisted of 38,000 October 2015 Warrants (see Note 11, "Warrant Liability"). The 2019 Domestic Warrants and 2019 Foreign Warrants (see Note 11, "Warrant Liability") were amended and exercised in July 2020 (see Note 12, "Stockholders' Equity (Deficit)"), resulting in a decrease of $9.1 million in warrant liability. The 2019 Ladenburg Warrants were also amended in July 2020 (see Note 12, "Stockholders' Equity (Deficit)"), resulting in a decrease of $197 thousand in warrant liability.

A liability for warrants that are expected to be issued upon the achievement of future milestones by TLF Bio Innovation (See Note 8, "Commitments and Contingencies") is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions in the valuation of this liability. The Company determined the fair value of the liability using the Monte Carlo simulation model. The liability is included in accrued liabilities in the Company's condensed consolidated balance sheet.

The embedded derivative liability related to the Convertible Note (as defined below) was fully settled in September 2020. See Note 10, "Convertible Note" for further discussion of the settlement of the Convertible Note and embedded derivative liability during the quarter ended September 30, 2020.

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2020:

(in thousands)	Balance at September 30, 2020	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Restricted cash held as a certificate of deposit	$ 324	$ 324	$ —	$ —
Deposit held as a certificate of deposit	151	151	—	—
Total assets	$ 475	$ 475	$ —	$ —
Liabilities				
Warrant liability	$ 20	$ —	$ —	$ 20
TLF Bio Innovation consulting service liability related to potential warrant issuance	109	—	—	109
Total liabilities	$ 129	$ —	$ —	$ 129

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2019:

(in thousands)	Balance at December 31, 2019	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Restricted cash held as a certificate of deposit	$ 324	$ 324	$ —	$ —
Deposit held as a certificate of deposit	151	151	—	—
Total assets	$ 475	$ 475	$ —	$ —
Liabilities				
Warrant liability	$ 4,089	$ —	$ —	$ 4,089
Embedded derivative liability	3	—	—	3
Total liabilities	$ 4,092	$ —	$ —	$ 4,092

The following is a reconciliation of the beginning and ending balances for the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the three and nine months ended September 30, 2020:

(in thousands)	Level 3 liabilities
Fair value of warrant liability and embedded derivative liability at December 31, 2019	$ 4,092
Decrease in fair value of warrant liability	(122)
Decrease in fair value of embedded derivative liability at March 31, 2020	(2)
Decrease in fair value related to warrants expired	(15)
Fair value of warrant liability and embedded derivative liability at March 31, 2020	$ 3,953
Increase in fair value of warrant liability	3,772
Fair value of warrant liability and embedded derivative liability at June 30, 2020	$ 7,725
Increase in fair value of warrant liability	1,589
Fair value of 2019 Preferred Warrant and 2019 Common Warrant liability transferred to equity upon exercise	(9,096)
Fair value of 2019 Ladenburg Warrant liability transferred to equity upon warrant modification	(197)
Elimination of embedded derivative liability upon settlement of convertible note	(1)
TLF Bio Innovation consulting service liability related to potential warrant issuance	109
Fair value of warrant liability and TLF Bio Innovation consulting service liability at September 30, 2020	$ 129

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

(in thousands)	September 30, 2020	December 31, 2019
Prepaid insurance	$ 314	$ 94
Prepaid inventory	84	—
Prepaid patents	78	85
Prepaid security deposit for lease	65	65
Prepaid sales rebates	63	401
Prepaid dues and subscription	14	82
Retainer	—	46
Other	77	113
Total prepaid expenses and other current assets	$ 695	$ 886

NOTE 5. INVENTORY

Inventory consisted of the following:

(in thousands)	September 30, 2020	December 31, 2019
Raw materials and supplies	$ 172	$ 185
Finished goods	807	554
Less: Reserve for excess and obsolete inventory	(194)	(247)
Total inventory, net	$ 785	$ 492

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	September 30, 2020	December 31, 2019
Office and laboratory equipment	$ 20	$ 20
Furniture and fixtures	157	157
Computer equipment and software	347	349
Production equipment	65	65
Leasehold improvements	79	79
Total property and equipment, at cost	668	670
Less: accumulated depreciation and amortization	(592)	(560)
Total property and equipment, net	$ 76	$ 110

Depreciation and amortization expense was $12 thousand and $17 thousand for the three months ended September 30, 2020 and 2019, respectively, and $40 thousand and $50 thousand for the nine months ended September 30, 2020 and 2019, respectively.

There was no impairment charge during the three months ended September 30, 2020. During the three months ended September 30, 2020, the Company disposed of damaged, unusable and fully depreciated property and equipment. As a result, the Company recognized an immaterial loss on the disposal of these assets. During the three and nine months ended September 30, 2019, the Company recorded an impairment charge of $32 thousand related to previously capitalized software.

NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	September 30, 2020	December 31, 2019
Settlement liability related to John McGovern case – see Note 8	$ 502	$ —
Avenova contract liabilities	380	822
Employee payroll and benefits	246	463
Sublease security deposit	198	198
TLF Bio Innovation consulting service liability related to potential warrant issuance	109	—
Related party consulting service	—	33
Consulting service	43	109
Other	177	153
Total accrued liabilities	$ 1,655	$ 1,778

NOTE 8. COMMITMENTS AND CONTINGENCIES

Directors and Officers Indemnification

As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, it has not recorded any liabilities for these agreements as of September 30, 2020.

In the normal course of business, the Company provides indemnification of varying scope under its agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, it generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with the use or testing of its products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to its products. The term of these indemnification agreements is generally perpetual. The potential future payments the Company could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit its exposure. As a result, it believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2020.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business.

On July 29, 2019, Mr. John McGovern, the Company's former Interim President & Chief Executive Officer and Chief Financial Officer, submitted a demand for arbitration in connection with his separation from service with the Company. On September 29, 2020, Mr. McGovern was granted severance in the amount of $370 thousand in an interim arbitration award; the arbitration is ongoing as relates to additional damages. As of September 30, 2020, the Company has accrued a liability of $502 thousand related to the matter.

As of September 30, 2020, there are no other matters that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company's financial position, results of operations or cash flows.

Leases

The Company leases office space for its corporate headquarters located in Emeryville, California. The initial lease term is through February 28, 2022. The Company has the option to extend the term of the lease for one five (5)-year period upon written notice to the landlord. The Company intends to exercise the renewal option for this lease.

The Company also had a lease commitment for laboratory facilities and office space at EmeryStation North in Emeryville, California ("EmeryStation") under an operating lease. In July 2016, the Company subleased the EmeryStation space (the "Sublease Agreement"). The Sublease Agreement commenced September 8, 2016. The EmeryStation lease and Sublease Agreement were terminated as of August 31, 2020 pursuant to a sublease termination agreement executed on July 31, 2020. In conjunction with the termination, the Company recognized a gain of $54 thousand which is recorded within the operating expenses in the Company's condensed consolidated statements of operations and comprehensive loss for the three months ending September 30, 2020.

In addition to the facility leases, the Company previously leased 54 vehicles under a master fleet lease agreement. Each lease was for a period of 36 months, which commenced upon the delivery of the vehicles during the first quarter of 2017. During the first quarter of 2019, in connection with the restructuring of its U.S. sales force, the Company reviewed its fleet leases for impairment. The Company estimated fair value based on the lowest level of identifiable estimated future cash flows and recorded an impairment charge of $125 thousand, which is included in sales and marketing expenses within the operating expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2019. During the fourth quarter of 2019, the Company terminated the lease agreement related to the idled vehicles early and had 15 leased vehicles as of December 31, 2019. The lease agreement expired in the first quarter of 2020.

In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use assets and lease liability for leases being greater than if the policy election was not applied. The leases include variable components (e.g. common area maintenance) that are paid separately from the monthly base payment based on actual costs incurred and therefore were not included in the right-of-use assets and lease liability, but are reflected as an expense in the period incurred.

Total operating lease costs and supplemental cash flow information related to operating leases for the three and nine months ended September 30, 2020 were as follows (in thousands):

Lease Costs	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
	2020	**2019**	**2020**	**2019**
Operating lease cost	$ 212	$ 273	$ 726	$ 861
Sublease income	(105)	(158)	(421)	(474)
Net lease cost	$ 107	$ 115	$ 305	$ 387
Other information				
Operational cash flow used for operating leases	$ 236	$ 322	$ 816	$ 970

The Company has measured its operating lease liabilities at its incremental borrowing rate over the remaining term for each operating lease. The weighted average remaining lease term and the weighted average discount rate are summarized as follows:

	September 30,	
	2020	**2019**
Weighted-average remaining lease term (in years)	1.5	1.8
Weighted-average discount rate	12%	12%

Future lease payments under non-cancelable leases as of September 30, 2020 were as follows (in thousands):

Remaining in 2020	$ 111
2021	454
2022	88
Thereafter	—
Total future minimum lease payments	653
Less imputed interest	(56)
Total	$ 597
Reported as:	
Operating lease liabilities	$ 400
Operating lease liabilities- non-current	197
Total	$ 597

Contracts

On May 13, 2020, the Company entered into an agreement with TLF Bio Innovation Lab LLC ("TLF Bio Innovation"), a related party, to manage the relaunch of the Company's CelleRx product (the "TLF Agreement") which was further amended on September 4, 2020. Under the agreement, the Company pays TLF Bio Innovation a monthly cash fee. Additionally, upon the successful completion of certain milestones, TLF Bio Innovation is eligible to receive warrants exercisable for up to 2 million shares of the Company's common stock with an exercise price equal to the average closing price of the Company's common stock for the last calendar month immediately prior to the date on which an individual milestone was achieved. As of September 30, 2020, the achievement of the first milestone was deemed probable. As a result, during the three months ended September 30, 2020, the Company recorded a $109 thousand consulting expense and related liability for the expected warrant issuance. The expense was included in sales and marketing expenses within operating expenses in the condensed consolidated statements of operations and comprehensive loss. The expense was based on the fair value of the warrants calculated using the Black-Scholes valuation model and management's estimates of the probable dates of issuance of the warrants, the number of warrants probable of being issued, as well as the estimated exercise price calculated using the Monte Carlo valuation model as of September 30, 2020. The key assumptions used in the Monte Carlo valuation model to calculate the estimated exercise price were as follows:

Assumption	**As of September 30, 2020**
Stock price	$ 0.73
Expected equity volatility	89%
Risk-free interest rate	0.09%
Expected term (in days)	71

The key assumptions used in the Black-Scholes valuation model to value the TLF Bio Innovation consulting service liability related to potential warrant issuance as of September 30, 2020 were as follows:

Assumption	**As of September 30, 2020**
Expected equity volatility	136%
Risk-free interest rate	0.28%
Expected term (in years)	5.00
Weighted-average fair value of warrants	$ 0.64

On April 16, 2020, the Company entered into an international distribution agreement with Shenzhen Microprofit Biotech Co., LTD, ("Microprofit") (the "Microprofit Agreement"). The Microprofit Agreement grants the Company exclusive rights to distribute Microprofit's SARS-CoV-2 IgG and IgM Antibody Combined Test Kit ("Test Kits") in the United States through December 31, 2021. In accordance with the Microprofit Agreement, the Company is assisting Microprofit to apply for approval of the

Test Kits by the U.S. Food & Drug Administration ("FDA"). Under the terms of the Microprofit Agreement, if such approvals are granted, the Company will issue warrants to certain Microprofit officers exercisable for an aggregate number of shares of the Company's common stock equivalent to 12% of the Company's outstanding common stock on the date of approval. As of September 30, 2020, the Company has determined that the issuance of warrants under this agreement is not probable.

In connection with the Microprofit Agreement, on April 16, 2020, the Company entered into an intermediary distribution agreement with Chongqing Pioneer Pharma Holdings Limited ("Chongqing Pioneer"), a related party, which was subsequently amended on June 29, 2020. The amended agreement provides that the Company will purchase all Test Kits from Pioneer as an intermediary.

NOTE 9. RELATED PARTY NOTE PAYABLE

On February 27, 2019, the Company issued a $1.0 million promissory note payable to Pioneer Pharma (Hong Kong) Company Ltd. ("Pioneer Pharma"), which was amended on June 25, 2019 and May 14, 2020 (the "Promissory Note"). The Promissory Note provided for an interest payment of $150 thousand which was initially amended to a payment of $300 thousand and subsequently to the delivery of 65,178 units of NeutroPhase (40ml) to Pioneer Pharma, inclusive of 40,644 units previously delivered in the first quarter of 2020. The second amendment to the Promissory Note also provided the Company with the right to repay the note at any time. On May 14, 2020, the Company repaid the $1.0 million principal balance of the Promissory Note using proceeds raised through the ATM program (see Note 12, "Stockholders' Equity (Deficit)"). As of September 30, 2020, the remaining interest payable was $104 thousand, which was settled through the delivery of 24,534 units of NeutroPhase subsequent to September 30, 2020 in October 2020. Upon full repayment of principal and interest during the fourth quarter of 2020, the Company was released from the Promissory Note with Pioneer Pharma.

In connection with the Promissory Note, the Company paid China Kington a 2% fee for brokering the transaction and entered into a consulting agreement with China Kington for a term of one year, which expired on March 1, 2020. Bob Wu, acting in a dual role as a member of the Company's Board of Directors and as principal of China Kington, was paid $100 thousand pursuant to such consulting agreement. Upon the expiration of the original consulting agreement, the parties entered into a consulting agreement, in which no cash compensation will be paid. Debt issuance costs associated with the issuance of the Promissory Note of $20 thousand was recognized and recorded as an offset to the related party note payable in the condensed consolidated balance sheet.

The interest expense recognized, including amortization of the issuance costs, was $0 and $75 thousand during the three and nine months ended September 30, 2020, respectively. The interest expense recognized, including amortization of the issuance costs, was $45 thousand and $175 thousand during the three and nine months ended September 30, 2019, respectively.

NOTE 10. CONVERTIBLE NOTE

On March 26, 2019 (the "Closing Date"), the Company entered into a Securities Purchase Agreement (the "Iliad Securities Purchase Agreement) with Iliad Research and Trading, L.P. (the "Lender"), pursuant to which the Company issued a Secured Convertible Promissory Note (the "Convertible Note") to the Lender dated as of the Closing Date. The Convertible Note had an original principal amount of $2.2 million and an interest rate of 10% per annum. The Company received net proceeds of $2.0 million after deducting an original issue discount of $200 thousand and debt issuance cost of Lender's transaction fees of $15 thousand. The Company recognized an additional $182 thousand of debt issuance costs associated with the issuance of the Convertible Note. The Convertible Note was repaid in full prior to September 30, 2020. Upon full repayment, the Company was released from the Iliad Securities Purchase Agreement with Lender.

The Convertible Note provided the Lender with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into unregistered shares of the Company's common stock at a conversion price of $1.65 per share. Beginning on September 26, 2019, the Convertible Note also provided the Lender with the right to redeem all or any portion of the Convertible Note ("Redemption Amount") up to $200 thousand per calendar month. The payments of each Redemption Amount could be made, at the option of the Company, in cash, by converting such Redemption Amount into unregistered shares of Common Stock ("Redemption Conversion Shares"), or a combination thereof. The number of Redemption Conversion Shares equaled the portion of the applicable Redemption Amount being converted divided by the lesser of $1.65 or the Market Price. The Market Price was defined as 85% of the lowest closing bid price during the 20 trading days immediately preceding the applicable measurement date. In addition, the Company could redeem the Convertible Note at its option at any time at a redemption price equal to 115% of the aggregate outstanding balance of principal and interest.

The Convertible Note contained events of default upon the occurrence and during the continuance of which all obligations could be declared immediately due and payable. Under certain events of default, the outstanding balance of principal and interest could be automatically due and payable in cash. Upon other events of default, the Lender, at its option, could elect to increase the outstanding balance by up to 15%, depending on the magnitude of the default, without accelerating the outstanding balance.

The Company's prepayment terms represented an embedded call option, the Lender's share redemption terms represent an embedded put option and certain events of default represent embedded derivatives, each of which required bifurcation. A single derivative comprising all bifurcated features was measured at fair value using a Monte Carlo simulation model. The fair value of the embedded derivative at issuance of the Convertible Note on March 26, 2019 was $0.4 million. The key assumptions used to value the combined embedded derivative upon issuance on March 26, 2019 were as follows:

Assumption	As of March 26, 2019
Stock price (latest bid price)	$ 1.28
Equity volatility	93.8%
Risk-free interest rate	2.34%
Remaining term (in years)	1.5

The key assumptions used to value the combined embedded derivative as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Stock price	$ 0.65
Equity volatility	192.6%
Risk-free interest rate	1.60%
Remaining term (in years)	0.74

A $627 thousand discount, including the original issue discount, and $197 thousand of debt issuance costs, including the Company's issuance costs and payment for the Lender's transaction fees, were recorded at issuance and classified as an offset to the Convertible Note on the condensed consolidated balance sheet. The discount and debt issuance costs were amortized to interest expense using the effective interest rate method over the term of the Convertible Note. During the three and nine months ended September 30, 2020, the effective interest rate on the Convertible Note was 22% and 20%, respectively. Interest expense recognized, including amortization of the issuance costs and debt discount, was $16 thousand and $215 thousand during the three and nine months ended September 30, 2020, respectively. During the three and nine months ended September 30, 2019, the effective interest rate on the Convertible Note was 52% and 53%, respectively. Interest expense recognized, including amortization of the issuance costs and debt discount, was $293 thousand and $615 thousand during the three and nine months ended September 30, 2019, respectively.

During the three and nine months ended September 30, 2020, the Company repaid a total of $0.4 million and $1.6 million in cash, which was applied against the outstanding principal balance of the convertible note, respectively.

NOTE 11. WARRANT LIABILITY

In July 2011, the Company sold common stock and warrants in a registered direct financing. As part of this transaction, 139,520 warrants were issued with an exercise price of $33.25 and were exercisable from January 1, 2012 to July 5, 2016. The terms of the warrants require registered shares to be delivered upon each warrant's exercise and also require possible cash payments to the warrant holders (in lieu of the warrant's exercise) upon specified fundamental transactions involving the Company's common stock, contractually defined to include various merger, acquisition or stock transfer activities. Under ASC 480, *Distinguishing Liabilities from Equity*, the Company's ability to deliver registered shares upon an exercise of the warrants and the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. The warrants contain a provision according to which the warrant holder would have the option to receive cash, equal to the Black-Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction. Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice model, and the changes in the fair value are recorded in the condensed consolidated statement of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, if the closing bid price per share of the common stock in the principal market equals or exceeds $66.50 for any ten trading days (which do not have to be consecutive) in a period of fifteen consecutive trading days, the Company has the right to require the exercise of one-third of the warrants then held by the warrant holders.

In October 2015, the holders of all warrants issued pursuant to the Company's securities purchase agreement, dated March 3, 2015 (the "2015 Securities Purchase Agreement"), agreed to reduce the length of notice required to such investors prior to the Company's issuance of new securities from twenty business days to two business days, for the remainder of such investors' pre-emptive right period (which expired March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in the October 2015 Offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both the warrants with a 15-month term (the "Short-Term Warrants") and warrants with a five-year term (the "Long-Term Warrants") issued pursuant to the 2015 Securities Purchase Agreement (together, the "March 2015 Warrants") and the warrants issued pursuant to the placement agent agreement, dated June 29, 2011 (the "July 2011 Warrants"). Specifically, the amendments decreased the exercise price for both the March 2015 Warrants and the July 2011 Warrants to $5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the July 2011 Warrants, which have since expired on March 6, 2020. A price protection provision also was added to both the July 2011 Warrants and March 2015 Warrants, such that if the Company subsequently sold or otherwise disposed of Company common stock at a lower price per share than $5.00 or any securities exchangeable for common stock with a lower exercise price than $5.00, the exercise price of such warrants would be reduced to that lower price.

In October 2015, the Company also entered into an underwriting agreement with Roth Capital Partners, LLC, relating to the public offering and sale of up to (i) 492,000 shares of the Company's common stock; and (ii) warrants to purchase up to 442,802 shares of the Company's common stock (the "October 2015 Warrants") with an exercise price of $5.00 per share (the "October 2015 Offering"). The shares of common stock and warrants were issued separately. Each warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in the October 2015 Offering was $5.00 per share of common stock and related warrant. The net proceeds to the Company were approximately $2.1 million after deducting underwriting discounts and commissions and offering expenses.

In February 2016, the strike price of the July 2011, March 2015 and October 2015 Warrants was reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Mr. Jian Ping Fu at that price.

In May 2019, the strike price of the July 2011 Warrants, March 2015 Warrants and October 2015 Warrants was further reduced to $0.2061 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Triton Funds LP at that price.

On March 6, 2020, 35,107 July 2011 Warrants and 7,419 March 2015 Warrants expired without being exercised. As of September 30, 2020, there were no July 2011 Warrants or March 2015 Warrants outstanding.

The key assumptions used to value the July 2011 Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	115%
Expected term (in years)	0.18
Risk-free interest rate	1.52%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.44

As noted above, the Company issued warrants in connection with the October 2015 Offering. The Company evaluated the terms of the October 2015 Warrants and noted that under ASC 480, the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the condensed consolidated statement of operations and comprehensive loss. The fair value of the warrants at issuance on October 27, 2015 was $1.3 million.

The key assumptions used to value the October 2015 Warrants as of September 30, 2020 and December 31, 2019 were as follows:

Assumption	As of September 30, 2020	As of December 31, 2019
Expected price volatility	108%	184%
Expected term (in years)	0.08	0.83
Risk-free interest rate	0.08%	1.59%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 0.52	$ 0.49

During the second quarter of 2019, a total of 158,400 warrants to purchase 158,400 shares of common stock were exercised related to the July 2011 Warrants and the October 2015 Warrants resulting in gross proceeds of $33 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $0.4 million, with any change in fair value recorded in the condensed consolidated statement of operations and comprehensive loss. The $0.4 million fair value was subsequently transferred to equity as of the date of exercise.

During the third quarter of 2019, a total of 102,602 warrants to purchase 102,602 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $21 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $0.2 million, with any change in fair value recorded in the condensed consolidated statement of operations and comprehensive loss. The $0.2 million fair value was subsequently transferred to equity as of the date of exercise.

As further described in Note 12, “Stockholders’ Equity (Deficit)”, in the third quarter of 2019, the Company issued the 2019 Domestic Warrants, the 2019 Foreign Warrants and the 2019 Ladenburg Warrants. Beginning on July 20, 2020, the Company and the holders of the 2019 Domestic Warrants and the 2019 Foreign Warrants entered into Exercise Agreements (as defined below) which resulted in a reduction of the exercise prices underlying the warrants as well as the cash exercise of these warrants at the reduced exercise price. The Company also entered into Reprice Agreement (as defined below) with Ladenburg and amend the 2019 Ladenburg Warrants to reduce the exercise price to $0.99 per share. Each of the 2019 Domestic Warrants, the 2019 Foreign Warrants and the 2019 Ladenburg Warrants were classified as liabilities prior to the Exercise Agreements. The fair value of these liabilities was determined using the Black-Scholes option pricing model with the changes in fair value recorded in the condensed consolidated statement of operations and comprehensive loss.

The fair value of the 2019 Domestic Warrants at issuance on August 13, 2019 was determined to be $3.1 million in accordance with the following key assumptions:

Assumption	As of August 13, 2019
Expected price volatility	149%
Expected term (in years)	5.50
Risk-free interest rate	1.58%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.75

The key assumptions used to value the 2019 Domestic Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	154%
Expected term (in years)	5.13
Risk-free interest rate	1.70%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

The fair value of the 2019 Domestic Warrants was determined to be $4.9 million and was subsequently transferred to equity in the Company's condensed consolidated balance sheets as of the date of exercise on July 21, 2020 in accordance with the following key assumptions:

Assumption	As of July 21, 2020
Expected price volatility	178%
Expected term (in years)	4.57
Risk-free interest rate	0.25%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 1.18

The fair value of the 2019 Foreign Warrants at issuance on August 13, 2019 was determined to be $2.0 million in accordance with the following key assumptions:

Assumption	As of August 13, 2019
Expected price volatility	149%
Expected term (in years)	5.50
Risk-free interest rate	1.58%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.75

The key assumptions used to value the 2019 Foreign Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	154%
Expected term (in years)	5.13
Risk-free interest rate	1.70%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

The fair value of the 2019 Foreign Warrants was determined to be $4.2 million and was subsequently transferred to equity in the Company's condensed consolidated balance sheets as of the date of exercise on July 21, 2020 in accordance with the following key assumptions:

Assumption	As of July 21, 2020
Expected price volatility	178%
Expected term (in years)	4.57
Risk-free interest rate	0.27%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 1.54

The fair value of the 2019 Ladenburg Warrants at issuance on August 13, 2019 was determined to be $124 thousand using the following key assumptions:

Assumption	As of August 13, 2019
Expected price volatility	155%
Expected term (in years)	5.00
Risk-free interest rate	1.57%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.74

The key assumptions used to value the 2019 Ladenburg Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	160%
Expected term (in years)	4.61
Risk-free interest rate	1.69%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

As further discussed below in Note 12, "Stockholders' Equity (Deficit)", in connection with the Reprice Agreement, the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur was renegotiated to only apply in situations within the Company's control. Pursuant to this change, the 2019 Ladenburg Warrants were no longer classified as liabilities.

The fair value of the 2019 Ladenburg Warrants was determined to be $0.2 million and was subsequently transferred to equity in the Company's condensed consolidated balance sheets upon amendment on July 21, 2020 in accordance with the following key assumptions:

Assumption	As of July 21, 2020
Expected price volatility	186%
Expected term (in years)	4.05
Risk-free interest rate	0.22%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 1.17

The 2019 Ladenburg Warrants will no longer be adjusted to fair value in future periods.

As of September 30, 2020, the total number of warrants that are classified as liability was 38,000 October 2015 Warrants, with a warrant liability of $20 thousand. The warrant liability is included in other current liabilities in the condensed consolidated balance sheets.

NOTE 12. STOCKHOLDERS' EQUITY (DEFICIT)

Preferred Stock

Under the Company's amended articles of incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock and with such rights and preferences as may be approved by the Board of Directors. As of September 30, 2020 and December 31, 2019, there were no shares of preferred stock outstanding.

On August 8, 2019, the Company entered into a securities purchase agreement for the sale of (i) 2,700,000 shares of the Series A Preferred Stock that automatically converted into 2,700,000 shares of common stock, at a ratio of 1:1, upon the approval of the Company's stockholders, which occurred on October 9, 2019, and (ii) 2,700,000 common stock purchase warrants exercisable for 2,700,000 shares of common stock (the "2019 Foreign Warrants).

As the conversion trigger was dependent upon stockholder approval which is considered to be outside the control of the Company, the Series A Preferred Stock was considered to be contingently redeemable and as a result, was classified as mezzanine equity in the Company's interim balance sheet as of September 30, 2019. Upon conversion of the Series A Preferred Stock into shares of the Company's common stock in October 2019, it was reclassified to equity in the Company's consolidated balance sheet.

The Company applied the fair value allocation methodology for allocating the proceeds of $2.7 million received from the Series A financing. The Company first allocated $2.0 million based on the fair value of the warrants as of the issuance date, with the residual amount being allocated to the Series A Preferred Stock. See Note 11, "Warrant Liability" for further discussion of the key assumptions used to value the warrants.

China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $162 thousand. The Company incurred additional issuance costs of $33 thousand. The Company allocated $93 thousand to the warrant liability, which was expensed during the period, and $102 thousand was recorded as a reduction to the Series A Preferred Stock.

On October 9, 2019, the Company held a special meeting of stockholders (the "Special Meeting"), at which the Company's stockholders approved (i) the conversion of 2,700,000 shares of the Series A Preferred Stock into 2,700,000 shares of the Company's common stock, and (ii) the 2,700,000 shares of Company common stock that may be issued upon the exercise of the 2,700,000 2019 Foreign Warrants, in accordance with the stockholder approval requirements of NYSE American. A beneficial conversion feature of $800 thousand was recorded as a discount to the preferred stock and an increase to additional paid in capital. Because the Series A Preferred Stock was perpetual, in October 2019, the Company fully amortized the discount related to the beneficial conversion feature on the deemed dividend in the consolidated statement of operations and comprehensive loss, which is reflected in the results for the year ended December 31, 2019.

Common Stock

On May 27, 2020, after receiving stockholder approval at the Company's 2020 Annual Meeting of Stockholders, the Company filed an amendment to its Amended and Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 50,000,000 to 75,000,000.

On March 29, 2019, the Company entered into a Common Stock Purchase Agreement with Triton Funds LP, a Delaware limited partnership ("Triton"), pursuant to which the Company had the right to sell up to $3.0 million of shares of common stock of the Company at a purchase price equal to 90% of the lowest trading price of the common stock of the Company for the five business days prior to the applicable closing date. The Company also entered into a Registration Rights Agreement on March 29, 2019 with Triton, pursuant to which the Company registered such shares for resale by Triton on a registration statement on Form S-3 filed with the Securities and Exchange Commission ("SEC") on April 1, 2019 and declared effective on April 12, 2019. In connection with the transaction with Triton Funds LP, the Company entered into a Letter Agreement with Triton Funds LLC, an affiliate of Triton, pursuant to which the Company issued 150,000 shares of common stock to Triton Funds LLC. During the second quarter of 2019, the Company issued to Triton Funds LP an aggregate of 1,747,312 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $360 thousand. The Company also incurred and paid other offering costs of $122 thousand. On September 5, 2019, the Company received an additional $288 thousand in connection with the financing (no additional shares were issued for such payment) and recorded the amount in additional paid-in capital from issuance of common stock. The Common Stock Purchase Agreement with Triton Funds LP expired as of December 31, 2019 and the remaining registered but unsold shares were deregistered on February 1, 2020.

On June 26, 2019, the Company entered into a private placement to sell 1,371,427 shares of Company common stock and warrants (the "June 2019 Warrants") to purchase an additional 1,371,427 shares of Company common stock for an aggregate subscription price of $2.4 million to three accredited investors including Messrs. Xiao Rui Liu, Hai Dong Pang and Ping Huang, each of whom subscribed for $1.0 million, $0.4 million and $1.0 million, respectively. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $144 thousand. The Company also incurred and paid other offering costs of $27 thousand.

On August 8, 2019, the Company entered into a purchase agreement for the sale and issuance of 4,198,566 shares of common stock at an offering price of $1.00 per share. In connection with such purchase agreement, the Company issued 4,198,566 warrants (the "2019 Domestic Warrants) to purchase 4,198,566 shares of Company common stock with an exercise price of $1.15. Ladenburg Thalmann & Co. Inc. ("Placement Agent") served as placement agent for the transaction in exchange for a commission representing six percent (6%) of the gross proceeds, totaling $252 thousand, and the issuance of the 2019 Ladenburg Warrants to purchase up to 167,942 shares of the Company's common stock with an exercise price of $1.25 per share. In addition, the Company reimbursed the Placement Agent $60 thousand for certain expenses. The Company also incurred and paid other offering costs of $312 thousand.

The Company applied the fair value allocation methodology for allocating the proceeds of $4.2 million received from the financing. The Company first allocated $3.1 million based on the fair value of the 2019 Domestic Warrants as of the issuance date, with the residual amount being allocated to the common stock. See Note 11, "Warrant Liability" for further discussion of the key assumptions used to value the warrants.

In connection with the financing, the Company incurred issuance cost of $488 thousand of which $233 thousand was allocated to the warrant liability and expensed during the period and $255 thousand was recorded as a reduction to additional paid-in capital from the issuance of common stock. As the 2019 Ladenburg Warrants were accounted for as a stock issuance cost, $59 thousand was allocated to the warrant liability and expensed during the period and $65 thousand was recorded as a reduction to additional paid-in capital from the issuance of common stock.

In July 2020, the holders of all the 2019 Domestic Warrants and the 2019 Foreign Warrants exercised their warrants at a reduced price of $0.99 per share, for which the Company received aggregate gross proceeds of approximately $6.8 million. The Company incurred and paid other offering costs of $0.2 million. The Company also incurred and paid a $0.2 million fee to China Kington for brokering the transaction, which equaled six percent (6%) of the gross proceeds from the 2019 Foreign Warrants. Please see the following subsection, "Stock Warrants," for further details regarding the reprice of the 2019 Domestic Warrants and 2019 Foreign Warrants, the reprice of the Ladenburg Warrants, as well as issuance of 6,898,566 New Warrants (as defined below) in July 2020.

On April 27, 2020, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with Ladenburg Thalmann & Co. Inc. ("Ladenburg") which established an at-the-market equity program (the "ATM Program") pursuant to which we may offer and sell shares of our common stock, par value $0.01 per share, from time to time as set forth in the ATM Agreement. The ATM Agreement provides for the sale of shares of our common stock having an aggregate offering price of up to the amount available pursuant to General Instruction I.B.6. of Form S-3, which was most recently up to 4,105,492. For additional information regarding the Agreement and the ATM Program, see the Company's Current Reports on Form 8-K filed with the SEC on April 27, 2020 and June 15, 2020, respectively. During the three months ended June 30, 2020, 5,836,792 shares of common stock were issued under the ATM Program for total proceeds of $5.6 million, net of offering costs of $0.4 million.

On May 13, 2020, TLF Bio Innovation, a related party, purchased 1,000 shares of the Company's common stock for total proceeds of $1 thousand in conjunction with the services agreement described in Note 8, "Commitments and Contingencies".

Stock Warrants

In February 2016, the exercise prices of the July 2011, March 2015, and October 2015 Warrants were reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Mr. Jian Ping Fu at that price. In May 2019, the strike price of the July 2011, March 2015, and October 2015 Warrants was further reduced to $0.2061 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Triton Funds LP at that price. The March 2015 Warrants were reclassified from warrant liabilities to equity upon adoption of ASU 2017-11. In March 2020, all remaining outstanding and unexercised July 2011 and March 2015 Warrants expired.

In May 2019, a down round feature was triggered as the strike price of the March 2015 Long-Term and Short-Term Warrants was reduced to $0.2061 per share resulting from the closing of the Common Stock Purchase Agreement with Triton Funds LP, pursuant to which the Company sold common stock to Triton Funds LP at $0.2061 per share. The Company measured the value of the effect of the down round feature as the difference between (1) the March 2015 Warrants' fair value (without the down round feature) using the pre-trigger exercise price and (2) the March 2015 Warrants' fair value (without the down round feature) using the reduced exercise price in accordance with ASC 820, and as a result, recorded a $29 thousand dividend, which is treated as a reduction to income available to common shareholders in the basic EPS calculation.

During the second quarter of 2019, a total of 158,400 warrants to purchase 158,400 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $33 thousand.

During the second quarter of 2019, a total of 133,167 warrants to purchase 133,167 shares of common stock were exercised related to the March 2015 Warrants. Out of the 133,167 warrants exercised, 70,000 warrants were exercised in a cashless transaction, resulting in 64,979 shares issued. The remaining warrants were exercised for gross proceeds of $13 thousand.

In June 2019, the Company issued 1,371,427 warrants to purchase 1,371,427 shares of Company common stock in a private placement. Please see the preceding subsection, "Common Stock," for further details regarding such private placement. Such warrants had a one (1)-year term and an exercise price of $0.87, callable by the Company if the closing price of the Company's common stock, as reported on the NYSE American, is $1.00 or greater.

In July 2019, a total of 102,602 warrants to purchase 102,602 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $21 thousand.

In August 2019, the Company issued 4,198,566 warrants to purchase 4,198,566 shares of Company common stock in connection with a registered direct offering of common stock. Such warrants were exercisable six months after date of issuance, with an exercise price of $1.15 per share. The Company issued 167,942 warrants to purchase 167,942 shares of Company common stock to the Placement Agent in connection with such offering. Such warrants were exercisable immediately upon issuance and will expire on August 8, 2024, with an exercise price of $1.25 per share. In August 2019, the Company also issued 2,700,000 warrants to purchase 2,700,000 shares of Company common stock in connection with its private placement of Series A Preferred Stock. Such warrants were exercisable upon stockholders' approval, with an exercise price of $1.15 per share.

Beginning on July 20, 2020, the Company and all holders of the 2019 Domestic Warrants and 2019 Foreign Warrants (collectively, the "Holders") entered into separate warrant repricing letter agreements (the "Exercise Agreements"). Pursuant to the Exercise Agreements, in consideration for the exercise in full of the Reprice Warrants (as defined below), the Company agreed to: (1) reduce the exercise price of an aggregate total of 4,198,566 Domestic Warrants and 2,700,000 Foreign Warrants (the "Reprice Warrants") to $0.99 per share, and (2) in a private placement, issue new common stock purchase warrants (the "New Warrants") to purchase up to a number of shares of common stock, equal to 100% of the number of 2019 Domestic Warrants and 2019 Foreign Warrants currently held by such Holders upon the Holders exercising their warrants. The Company also entered into warrant repricing letter agreement (the "Reprice Agreement) with Ladenburg and amend the 2019 Ladenburg Warrants to reduce the exercise price of an aggregate total of 167,942 Ladenburg Warrants to $0.99 per share. The New Warrants will be exercisable six months after their issuance, for an aggregate of 6,898,566 shares of common stock. The New Warrants will have an exercise price of $1.65 per share and will expire five and a half years after their issuance. In connection with the Exercise Agreements and Reprice Agreement, the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur was renegotiated to only apply in situations within the Company's control. Pursuant to this change, the New Warrants are classified as equity. The Company determined that the common stock issued from exercise of the 2019 Domestic and 2019 Foreign Warrants, and the New Warrants to be one unit of account, and therefore did not allocate the proceeds between the common stock and the New Warrants as, the proceeds, even if allocated, would be both recognized in additional paid-in capital.

During the first quarter of 2020, a total of 70,000 warrants to purchase 70,000 shares of common stock were exercised related to the March 2015 Warrants resulting in gross proceeds of $14 thousand.

On March 6, 2020, 35,107 July 2011 Warrants and 7,419 October 2015 Warrants expired unexercised. As of September 30, 2020, there were no July 2011 Warrants or March 2015 Warrants outstanding, and 38,000 October 2015 remained outstanding and will expire on October 27, 2020.

During the first quarter of 2020, a total of 228,571 warrants to purchase 228,571 shares of common stock were exercised related to the June 2019 Warrants resulting in gross proceeds of $199 thousand. The Company paid China Kington a fee equal to six percent (6%) of the gross proceeds, totaling $12 thousand, for brokering the exercise transaction.

During the second quarter of 2020, a total of 571,428 warrants to purchase 571,428 shares of common stock were exercised related to the June 2019 Warrants resulting in gross proceeds of $497 thousand. The Company paid China Kington a fee equal to six percent (6%) of the gross proceeds, totaling $29 thousand, for brokering the exercise transaction.

On June 17, 2020, 571,428 June 2019 Warrants expired unexercised. As of September 30, 2020, there were no June 2019 Warrants outstanding.

The details of all outstanding warrants as of September 30, 2020, were as follows:

	Warrants (in thousands)		Weighted-Average Exercise Price
Outstanding at December 31, 2019	8,588	$	1.09
Warrants granted	6,899	$	1.65
Warrants exercised	(7,769)	$	0.97
Warrants expired	(613)	$	0.82
Outstanding at September 30, 2020	7,105	$	1.63

NOTE 13. EQUITY-BASED COMPENSATION

Equity Compensation Plans

In October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of equity awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants, as determined by the Board of Directors (the "Board"). At the inception of the 2007 Plan, 80,000 shares were reserved for awards under the 2007 Plan.

For the years from 2009 to 2012, the number of shares of common stock authorized for awards under the 2007 Plan increased annually in an amount equal to the lesser of (a) 40,000 shares; (b) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year; or (c) such lesser number as determined by the Board. Accordingly, an additional 40,000, 37,427, and 37,207 shares of common stock were authorized for awards under the 2007 Plan in January 2012, 2011 and 2010, respectively. Beginning in 2013, the stockholders voted to remove the 40,000-share cap and the 2007 Plan's shares authorized for awards increased annually by 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year. Accordingly, an additional 139,449, 82,461, 32,646 and 59,157 shares of common stock were authorized for awards under the 2007 Plan in 2016, 2015, 2014 and 2013, respectively. On May 26, 2016, the stockholders of the Company approved an amendment to the 2007 Plan to increase the number of shares of Company common stock authorized for awards thereunder by 1,124,826 shares. In January 2017, the Company added 610,774 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. As a result of the foregoing, the aggregate number of shares authorized for awards under the 2007 Plan was 2,318,486 shares, prior to its expiration on March 15, 2017 (after taking into account prior awards under the 2007 Plan).

Upon expiration of the 2007 Plan, new awards cannot be issued pursuant to the 2007 Plan, but awards outstanding as of its March 15, 2017 plan expiration date will continue to be governed by its terms. Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and, if granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service.

In March 2017, the Company adopted the 2017 Omnibus Incentive Plan (the "2017 Plan"), which was approved by stockholders on June 2, 2017, to provide for the granting of equity awards, such as nonqualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock, performance shares, stock appreciation rights ("SARs"), RSUs and other share-based awards to employees, directors, and consultants, as determined by the Board. The 2017 Plan will not affect awards previously granted under the 2007 Plan. The 2017 Plan allows for awards of up to 2,318,486 shares of the Company's common stock, plus an automatic annual increase in the number of shares authorized for awards on the first day of each of the Company's fiscal years beginning January 1, 2018 through January 1, 2027 equal to (i) 4% of the number of shares of common stock outstanding on the last day of the immediately preceding fiscal year or (ii) such lesser number of shares of common stock than provided for in Section 4(a)(i) of the 2017 Plan as determined by the Board. As of September 30, 2020, there were 2,160,894 shares available for future awards under the 2017 Plan.

Under the terms of the 2017 Plan, the exercise price of NQSOs, ISOs and SARs may not be less than 100% of the fair market value of the common stock on the date of grant and, if ISOs are granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. The term of awards will not be longer than ten years, or in the case of ISOs, not longer than five years with respect to holders of more than 10% of the Company's stock. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service. The Company issues new shares to satisfy option exercises under the 2007 Plan and the 2017 Plan.

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding as of September 30, 2020, and activity during the nine-month period then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	2,183	$ 4.03	6.6	$ 43
Options granted	1,256	$ 1.01		
Restricted stock units granted	353	$ —		
Options exercised	(20)	$ 0.30		
Restricted stock units vested	(196)	$ —		
Options forfeited/cancelled	(247)	$ 6.73		
Restricted stock units cancelled	(1)	$ —		
Outstanding at September 30, 2020	3,328	$ 2.52	7.44	$ 163
Vested and expected to vest at September 30, 2020	3,058	$ 2.66	7.24	$ 140
Vested at September 30, 2020	1,819	$ 3.77	5.70	$ 43
Exercisable at September 30, 2020	1,819	$ 3.77	5.70	$ 43

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of the Company's common stock as quoted on the NYSE American as of the dates noted in the table above for options that have a quoted market price in excess of the exercise price. There were 20 thousand stock option awards exercised during the three and nine months ended September 30, 2020 for which the Company received cash payments of $6 thousand. There was an intrinsic value of approximately $9 thousand for stock option awards exercised for the nine months ended September 30, 2020. There were 83 thousand stock option awards exercised during the nine months ended September 30, 2019 for which the Company received cash payments of $189 thousand. There was no intrinsic value for stock option awards exercised for the nine months ended September 30, 2019.

As of September 30, 2020, total unrecognized compensation cost related to unvested stock options and restricted stock units was approximately $1,167 thousand. This amount is expected to be recognized as stock-based compensation expense in the Company's unaudited condensed consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.81 years.

Stock Option Awards to Employees and Directors

The Company grants options to purchase common stock to its employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. The Company has estimated the value of stock option awards as of the date of grant by applying the Black-Scholes option pricing model using the single-option valuation approach. The application of this valuation model involves assumptions that are judgmental and subjective in nature. See Note 2, "Summary of Significant Account Policies," for a description of the accounting policies that the Company applied to value its stock-based awards.

During the nine months ended September 30, 2020 and 2019, the Company granted options to employees and directors to purchase an aggregate of 1,156,000 and 140,000 shares of common stock, respectively.

The weighted-average assumptions used in determining the value of options are as follows:

	Nine Months Ended September 30,	
Assumption	**2020**	**2019**
Expected price volatility	160.57%	111.15%
Expected term (in years)	6.45	6.14
Risk-free interest rate	0.45%	2.01%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	$ 0.94	$ 0.30

Expected Price Volatility—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. The computation of expected volatility was based on the historical volatility of our own stock.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. The expected life assumption is based on the Company's historical data.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option.

Dividend Yield—We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future.

Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

In addition, during the nine months ended September 30, 2020, the Company granted 160,000 RSUs to employees. During the nine months ended September 30, 2019, the Company did not grant RSUs to employees.

For the three months ended September 30, 2020 and 2019, the Company recognized stock-based compensation expense of $159 thousand and $92 thousand, respectively, for stock-based awards to employees and directors. For the nine months ended September 30, 2020 and 2019, the Company recognized stock-based compensation expense of $332 thousand and $315 thousand, respectively, for stock-based awards to employees and directors.

In April 2019, the Company modified stock options held by Mr. Yonghao (Carl) Ma, who resigned as a director of the Company, effective April 29, 2019. The option exercise period for Mr. Ma was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $14 thousand, which is included in the figure above.

In May 2019, the Company modified stock options held by Mr. Yanbin (Lawrence) Liu, who resigned as a director of the Company, effective May 1, 2019. The option exercise period for Mr. Liu was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $7 thousand, which is included in the figure above.

In July 2019, the Company modified stock options held by Mr. Mark Sieczarek, who resigned as a director of the Company, effective July 20, 2019. The option exercise period for Mr. Mark Sieczarek was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $60 thousand, which is included in the figure above.

In September 2019, the Company modified stock options held by Mr. Todd Zavodnick, who resigned as a director of the Company, effective September 11, 2019. The option exercise period for Mr. Zavodnick was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $24 thousand, which is included in the figure above.

In April 2020, the Company modified stock options held by Ms. Gail Maderis, who resigned as a director of the Company, effective April 1, 2020. The option exercise period for Ms. Maderis was extended from three months to three years, calculated from her date of resignation. Also, her stock option awards became fully vested at the date of her resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $36 thousand, which is included in the figure above.

In August 2020, the Company modified stock options held by Mr. Xiaopei Wang, who resigned as a director of the Company, effective August 21, 2020. The option exercise period for Mr. Wang was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $17 thousand, which is included in the figure above.

Stock-Based Awards to Non-Employees

During the nine months ended September 30, 2020, the Company granted 100,000 options exercisable for shares of common stock to non-employees in exchange for advisory and consulting services. During the nine months ended September 30, 2019, the Company did not grant options exercisable for shares of common stock to non-employees in exchange for advisory and consulting services.

The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes option pricing model based upon the following assumptions:

	Nine Months Ended September 30,
Assumption	**2020**
Expected price volatility	162.30%
Expected term (in years)	6.34
Risk-free interest rate	0.33%
Dividend yield	0.00%
Weighted-average fair value of options granted during the period	$ 1.27

For the three months ended September 30, 2020 and 2019, the Company recognized stock-based compensation expense of $17 thousand and $14 thousand, respectively, related to non-employee consultant stock and option grants. For the nine months ended September 30, 2020 and 2019, the Company recognized stock-based compensation expense of $27 thousand and $28 thousand, respectively, related to non-employee consultant stock and option grants.

In connection with Mr. Mark Sieczkarek resignation as discussed above, the Company granted 168 thousand shares of fully vested registered stock to Mr. Sieczkarek in the nine months ended September 30, 2019, as part of his settlement agreement. The expense related to this separation agreement was accrued for and expensed during July 2019. The Company also entered into a two-year consulting agreement with Mr. Sieczkarek (the “Consulting Agreement), pursuant to which Mr. Sieczkarek will provide consulting service to the Company in exchange for restricted stock units from the Company’s 2017 Omnibus Incentive Plan with an aggregate fair market value equal to $440 thousand as of the date of grant. The restricted stock units will be issued in two equal tranches on July 1, 2020 and July 1, 2021, respectively, with the share amount calculated using the closing price on each respective grant date. The shares will be fully vested as of the date of grant. The expense related to this separation agreement is being recorded over the term of the Consulting Agreement. In July 2020, the Company issued Mr. Sieczkarek 192,983 fully vested shared of registered stock pursuant to the Consulting Agreement.

Summary of Stock-Based Compensation Expense

A summary of the stock-based compensation expense included in results of operations for the options and restricted stock awards discussed above is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Research and development	$ 8	$ 12	$ 22	$ 36
Sales and Marketing	29	18	49	64
General and administrative	139	76	288	243
Total stock-based compensation expense	$ 176	$ 106	$ 359	$ 343

NOTE 14. REVENUE

Transactions under the Company's major distribution agreements are recognized upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to. The Company records contract liabilities for the amounts that are estimated to be subject to significant reversal, including allowances for services, discounts, rebate programs, chargebacks, and product returns.

The following table presents changes in the Company's contract assets and liabilities for the nine months ended September 30, 2020:

(in thousands)	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
		(in thousands)		
Contract Liabilities: Deferred Revenue	$ —	$ 702	$ (674)	$ 28
Contract Liabilities: Accrued Liabilities	434	1,496	(1,590)	340
Total	$ 434	$ 2,198	$ (2,264)	$ 368

During the nine months ended September 30, 2020 and 2019, the Company recognized the following revenue:

(in thousands)	Nine Months Ended September 30, 2020	2019
Revenue recognized in the period from:		
Amounts included in contract liabilities at the beginning of the period:		
Performance obligations satisfied	$ 434	$ 1,473
New activities in the period:		
Performance obligations satisfied	7,612	3,422
	$ 8,046	$ 4,895

License, Collaboration and Distribution Agreements

In January 2012, the Company entered into a distribution agreement with China Pioneer Pharma Holdings Limited ("China Pioneer"), a Shanghai-based company that markets high-end pharmaceutical products in China and the Company's largest stockholder, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of $313 thousand. NovaBay also received $313 thousand in January 2013, related to the submission of the first marketing approval for the product to the Chinese Food and Drug Administration (the "CFDA"). The deferred revenue was recognized as the purchase discounts were earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received $625 thousand upon receipt of a marketing approval of the product from the CFDA.

In September 2012, the Company entered into two agreements with China Pioneer: (1) an international distribution agreement ("Distribution Agreement") and (2) a unit purchase agreement ("Purchase Agreement"). These agreements were combined and accounted for as one arrangement with one unit of accounting for revenue recognition purposes.

Pursuant to the terms of the Distribution Agreement, China Pioneer has the right to distribute NeutroPhase, upon a marketing approval from a Regulatory Authority, in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, the Company received an upfront payment, which was recorded as deferred revenue. China Pioneer is also obligated to make certain additional payments to the Company upon receipt of the marketing approval. The Distribution Agreement further provides that China Pioneer is entitled to a cumulative purchase discount not to exceed $500 thousand upon the purchase of NeutroPhase product, payable in NovaBay unregistered restricted common stock.

Pursuant to the Purchase Agreement, we also received $2.5 million from China Pioneer for the purchase of units (comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012; and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per unit. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and the fair value of the warrants based on the Black-Scholes option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1.0 million, we reallocated $600 thousand from deferred revenue to stockholders' equity as consideration for the purchase of the units.

In December 2013, the Company announced it had expanded its NeutroPhase commercial partnership agreement with China Pioneer. The expanded agreement included licensing rights to Avenova and CelleRx, which were developed internally by NovaBay. The expanded partnership agreement covers the commercialization and distribution of these products in China and 11 countries in Southeast Asia.

The Distribution Agreement and the Purchase Agreement expired on December 31, 2019 and were not renewed.

During the three and nine months ended September 30, 2019, the Company earned $0 and $41 thousand in revenue due to the Company being relieved of contract liability as a result of changes in contract terms associated with the distribution agreement with China Pioneer.

During the three and nine months ended September 30, 2020, the Company earned $0 and $173 thousand for sales of NeutroPhase to China Pioneer. During the three and nine months ended September 30, 2019, the Company earned $0 and $209 thousand for sales of NeutroPhase to China Pioneer. The sales are recorded in the product sales in the unaudited condensed consolidated statements of operations and comprehensive loss.

As further described in Note 8, "Commitments and Contingencies", on April 16, 2020, the Company entered into an international distribution agreement with Microprofit and the related intermediary distribution agreement with Chongqing Pioneer, a related party, which was subsequently amended on June 29, 2020.

On February 26, 2019, the Company entered into a private label agreement with PhaseOne Health, LLC., ("PhaseOne") to distribute a private label product with hypochlorous acid concentration of 0.025%. During the three and nine months ended September 30, 2020, the Company recognized revenue of $225 thousand related to this contract.

Prescription Avenova Distribution Agreements

Prescription Avenova is made available in local pharmacies and major retail chains such as Wal-Mart, Costco, CVS and Target under nationwide distribution agreements with McKesson Corporation ("McKesson"), Cardinal Health and AmerisourceBergen. During the three months ended September 30, 2020 and 2019, the Company recorded $0.6 million and $1.1 million, respectively, and $1.6 million and $3.6 million, respectively, for the nine months ended September 30, 2020 and 2019, in product revenue under these agreements.

Under the prescription Avenova product distribution arrangements, the Company had a contract liability balance of $0.4 million as of September 30, 2020 and $0.4 million as of December 31, 2019. The contract liability is included in accrued liabilities in the condensed consolidated balance sheets. The Company also recorded a prepayment of $63 thousand and $434 thousand rebate related to these distribution agreement as of September 30, 2020 and December 31, 2019, respectively, that is recorded in the prepaid expenses and other current assets in the condensed consolidated balance sheets (see Note 4, "Prepaid Expenses and Other Current Assets").

During 2019 and through September 30, 2020, the number of pharmacies in our Partner Pharmacy Program increased from 4 to 16. Our partner pharmacies provide patients with a quality experience that includes a relatively short time between receiving the initial prescription and filling it, fast refills and home delivery. The combination of a pre-negotiated price along with a reduction in coupon and rebate usage improves our gross-to-net and per-script profitability. During the three months ended September 30, 2020 and 2019, the revenue generated from these pharmacies comprised 5% and 20% of our total product revenue, respectively. During the nine months ended September 30, 2020 and 2019, the revenue generated from these pharmacies comprised 7% and 23% of our total product revenue, respectively.

Avenova Direct

In an effort to improve patient access, non-prescription Avenova Direct was launched on June 1, 2019 to U.S. customers. Avenova Direct is offered primarily for sale on Amazon.com, the Company's website (Avenova.com) and Walmart.com. Avenova Direct is the same strength hypochlorous formulation as our prescription Avenova product, but comes in a 20mL size. This channel provides the Company with more stable pricing and provides customers with easy access to our product. This model capitalizes on a trend to sell pharmaceutical products directly to consumers in response to high-deductible health plans, allowing customers to forego a time-consuming doctor visit and trip to the pharmacy. We are promoting this program through complementary digital and social media marketing to target consumers in specific demographics, as well as to ophthalmologists, optometrists, and current and former Avenova patients. During the three and nine months ended September 30, 2020, the revenue generated from Avenova Direct was $1.0 million and $2.4 million, respectively. During the three and nine months ended September 30, 2019, the revenue generated from Avenova Direct was $0.3 million and $0.4 million, respectively.

KN95 Masks

During 2020, predominantly in the second quarter, the Company engaged in reselling KN95 Masks. Revenue generated from the sale of KN95 Masks was $69 thousand during the three months ended September 30, 2020. Revenue generated from the sale of KN95 Masks was $3.1 million during the nine months ended September 30, 2020. There was no comparable revenue during the three and nine months ended September 30, 2019.

NOTE 15. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan covering all eligible employees. The Company is not required to contribute to the plan and made no contributions during the three and nine months ended September 30, 2020 or 2019.

NOTE 16. RELATED PARTY TRANSACTIONS

Related Party Financing

See Note 9, "Related Party Note Payable" for a description of the Promissory Note issued on February 27, 2019, as amended on June 25, 2019 and May 14, 2020 and Note 12, "Stockholders' Equity (Deficit)" for a description of the Company's financing transactions in June 2019 and August 2019. During the second quarter of 2020, the Company repaid the $1.0 million principal balance of the Promissory Note using proceeds raised through the ATM Program pursuant to the ATM Agreement, dated April 27, 2020, with Ladenburg.

Related Party Revenue

The following table summarizes information about the Company's related party revenue and cost of goods sold during the three and nine months ended September 2020 and 2019, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Related party revenue:				
NeutroPhase	$ —	$ —	$ 173	$ 209
Licensing	—	—	—	41
Total related party revenue	$ —	$ —	$ 173	$ 250
Cost of goods sold				
NeutroPhase	$ —	$ —	$ 90	$ 176
Licensing	—	—	—	—
Total related party expenses	$ —	$ —	$ 90	$ 176

There were no related party accounts receivable as of September 30, 2020 and December 31, 2019, respectively, associated with related party revenue.

Related Party Expenses

During the three and nine months ended September 30, 2020, the Company purchased KN95 Masks through an affiliate of China Pioneer. As of September 30, 2020 and December 31, 2019, related party accounts payable was $0.

The following table summarizes information about the Company's related party expenses during the three and nine months ended September 2020 and 2019, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Commissions to China Kington related to:				
June 2019 Private Placement	$ —	$ —	$ —	$ 144
August 2019 Private Placement	—	162	—	162
Exercise of June 2019 Warrants	—	—	41	—
Exercise of 2019 Foreign Warrants	160	—	160	—
Promissory Note to Pioneer Pharma (Hong Kong) Company Ltd.	—	—	—	20
Total commissions to China Kington	160	162	201	326
Board Director Bob Wu consulting fee	—	—	50	50
Total related party expenses	$ 160	$ 162	$ 251	$ 376

See Note 9, "Related Party Note Payable", Note 11, "Warrant Liability", and Note 12, "Stockholders' Equity (Deficit)" – "Common Stock" for additional information regarding details of the transactions and fees and commissions paid to China Kington and Board Director Bob Wu.

As further described in Note 8, "Commitments and Contingencies", on May 13, 2020, the Company entered into a services agreement with TLF Bio Innovation. On September 4, 2020, the parties entered into an amendment to the service agreement (the "First Amendment"). The Manager of TLF Bio Innovation is the god daughter of the Company's former largest stockholder. The Company paid related party cash fees of $113 thousand and $188 thousand to TLF Bio Innovation during the three and nine months ended September 30, 2020, respectively, under the agreement. During the three and nine months ended September 30, 2020, the Company also recorded $109 thousand in consulting service expense related to warrants that TLF Bio Innovation is eligible to receive under the services agreement (see Note 8, "Commitments and Contingencies"). TLF Bio Innovation also purchased 1,000 shares of the Company's common stock for total proceeds of $1 thousand in conjunction with the agreement as described in Note 12, "Stockholders' Equity (Deficit)".

Other Related Party Transactions

As further described in Note 8, "Commitments and Contingencies", in connection with the Microprofit Agreement, on April 16, 2020, the Company entered into an intermediary distribution agreement with Pioneer, which was subsequently amended on June 29, 2020.

NOTE 17. PAYCHECK PROTECTION PROGRAM

On May 6, 2020, the Company received loan proceeds in the amount of $901 thousand from Wells Fargo Bank, N.A. (the "PPP Loan") pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), which was enacted on March 27, 2020.The terms of the PPP Loan were subsequently revised in accordance with the provisions of the Paycheck Protection Flexibility Act of 2020, or the PPP Flexibility Act, which was enacted on June 5, 2020. The PPP loan provides for an interest rate of 1.00% per year, and matures two years after the date of initial disbursement, with initial principal and interest payments coming due late in fiscal 2021. The Note may be prepaid by the Company at any time prior to the maturity with no prepayment penalties. Funds from the PPP Loan may only be used for payroll costs, costs used to continue group health care benefits, rent and utilities incurred during the 24-week period after receiving the PPP Loan (collectively, "Qualifying Expenses") in order for the PPP Loan to be forgiven in whole or in part. The Company used the entire PPP Loan amount for the Qualifying Expenses and expects the PPP Loan to be forgiven in whole prior to repayment.

Since the Company determined that there is reasonable assurance that it will meet the conditions for forgiveness of the full loan amount, we accounted for the forgivable PPP Loan as a government grant that we earned through the Company's compliance with the loan forgiveness criteria. PPP proceeds received was accounted for as an income grant. A deferred income liability was recognized upon receipt of the forgivable loan proceeds. The deferred income liability was recognized as other income as Qualifying Expenses were incurred. For the three and nine months ended September 30, 2020, $432 thousand and $901 thousand was recognized as other income and recorded in the condensed consolidated statements of operations and comprehensive loss, respectively.

NOTE 18. SUBSEQUENT EVENTS

On October 13, 2020, the Company was notified by NYSE American that the Company had regained compliance with the minimum stockholders' equity requirements of Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part I, Item 1 of this report, and with our consolidated financial statements and related notes, 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, which was filed with the Securities and Exchange Commission (the "SEC") on March 26, 2020. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," "goals," "plans," "believes," "estimates," variations of these words, and similar expressions are intended to identify these forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions, estimates and facts as of the date hereof and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- *our assumptions, estimates and beliefs regarding the possible effects of the COVID-19 pandemic on general economic conditions, public health and consumer demand, and the Company's results of operations, liquidity, capital resources and general performance in the future;*
- *the possible impact of COVID-19 on our ability to obtain financing;*
- *our expectations regarding the use of funds from the Company's PPP Loan and the potential for forgiveness of the PPP Loan under the terms of the PPP;*
- *our limited cash and our history of losses;*
- *our ability to achieve profitability;*
- *whether demand develops for our proprietary products;*
- *the impact of competitive or alternative products and pricing;*
- *our ability to obtain adequate financing in the future, as and when we need it;*
- *our ability to continue as a going concern;*
- *the adequacy of protections afforded to us by the patents that we own and the cost to us of maintaining, enforcing and defending those patents;*
- *our exposure to and ability to defend third-party claims and challenges to our patent and other intellectual property rights;*
- *our success at managing the risks involved in the foregoing items; and*
- *other factors discussed in this report and our other filings with the SEC.*

As a result of many factors, such as those listed above and set forth under the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.

Overview

We are a medical device company predominantly focused on eye care. We are currently focused primarily on commercializing Avenova®, an FDA cleared product sold in the United States that has proven in laboratory testing to have broad antimicrobial properties as it removes foreign material including microorganisms and debris from skin around the eye, including the eyelid. Avenova is formulated with our proprietary, stable and pure form of hypochlorous acid. Avenova is available direct to consumers through our on-line sales channels and is also often prescribed and dispensed by eyecare professionals for blepharitis and dry-eye disease.

Avenova is available through four primary distribution channels: (1) Avenova Direct, our direct-to-consumer model, allowing customers to forego time-consuming doctor visits and trips to the pharmacy; (2) retail pharmacies, selling to consumers through local pharmacies across 50 states; (3) our Partner Pharmacy Program, providing a consistent patient experience at contracted pricing; and (4) our Buy-and-Sell channel, allowing patients to buy Avenova during office visits to their preferred eye care specialist.

Avenova Direct was launched during the second quarter of 2019 to improve patient access to Avenova. By creating an over the counter product that does not require a doctor's prescription, we made the product available to many more potential customers and broadened our addressable market. Avenova Direct is now our leading product by unit sales and net revenue despite having a lower average net selling price than prescription Avenova. Prescription Avenova remains an important source of revenue and the "doctor recommended" halo effect around our brand remains strong.

Despite the change in reimbursement conditions in 2019, we continue to pursue an increase in Avenova sales in all four of our distribution channels. During the third quarter of 2020, we experienced an improvement in unit sales and net revenue in all these channels when compared to the prior quarter. This was due in part to the easing of pandemic-related shelter-in-place restrictions in certain geographies across the country. The third quarter recovery in sales was most notable in the Avenova Direct channel which also benefitted from an increase in focus and spending on digital marketing and public relations initiatives. Avenova Direct unit sales and net revenue during the third quarter of 2020 were the highest since its launch in the second quarter of 2019.

In the fourth quarter we will launch a rebranded CelleRx into the beauty industry as CelleRx Clinical Reset. Clinical Reset is formulated with NovaBay's patented, pure, prescription-grade hypochlorous acid (HOCl), the same molecule produced by the human body's immune system to fight infection and heal wounds. It keeps the skin's natural barrier intact, which when out of balance can allow acne, rosacea and infection to set in. Clinical Reset is complementary to a daily beauty regime for use on clean skin or over makeup. Prior to this relaunch, our marketing of CelleRx focused on medical professionals only. With the rebranding, we intend to leverage new consumer focused messaging and the product's pharmaceutical pedigree in robust social media and print advertising campaigns marketing CelleRx Clinical Reset in the beauty industry.

Beyond Avenova and CelleRx, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® and PhaseOne® for the wound care market.

In addition to our proprietary products, we responded to the national need for protective personal equipment (PPE) in the first quarter of 2020 by tapping into our international supply network and launching the sale of KN95 Masks and other PPE. Although sales from the KN95 Masks were significant in the second quarter of 2020, we experienced a significant decrease in PPE sales in the third quarter as supply shortages narrowed, prices declined and distribution competition increased. As we return focus to our core business in eyecare, we do not currently anticipate dedicating significant future Company resources toward the sale of PPE and we do not expect significant future revenue from PPE sales.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. In preparing these condensed consolidated financial statements, management has made its best estimates and judgments of certain amounts, giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to property and equipment and related depreciation calculations, , assumptions for valuing options and warrants, income taxes, and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies", of the Notes to Unaudited Condensed Consolidated Financial Statements, included in Part I, Item 1 of this report, we believe that the following accounting policies are most critical to fully understanding and evaluating our reported financial results.

Allowance for Doubtful Accounts

We charge "Bad Debt" expense and set up an "Allowance for Doubtful Accounts" when management identifies amounts due that are in dispute and believes it unlikely a specific invoice will be collected.

Management did not record any reserves for accounts receivable at September 30, 2020. At December 31, 2019, management reserved $51 thousand based on specific amounts that were in dispute or were over 120 days past due as of those dates.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method. At September 30, 2020 and December 31, 2019, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $194 thousand and $247 thousand, respectively.

Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019. Using the optional transition method, prior period financial statements have not been recast to reflect the new lease standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use assets may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component for all leases in which it is a lessee or a lessor. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. As a result, as of the effective date, the Company no longer recognizes deferred rent on the condensed consolidated balance sheet.

Revenue Recognition

Revenue generated through the Company's webstore for Avenova and KN95 Masks is recognized upon receipt by the customer through multiple third-party carriers. Shipping and handling costs are expensed as fulfillment costs are incurred and included in cost of goods sold in the condensed consolidated statements of operations and comprehensive loss. We present revenue net of sales taxes and refunds.

Revenue generated through Amazon.com for Avenova and other products is recognized upon fulfillment, which generally occurs upon delivery of the related products to a third-party carrier or, in the case of an Amazon delivery, to the customer. We present revenue net of commissions and any related fulfillment and shipping fees charged by these partners. Fees paid to partners for promoting our product are expensed as incurred and are included in sales and marketing expenses within the operating expenses in the condensed consolidated statements of operations and comprehensive loss.

The Company also generates Avenova product revenue through product sales to its major distribution partners. Product supply of Avenova is the only performance obligation contained in these arrangements, and the Company recognizes product revenue upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to, generally upon shipment to the distributor on a "sell-in" basis. Upon recognition of product sales, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because the Company does not have sufficient historical data to compute its own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. The Company updates the return rate assumption quarterly and applies it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the distributor. At any point in time there is generally one month of inventory in the sales channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved one month from when control is transferred.

Revenue generated through the Company's partner pharmacies is recognized when control of the product transfers to the end customer.

Bulk orders of KN95 Masks are shipped directly to the customer from a manufacturer in China. Revenue is recognized when control of the product passes to the customer, which is upon delivery of the KN95 Masks to the customer. As such, customer orders are recorded as deferred revenue prior to product delivery.

The following table summarizes the activity in the accounts related to product revenue allowances (in thousands) during the nine months ended September 30, 2020:

	Wholesaler/ Pharmacy fees	Cash discounts	Rebate	Returns	Total
Balance at December 31, 2019	$ (142)	$ (13)	$ 153	$ (432)	$ (434)
Current provision related to sales made during current period	(316)	(49)	(1,085)	(46)	(1,496)
Payments	364	52	891	283	1,590
Balance at September 30, 2020	$ (94)	$ (10)	$ (41)	$ (195)	$ (340)

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping and handling costs, and other costs associated with products sold. Cost of goods sold also includes any necessary allowance for excess and obsolete inventory along with lower of cost and estimated net realizable value.

Research and Development Costs

The Company charges research and development costs to expense as incurred. These costs include all costs associated with research, development and regulatory activities, including Emergency Use Authorization ("EUA") submissions to the Food and Drug Administration ("FDA"). Research and development costs may vary depending on the type of item or service incurred, location of performance or production, level of availability of the item or service, and specificity required in production for certain compounds.

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units, or RSUs, to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's condensed consolidated statements of stockholders' equity (deficit) based on their fair values as they are earned under the applicable vesting terms. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes option pricing model. See Note 13, "Equity-Based Compensation", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. The Company accounts for RSUs issued to employees and non-employees (consultants and advisory board members) based on the fair value of the Company's common stock as of the date of issuance.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized.

Common Stock Warrant Liabilities

The Company accounts for common stock purchase warrants issued in connection with its equity offerings in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*.

The Company accounts for common stock purchase warrants issued in connection with share-based compensation agreements in accordance with the provisions of ASC 718, *Stock Compensation,* which encompasses the provisions of ASC 480, *Distinguishing Liabilities from Equity*.

The common stock purchase warrants issued in connection with share-based compensation agreements are variable compensation for services performed. At contract inception and at each reporting period, the Company evaluates whether the achievement of variable compensation criteria are considered probable of being reached and, if considered probable, are recognized at fair value for proportionate service-to-date.

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). Additionally, for common stock purchase warrants accounted for in accordance with ASC 718, *Stock Compensation,* the Company classifies as liabilities any contracts where it believes the warrants will vest within six months.

For warrants that are classified as liabilities, the Company records the fair value of the warrants at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the condensed consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Black-Scholes option pricing model, the Binomial Lattice ("Lattice") valuation model, or the Monte Carlo simulation model where deemed appropriate. These values are subject to a significant degree of management's judgment.

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report for information on recent accounting pronouncements.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

(in thousands)	Three Months Ended September 30, 2020	2019	Dollar Change	Percent Change
Statement of Operations				
Sales:				
Product revenue, net	$ 2,167	$ 1,615	$ 552	34%
Other revenue, net	3	—	3	100%
Total sales, net	2,170	1,615	555	34%
Product cost of goods sold	536	401	135	34%
Gross profit	1,634	1,214	420	35%
Research and development	125	49	76	155%
Sales and marketing	1,692	1,544	148	10%
General and administrative	1,879	1,333	546	41%
Total operating expenses	3,696	2,926	770	26%
Operating loss	(2,062)	(1,712)	(350)	20%
Non-cash (loss) gain on changes in fair value of warrant liability	(1,589)	1,480	(3,069)	(207%)
Non-cash gain on changes in fair value of embedded derivative liability	1	669	(668)	(100%)
Other income (expense), net	429	(719)	1,148	(160%)
Loss before provision for income taxes	(3,221)	(282)	(2,939)	1042%
Provision for income tax	—	—	—	—
Net loss and comprehensive loss	$ (3,221)	$ (282)	$ (2,939)	1042%

Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, increased by $0.6 million, or 34%, to $2.2 million for the three months ended September 30, 2020 from $1.6 million for the three months ended September 30, 2019. The increase was primarily the result of a $0.2 million increase in Avenova revenue as well as an additional $0.2 million in revenue generated from sales of PhaseOne, a private label prescription skin and wound care product, during the three months ended September 30, 2020 with no comparable revenue in the 2019 period.

Avenova revenue, net, increased by $0.2 million from $1.6 million for the three months ended September 30, 2019 to $1.8 million for the three months ended September 30, 2020. The increase was the net result of an overall increase in Avenova units sold which was partially offset by an overall decrease in the average net selling price of Avenova products. The increase in units sold reflects a higher number of Avenova Direct and buy-and-sell units sold, partially offset by a decrease in the number of prescription units sold. The decrease in the overall net selling price was largely due to a lower net selling price associated with Avenova Direct, which was launched in June 2019.

Product cost of goods sold increased by $135 thousand, or 34%, to $536 thousand for the three months ended September 30, 2020, from $401 thousand for the three months ended September 30, 2019. The increase was primarily the result of an overall increase in the number of Avenova units sold as well as the sale of PhaseOne units during the three months ended September 30, 2020 with no comparable sales in the 2019 period.

Gross profit increased by $0.4 million, or 35%, to $1.6 million for the three months ended September 30, 2020 from $1.2 million for the three months ended September 30, 2019. The increase in gross profit was primarily due to increased sales of Avenova and PhaseOne as discussed above.

Research and Development

Research and development expenses increased by $76 thousand, or 155%, to $125 thousand for the three months ended September 30, 2020, from $49 thousand for the three months ended September 30, 2019. The increase is primarily the result of regulatory expenses incurred under the Microprofit Agreement as further described in Note 8, "Commitments and Contingencies", of the Notes to Unaudited Condensed Consolidated Financial Statements, included in Part I, Item 1 of this report.

Sales and marketing

Sales and marketing expenses increased by $148 thousand, or 10%, to $1.7 million for the three months ended September 30, 2020, from $1.5 million for the three months ended September 30, 2019. The increase was primarily due to the increase in Avenova Direct digital advertising and costs associated with the Company's planned relaunch of CelleRx, which we expect during the fourth quarter. This increase was partly off-set by a decrease in sales representative headcount, and lower travel and related expenses due to the impact of COVID-19.

General and administrative

General and administrative expenses increased to $1.9 million for the three months ended September 30, 2020, up from $1.3 million for the three months ended September 30, 2019. The increase is primarily a result of increased legal expenses incurred and the settlement amount expected to be paid in conjunction with a dispute with the Company's former Interim President & Chief Executive Officer and Chief Financial Officer (see Note 8, "Commitments and Contingencies").

Non-cash (loss) gain on changes in fair value of warrant liability

The adjustments to the fair value of warrant liability resulted in a loss of $1.6 million for the three months ended September 30, 2020 as compared to a gain of $1.5 million for the three months ended September 30, 2019. For additional information regarding the valuation of warrant liabilities, please see Note 11, "Warrant Liability", of the Notes to Unaudited Condensed Consolidated Financial Statements.

Non-cash gain on changes in fair value of embedded derivative liability

The adjustments to the fair value of derivative liability resulted in a $1 thousand gain for the three months ended September 30, 2020 and a gain of $669 thousand for the three months ended September 30, 2019. For additional information regarding the valuation of derivative liabilities, please see Note 10, "Convertible Note", in the Notes to Unaudited Condensed Consolidated Financial Statements.

Other income (expense), net

We recognized other income, net, of $429 thousand for the three months ended September 30, 2020. The balance consisted primarily of income of $432 thousand representing qualifying expenses which were incurred under the PPP Loan program. Please see Note 17, "Paycheck Protection Program", of the Notes to Unaudited Condensed Consolidated Financial Statements.

We incurred other expense, net, of $719 thousand for the three months ended September 30, 2019. The expense was due to the interest due on the Promissory Note issued in February 2019 and the amortization of discount and issuance cost related to the Convertible Note issued in March 2019. For additional information regarding the Promissory Note, please see Note 9, Related Party Note Payable", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report. For additional information regarding the Convertible Note, please see Note 10, "Convertible Note", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report.

Comparison of the Nine Months Ended September 30, 2020 and 2019

(in thousands)	Nine Months Ended September 30, 2020	2019	Dollar Change	Percent Change
Statement of Operations				
Sales:				
Product revenue, net	$ 8,038	$ 4,854	$ 3,184	66%
Other revenue, net	8	41	(33)	(80%)
Total sales, net	8,046	4,895	3,151	64%
Product cost of goods sold	3,157	1,145	2,012	176%
Gross profit	4,889	3,750	1,139	30%
Research and development	249	166	83	50%
Sales and marketing	4,675	6,610	(1,935)	(29%)
General and administrative	4,633	4,136	497	12%
Total operating expenses	9,557	10,912	(1,355)	(12%)
Operating loss	(4,668)	(7,162)	2,494	(35%)
Non-cash (loss) gain on changes in fair value of warrant liability	(5,224)	936	(6,160)	(658%)
Non-cash gain on changes in fair value of embedded derivative liability	3	423	(420)	(99%)
Other income (expense), net	605	(1,166)	1,771	(152%)
Loss before provision for income taxes	(9,284)	(6,969)	(2,315)	33%
Provision for income tax	(1)	(3)	2	(67%)
Net loss and comprehensive loss	$ (9,285)	$ (6,972)	$ (2,313)	33%

Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, increased by $3.2 million, or 66%, to $8.0 million from $4.9 million for the nine months ended September 30, 2020, compared to the nine months ended September 30, 2019.

The change in product revenue, net, is primarily the result of $3.1 million in product revenue, net, generated from the sale of KN95 Masks during the nine months ended September 30, 2020 with no comparable revenue in the 2019 period.

Avenova revenue decreased $0.1 million from $4.6 million for the nine months ended September 30, 2019 to $4.5 million for the nine months ended September 30, 2020. The decrease was the net result of an overall decrease in the average net selling price of Avenova products which was partially offset by an overall increase in Avenova units sold. The decrease in the overall net selling price was largely due to a lower net selling price associated with Avenova Direct, which was launched in June 2019. The increase in units sold reflects a higher number of Avenova Direct units sold, partially offset by a decrease in the number of prescription units sold.

Product cost of goods sold increased by $2.0 million, or 176%, to $3.2 million for the nine months ended September 30, 2020, from $1.1 million for the nine months ended September 30, 2019. The increase was the result of the cost of KN95 Masks sold during the nine months ended September 30, 2020 with no comparable sales in the 2019 period, as well as an increase in the number of Avenova units sold in the nine months ended September 30, 2020 as compared to the 2019 period.

Gross profit increased by $1.1 million, or 30%, to $4.9 million for the nine months ended September 30, 2020 from $3.8 million for the nine months ended September 30, 2019. The increase in gross profit was primarily due to the addition of the KN95 Masks sales.

Research and Development

Research and development expenses increased by $83 thousand, or 50%, to $249 thousand for the nine months ended September 30, 2020, from $166 thousand for the nine months ended September 30, 2019. The increase is primarily the result of regulatory expenses incurred under the Microprofit Agreement as further described in Note 8, “Commitments and Contingencies”, of the Notes to Unaudited Condensed Consolidated Financial Statements, included in Part I, Item 1 of this report.

Sales and marketing

Sales and marketing expenses decreased by $1.9 million, or 29%, to $4.7 million for the nine months ended September 30, 2020, down from $6.6 million for the nine months ended September 30, 2019. The decrease was primarily due to a decrease in sales representative headcount, and lower travel and related expenses due to the impact of COVID-19. This decrease was partly off-set by an increase in Avenova Direct digital advertising and costs associated with the Company's planned relaunch of CelleRx, which we expect during the fourth quarter.

General and administrative

General and administrative expenses increased to $4.6 million for the nine months ended September 30, 2020, up from $4.1 million for the nine months ended September 30, 2019. The increase is primarily a result of increased legal expenses incurred and the settlement amount expected to be paid in conjunction with a dispute with the Company's former Interim President & Chief Executive Officer and Chief Financial Officer (see Note 8, "Commitments and Contingencies").

Non-cash (loss) gain on changes in fair value of warrant liability

The adjustments to the fair value of warrant liability resulted in a loss of $5.2 million for the nine months ended September 30, 2020, compared to a gain of $0.9 million for the nine months ended September 30, 2019. For additional information regarding the warrants and their valuation, please see Note 11, "Warrant Liability", in the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report.

Non-cash gain on changes in fair value of embedded derivative liability

The adjustments to the fair value of embedded derivative liability resulted in a gain of $3 thousand for the nine months ended September 30, 2020, compared to a gain of $423 thousand for the nine months ended September 30, 2019. For additional information, please see Note 10, "Convertible Note", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report.

Other income (expense), net

We recognized other income, net, of $605 thousand for the nine months ended September 30, 2020. The Company recorded income of $901 thousand as the result of income recognized as qualifying expenses incurred under the PPP Loan. Please see Note 17, "Paycheck Protection Program", of the Notes to Unaudited Condensed Consolidated Financial Statements. This income was partially offset by the interest due on the Promissory Note issued in February 2019 and the amortization of discount and issuance cost related to the Convertible Note issued in March 2019.

We incurred other expense, net, of $1.2 million for the nine months ended September 30, 2019. The expense was due to the interest due on the Promissory Note issued in February 2019 and the amortization of discount and issuance cost related to the Convertible Note issued in March 2019. For additional information regarding the Promissory Note, please see Note 9, "Related Party Note Payable", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report. For additional information regarding the Convertible Note, please see Note 10, "Convertible Note", of the Notes to Unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this report.

Financial Condition, Liquidity and Capital Resources

As of September 30, 2020, our cash and cash equivalents were $13.4 million, compared to $6.9 million as of December 31, 2019. Based primarily on the funds available at September 30, 2020, management believes that the Company's existing cash and cash equivalents and cash flows generated from product sales will be sufficient to enable the Company to meet its planned operating expenses at least through November 12, 2021. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. Additionally, our future results, cash expenditures and ability to obtain additional external financing could be adversely affected by the COVID-19 pandemic and general adverse economic conditions.

Net Cash Used In Operating Activities

Net cash used in operating activities was $3.3 million for the nine months ended September 30, 2020, which consisted primarily of a net loss of $9.3 million, adjusted by non-cash loss of $5.2 million on the change in fair value of warrant liability, stock compensation expenses of $0.4 million, issuance of RSUs for services of $0.2 million, non-cash interest expense related to amortization of debt issuance cost and debt discount of $0.1 million, and a net increase of $0.1 million in our net operating assets and liabilities.

Net cash used in operating activities was $6.5 million for the nine months ended September 30, 2019, which consisted primarily of a net loss of $7.0 million, adjusted by non-cash gain of $0.9 million on the change in fair value of warrant liability, non-cash interest expense related to amortization of debt issuance cost and debt discount of $0.5 million, non-cash gain of $0.4 million on the change in fair value of embedded derivative liability, stock compensation expenses of $0.3 million, issuance of RSUs related to employee separation agreement of $0.2 million, non-cash impairment of operating lease right-of-use assets of $0.1 million and a net increase of $0.5 million in our net operating assets and liabilities.

Net Cash Used In Investing Activities

For the nine months ended September 30, 2020, net cash used in investing activities for the purchase of property and equipment was $5 thousand, compared to $19 thousand for the nine months ended September 30, 2019.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $9.8 million for the nine months ended September 30, 2020. The Company received net proceeds of $5.2 million from the ATM Program, and an additional $7.1 million from exercise of warrants, which was offset by repayments of $1.6 million on the Convertible Note issued to Iliad Research and Trading L.P. and repayment of $1.0 million on the Promissory Note using proceeds raised through the ATM program pursuant to the ATM Agreement, dated April 27, 2020, with Ladenburg.

Net cash provided by financing activities was $12.4 million for the nine months ended September 30, 2019, which was mainly attributable to the net proceeds from the private placement with three accredited investors, issuance of common stock to Triton Funds LP, issuance of the Promissory Note to Pioneer Pharma (Hong Kong) Company Ltd. and issuance of the Convertible Note to Iliad Research and Trading L.P.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2019, we had net operating loss carryforwards for federal and state income tax purposes of $111.0 million and $90.5 million, respectively. The federal net operating loss carryforwards consisted of $94.9 million generated before January 1, 2018, which will begin to expire in 2024 and $16.2 million that will carryforward indefinitely but are subject to the 80% taxable income limitation. The state net operating loss carryforwards will begin to expire in 2028. As of December 31, 2019, we also had tax credit carryforwards for federal income tax purposes of $1.3 million and $0.3 million for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2026. The state tax credits have an indefinite carryover period.

Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future, although there can be no assurances that our business will not be affected by inflation in the future.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2020.

Seasonality

Consistent with our peers in the United States pharmaceutical industry, our business experiences seasonality with the first quarter of each year typically being the lowest revenue quarter. This annual phenomenon is due to consumers facing the need to satisfy health insurance deductibles and changes to copays as each new insurance year begins.

Contractual Obligations

Our contractual cash commitments as of September 30, 2020 were as follows (in thousands):

Contractual Obligations	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Facility leases	$ 435	$ 185	$ -	$ -	$ 620
Equipment leases	16	17	-	-	33
Total	$ 451	$ 202	$ -	$ -	$ 653

Our commitments as of September 30, 2020 consist primarily of a facility operating lease and an operating lease for two copiers.

The total commitment for the facility lease as of September 30, 2020 was $0.6 million due over the lease term, compared to $0.9 million as of December 31, 2019.

We have an operating lease for 2 copiers as of September 30, 2020. The total commitment for the lease as of September 30, 2020 was $33 thousand due over the lease term, compared to $45 thousand as of December 31, 2019.

See Note 8, "Commitments and Contingencies" in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item 1 of this report for further information regarding these leases.

Recent Events

On October 13, 2020, the Company was notified by NYSE American that the Company had regained compliance with the minimum stockholders' equity requirements of Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk consists principally of interest rate risk on our cash and cash equivalents.

With most of our focus on Avenova in the domestic U.S. market, we do not have any material exposure to foreign currency rate fluctuations.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system 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. Assessing the costs and benefits of such controls and procedures necessarily involves the exercise of judgment by management. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter 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 1A. RISK FACTORS

Our business is subject to a number of risks, the most important of which are discussed below. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC before deciding to buy, sell or hold our common stock. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations.

Risks Relating to Our Liquidity

We have a history of losses and we may never achieve or maintain sustained profitability.

We have historically incurred net losses, and we may never achieve or maintain sustained profitability. In addition, at this time:

- we expect to incur substantial marketing and sales expenses as we continue efforts to increase sales of our Avenova and CelleRx products; and
- our results of operations may fluctuate significantly.

We will need to generate significant revenues to achieve and maintain profitability. Even with current Avenova sales and the additional revenue of KN95 Masks and other COVID-19 related items, if we cannot successfully market and sell Avenova or successfully relaunch CelleRx as a lifestyle hygiene product, we may not be able to generate sufficient revenues to achieve or maintain profitability. Our failure to achieve and subsequently maintain profitability could have a material adverse impact on the market price of our common stock.

Risks Relating to Owning Our Common Stock

If our stockholders' equity does not meet the minimum standards of the NYSE American, we may be subject to delisting procedures.

On April 12, 2019, we received a letter from the NYSE American notifying us that our stockholders' equity as of December 31, 2018 was below the minimum requirements of Section 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide") (requiring stockholders' equity of $6.0 million or more if a company has reported losses from continuing operations and/or net losses in its five most recent fiscal years) and requiring the Company to submit a plan to regain compliance by October 12, 2020. On May 16, 2019, the Company was further notified by NYSE American that the Company was not in compliance with the minimum stockholders' equity requirements of Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide requiring stockholders' equity of $2.0 million or more and $4.0 million or more, respectively, if the Company has reported losses from continuing operations and/or net losses in three of the four most recent fiscal years. The Company submitted a plan to regain compliance on May 11, 2019. The Company was notified on June 27, 2019 that the Company's plan to regain compliance had been accepted. On October 13, 2020, the Company was notified by the NYSE American that the Company had regained compliance with the minimum stockholders' equity requirements of Section 1003(a)(i) and 1003(a)(ii) of the Company Guide.

In accordance with Section 1009(h) of the Company Guide, if the Company is again determined to be below any of the continued listing standards prior to October 13, 2021, the NYSE American will examine the relationship between the two incidents of non-compliance and re-evaluate the Company's method of financial recovery from the first incident. The NYSE American will take the appropriate action which, depending on the circumstances, may include initiating its compliance procedures or initiating delisting proceedings. If our common stock is delisted, this could, among other things, substantially impair our ability to raise additional funds; result in a loss of institutional investor interest and fewer financing opportunities for us; and/or result in potential breaches of representations or covenants of our warrants, subscription agreements or other agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

The price of our common stock may fluctuate substantially, which may result in losses to our stockholders.

The stock prices of many companies in the pharmaceutical and biotechnology industry have generally experienced wide fluctuations, which are often unrelated to the operating performance of those companies. The market price of our common stock is likely to be volatile and could fluctuate in response to, among other things:

- the announcement of new products by us or our competitors;
- the announcement of partnering arrangements by us or our competitors;
- quarterly variations in our or our competitors' results of operations;
- announcements by us related to litigation;
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates;
- developments in our industry; and
- general, economic and market conditions, including volatility in the financial markets, a decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors.

Our common stock is subject to the risk of high volatility.

As publicly disclosed, we have a number of large stockholders, including China Pioneer Pharma Holdings Limited ("China Pioneer") and several passive investors. As of September 30, 2020, based on publicly-filed reports, China Pioneer owned approximately 12.7% of our common stock. The sale of a substantial number of shares of common stock by such large stockholders within a short period of time could cause our stock price to decrease substantially.

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that could discourage a third party from making a takeover offer that is beneficial to our stockholders.

Anti-takeover provisions of our amended and restated certificate of incorporation, bylaws and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

- a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without stockholder approval; and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a Delaware corporation, we are subject to the Delaware General Corporation Law ("DGCL"), which includes provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our Company. Provisions of the DGCL could make it more difficult for a third party to acquire a majority of our outstanding voting stock by discouraging a hostile bid, or delaying, preventing or deterring a merger, acquisition or tender offer in which our stockholders could receive a premium for their shares, or effect a proxy contest for control of NovaBay or other changes in our management.

We have not paid dividends or repurchased stock in the past and do not expect to pay dividends or repurchase stock in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on, or repurchased shares of, our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on, or the repurchase of shares of, our earnings, financial condition and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends or repurchase stock, you will experience a return on your investment in our shares only if our stock price appreciates. We cannot assure you that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment.

China Pioneer and/or China Kington might influence our corporate matters in a manner that is not in the best interest of our other stockholders.

Pioneer Hong Kong, a subsidiary of China Pioneer, beneficially owns approximately 12.7% of our outstanding common stock. Our director Mr. Xinzhou "Paul" Li is the chairman of China Pioneer. Pursuant to the arrangement of a certain bridge loan, facilitated by China Kington in January 2016, two (2) directors were nominated by China Kington, one of which currently serves on the Company's Board of Directors, Mr. Mijia "Bob" Wu, who is the Managing Director of China Kington and Non-Executive Director of Pioneer Hong Kong.

As a result, China Pioneer and China Kington have input on all matters before our Board of Directors and may be able to exercise significant influence over all matters requiring board and stockholder approval. China Pioneer and China Kington may choose to exercise their influence in a manner that is not in the best interest of our other stockholders.

Subject to the satisfaction of certain conditions, we may issue warrants to certain officers of Shenzehn Microprofit Biotech Co., Ltd. and to TLF Bio Innovation Lab, LLC, which, if issued and/or exercised, could dilute the ownership percentages of our existing stockholders or cause the price of our common stock to decline.

On April 16, 2020, we entered into the Microprofit Agreement. As consideration for the exclusive right to distribute the Test Kits, and subject to receipt of the Regulatory Approvals and stockholder approval of the increase in the number of the Company's authorized shares of common stock, the Company will issue warrants (the "Microprofit Warrants") for the Company's common stock, par value $0.01, to certain Microprofit officers, exercisable for an aggregate number of shares of the Company's common stock equivalent to twelve percent (12%) of the Company's outstanding common stock on the same date. Subsequently, on May 26, 2020, the Company received stockholder approval to increase the Company's authorized shares of common stock with the Regulatory Approval still pending as of September 30, 2020. On May 13, 2020, we entered into that certain services agreement with TLF Bio Innovation, as amended on September 4, 2020. Pursuant to the agreement, upon TLF Bio Innovation's successful completion of certain milestones and revenue metrics being met, the Company will issue TLF Bio Innovation up to 2,000,000 warrants for the Company's common stock (the "TLF Bio Warrants"). As a result, stockholders may incur dilution if the Microprofit Warrants and/or the TLF Bio Warrants are issued and/or exercised. In addition, we cannot predict the effect, if any, that the issuance and/or exercise of the Microprofit Warrants and/or TLF Bio Warrants will have on the market price of our common stock but it could adversely affect such price.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in one or more changes of control, as defined by Section 382 of the Code. We have not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since our formation, due to the significant complexity and cost associated with such study. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. If we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Risks Relating to Our Business

Our business may be adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. In January 2020, COVID-19 spread to other countries, including the United States, and efforts to contain the spread of this coronavirus intensified. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 outbreak, "shelter in place" orders and other public health measures were implemented across much of the United States, including the San Francisco Bay area counties where the Company's headquarters is located. Due to "shelter in place" orders and other public health guidance measures, the Company has implemented a work-from-home policy for all staff members. As the shelter-in-place restrictions are lifted, the Company has opened its business in phases by staggering the timeline for returning employees to work. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business, financial condition and results of operation, particularly in relation to our field sales representatives. In particular, in the second quarter of 2020, we experienced a slowdown in Avenova sales in our prescription and in-office direct channels, as patient visits to eyecare specialists decreased substantially due to the nationwide shelter-in-place mandates. It is possible we may experience another similar slowdown this winter if there is a COVID-19 resurgence and patient visits again decline. When and as needed to work from home during this time, our salesforce is keeping engaged with these specialists through phone contact to support sales following the lifting of shelter-in-place restrictions.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and elsewhere, business closures or business disruptions and the effectiveness of actions taken in the United States and elsewhere to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our business, financial condition and results of operations.

Our business may be adversely affected if there is a default on the PPP Loan.

We entered into a PPP Loan with Wells Fargo Bank, N.A. in an aggregate principal amount of $900,505, which was established under the CARES Act. Under the terms of the CARES Act, recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for certain permissible purposes as set forth in the PPP, including, but not limited to, payroll costs (as defined under the PPP) and mortgage interest, rent or utility costs and the maintenance of employee and compensation levels. The Small Business Administration has issued additional guidance on loan forgiveness. While we believe that we meet the qualifications for loan forgiveness, there is no assurance that the Company will obtain forgiveness of the PPP Loan, in whole or in part, and therefore, the Company may be liable for paying the PPP Loan back.

The PPP Loan contains customary events of default relating to, among other things, payment defaults or breach of representations and warranties. If the PPP Loan is not forgiven, the Company may default on the PPP Loan and trigger the immediate repayment of all amounts outstanding and/or the Lender filing suit and obtaining judgment against the Company.

If the Test Kits are unable to gain acceptance in the market, prove to be ineffective or less effective than expected, and/or we do not receive the Regulatory Approvals, we may not realize anticipated revenue from the Test Kits and our results of operation could be materially harmed.

Although we believe that the Test Kits represent promising tests for COVID-19 virus exposure, they may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for the Test Kits and other companies are working to produce or have produced tests for COVID-19, which may lead to the diversion of customers. Gaining acceptance in medical communities requires increasing awareness of the Test Kits and its benefits. Industry professionals and regulatory agencies may not consider the results of the Test Kits sufficiently safe, effective or accurate.

Our ability to successfully market the Test Kits will depend on numerous factors, including:

- the level of approvals granted by the FDA;
- our ability to demonstrate the efficacy, speed and cost of the Test Kits;
- whether health care providers and governmental agencies believe the Test Kits are sufficiently safe, effective, and accurate; and
- whether the medical community accepts the Test Kits as a supplement to, alternative to, or complementary to, current other tests for COVID-19 infection.

There can be no assurance that governmental agencies, including the FDA, will provide the Regulatory Approvals. Failure to achieve widespread market acceptance of the Test Kits, or failure to obtain the Regulatory Approvals, could materially harm our business, financial condition, and results of operations. The Test Kits are new tests that have not yet generated any revenue and may not result in any revenue for us.

Additionally, we are committing financial resources and personnel to the marketing and sale of the Test Kits. This resource allocation may cause delays in, or otherwise negatively impact, our other business lines and products, including Avenova. Our business could also be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate and there is no guarantee that current or anticipated demand will continue.

We rely on a third party to manufacture the Test Kits.

With respect to the Test Kits, assuming Regulatory Approvals, we plan to act as a distributor of tests manufactured by a third party, Microprofit. We have limited control over Microprofit and any performance failure on its part (including timely cooperation with the FDA to receive the Regulatory Approvals, failure to deliver compliant, quality components or finished goods on a timely basis) could affect our ability to market the Test Kits, supply Test Kits to our customers, produce additional losses and reduce or delay revenues. In addition, if something were to impair the relationship between us and Microprofit, or if Microprofit violates or is alleged to have violated any laws or regulations during the performance of its obligations to us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Revenue generated from the KN95 Masks and the Test Kits, if any, likely represents a temporary source of revenue for the Company.

During the global pandemic of the coronavirus (COVID-19), we tapped into our global healthcare supply network to secure the KN95 Masks and, after receiving the Regulatory Approvals, the Test Kits that we can offer at reasonable prices. While receiving a modest profit margin on the KN95 Masks and the Test Kits, if distributed, the Company does not believe that the revenue generated from the KN95 Masks and/or the Test Kits, if any, will be a long-term source of revenue for the Company. Once the demand for the KN95 Masks and/or the Test Kits declines, the Company will likely no longer be able to generate any revenue through the sales of the KN95 Masks and/or the Test Kits, if ever. The Company does not expect this revenue source to extend past the current COVID-19 pandemic.

Our future success is largely dependent on the successful commercialization of Avenova.

If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to successfully commercialize our products. While we believe we are creating an efficient commercial organization, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of Avenova and/or CelleRx, which could cause our commercialization efforts to be unprofitable or less profitable than expected.

We expect continuous revenue from sales of Avenova, which is classified as a cleared medical device by the FDA, but we cannot guarantee that the FDA will continue to allow us to market and sell Avenova as a cleared medical device, which would halt our sales and marketing of Avenova and cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Although we are having short-term revenue generation from the sales of KN95 Masks and hope to receive revenue from the distribution of the Test Kits and the relaunch of CelleRx as a lifestyle hygiene product, our ability to generate product sales will depend primarily on the commercial success of Avenova. Our ability to continue to commercialize Avenova and generate revenue depends upon, among other things:

- the FDA allowing us to continue marketing Avenova as an FDA clearance;
- acceptance in the medical community;
- the safety of Avenova's predicate devices;
- the number of patients who use Avenova for the intended target;
- sufficient coverage or reimbursement by third party payors;
- our ability to successfully market Avenova;
- reopening and resurgence of patient visits to eyecare specialists after the nationwide shelter-in-place mandates cease; and
- the amount and nature of competition from competing companies with similar products and procedures.

The sale of Avenova will be subject to, among other things, regulatory and commercial and market uncertainties that may be outside of our control. Products that are approved or cleared for marketing by the FDA may be materially adversely impacted by the emergence of new industry standards and practices or regulations that could render Avenova as well as our other cleared products less competitive or obsolete. We cannot guarantee that Avenova, our other cleared products, or products that may be approved or cleared for marketing in the future will not be materially adversely impacted by a change in industry standards or regulations. If changes to Avenova or our other cleared products that we may market and sell in the future cause a delay in continued commercialization or if we cannot make a change to satisfy the industry standards and practices or regulations, we may not be able to meet market demand which may have a materially adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, the FDA may request that we submit another 510(k) premarket submission that compares to another predicate device. If we are unable to find an adequate predicate device that is substantially equivalent to Avenova for the treatment claims that we use to sell and market Avenova, we may not be able to obtain the necessary FDA clearance to continue to market and sell Avenova without performing comprehensive clinical trials. In such event, we would need to seek premarket approval from the FDA for the applicable product before we could continue to sell and market Avenova in the United States, which would be significantly more time consuming, expensive, and uncertain.

Our commercialized products such as Avenova and CelleRx, like our other cleared products, are not approved by the FDA as a drug, and we rely solely on the 510(k) clearance of our products as a medical device.

Our business and future growth depend on the development, use and sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA. As a medical device, we may only legally make very limited claims that pertain to our products' cleared intended use. Without claims of efficacy, market acceptance of our products may be slow. The 510(k) status of Avenova also affects our ability to obtain formal insurance reimbursement by payors, and affects our ability to obtain Medicare coverage. If and to the extent that the relaunch of CelleRx as a lifestyle hygiene product is successful, we would have similar restrictions due to the status of CelleRx as a 510(k) cleared product.

There is significant risk that the FDA or other federal or state law enforcement authorities may determine that the nature and scope of our sales and marketing activities constitutes the promotion of our products for non-FDA-approved uses in violation of applicable law and as the sale of unapproved drugs, which is prohibited under applicable law. We face the risk that the FDA may take enforcement action against us for the way that we promote and sell our products. This risk may grow with the increased visibility of Avenova Direct online. We also face the risk that the FDA or other regulatory authorities might pursue enforcement actions based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of unapproved drug products, off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and be required to substantially limit and change our sales, promotion, grant and educational activities.

We have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory clearance or approvals, if such clearances or approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory clearances or approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only one employee. As a result, we may experience delays in connection with obtaining regulatory clearances or approvals for our products, if such clearances or approvals are obtained at all. We are currently seeking regulatory approval from the FDA for the Test Kits, which requires the response and cooperation of the manufacturer of the Test Kits. There is no guarantee that the manufacturer of the Test Kits will fully and timely cooperate and that such approval, based on such cooperation or other factors as the FDA determines, will be received and that the Company will receive any revenue from the distribution of the Test Kits.

Developments after a product reaches the market may adversely affect sales of our products.

Even after obtaining regulatory clearances, certain developments may decrease demand for our products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of regulatory clearance of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of a product, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. In addition, some health authorities appear to have become more cautious when examining new products and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising, and promotion (in particular, direct to consumer advertising) and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products. If any of the above occurs to Avenova, our business, results of operations, financial condition and cash flows could be materially adversely affected.

We do not have our own manufacturing capacity, and we rely on partnering arrangements or third-party manufacturers for the manufacture of our products and potential products.

The FDA and other governmental authorities require that all of our products be manufactured in strict compliance with federal Quality Systems Regulations and other applicable government regulations and corresponding foreign standards. We do not currently operate manufacturing facilities for production of our products. As a result, we have partnered with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute our products and help us meet legal requirements. As we have limited control over our commercial partners, any performance failure on their part (including failure to deliver compliant, quality components or finished goods on a timely basis) could affect the commercialization of our products, producing additional losses and reducing or delaying product revenues. If any of our commercial partners or manufacturers have violated or is alleged to have violated any laws or regulations during the performance of their obligations to us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Our products require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Accordingly, we and our third-party manufacturers are also subject to periodic unannounced inspections by the FDA to determine compliance with the FDA's requirements, including primarily current Good Manufacturing Practice (“cGMP”), the Quality Systems Regulations (“QSR”), medical device reporting regulations, and other applicable government regulations and corresponding foreign standards, including ISO 13485.

The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective, make additional therapeutic claims that are not commensurate to the accepted labeling claims, or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

Avenova's FDA-clearance and our other products that have been cleared by the FDA or products that we may obtain FDA-clearance in the future, if at all, are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearance to one or all of our products that may be cleared in the future, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, FDA clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be materially adversely impacted.

We rely on a limited number of pharmaceutical wholesalers to distribute Avenova.

We rely primarily upon a limited number of pharmaceutical wholesalers in connection with the distribution of our prescription Avenova product. If we are unable to establish or maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability. We rely on our distribution agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation to fill Avenova prescriptions at most of the retail pharmacies in the United States. If they are not able to ensure consistent availability of our product at retail pharmacies, our revenues will suffer. We mostly rely on Amazon.com for sales of Avenova Direct. If something were to impair the relationship between NovaBay and Amazon.com, it may have a negative impact on our business.

If we grow and fail to manage our growth effectively, we may be unable to execute our business plan.

Our future growth, if any, may cause a significant strain on our management and our operational, financial and other resources. Our ability to grow and manage our growth effectively will require us to implement and improve our operational, financial and management information systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management information systems could have a material adverse effect on our business, financial condition, and results of operations.

Government agencies may establish usage guidelines that directly apply to our products or proposed products or change legislation or regulations to which we are subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of our products and products that we may develop. In addition, there can be no assurance that government regulations applicable to our products or proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could modify, prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or in other countries.

We are subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which may limit our ability to commercialize our products.

The clearance that we have received from the FDA for our Avenova, NeutroPhase, and CelleRx products is subject to strict limitations on the indicated uses for which the products may be marketed. The labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for our products are subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the products or the withdrawal of the products from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory clearance, product recalls, seizure of products, operating restrictions, injunctions, warning letters and other enforcement actions, and criminal prosecution. Any of these events could prevent us from marketing our products and our business may not be able to continue past such concerns.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products, such as Avenova, NeutroPhase, and CelleRx, in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our regulated products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If we experience unanticipated problems with the products, if or once approved or cleared for marketing, our products could be subject to restrictions or withdrawal from the market which may have a materially adverse impact on our business, financial condition, results of operations, and prospects.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for our cleared medical devices, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our current suppliers, and suppliers that we may have relationships with in the future, are required to comply with the FDA's Quality Systems Regulations ("QSR") including for the manufacture, testing, control, quality assurance, labeling, shipping, storage, distribution and promotion of our products. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances that have already been granted; (9) refusal to grant export clearance for our products; or (10) criminal prosecution.

If any of these actions were to occur, it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements we may be unable to produce our products on a timely basis and in the required quantities, if at all.

If our product or products cause a reaction in a patient that causes serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that our device or a similar device has likely caused or would likely cause or contribute to death. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If our product or products cause an unexpected reaction to a patient or patients in certain ways that may have caused or contributed to serious injury, we will be subject to product liability claims.

We cannot make assurances that any liability insurance coverage that we qualify for, if at all, will fully satisfy any liabilities brought for any event or injury that is attributed to our product or products. Even if our liability insurance satisfies any and all products liabilities brought against us, any product liability claims may significantly harm our reputation and delay market acceptance of our product or products that may be cleared or approved in the future, if at all.

We expect to rely on third parties to conduct any future studies of our technologies that may be required by the FDA, and those third parties may not perform satisfactorily.

Though we do not anticipate conducting further clinical trials in the near future, should we decide otherwise, we may not have the ability to independently conduct the clinical or other studies that will be required to obtain FDA clearance for one or all of our products currently in development or products that we may develop in the future. Should we conduct clinical trials, those trials may be performed by third parties that may not perform satisfactorily, which may have a materially adverse impact on our business, financial condition, results of operations, and prospects.

Our past clinical trials may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.

Even though we have concluded or suspended all of our clinical trials, an inherent risk remains. If a claim were to arise in the future based on our past clinical trial activity, we would most likely incur substantial expenses. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our products or product candidates. Our current clinical trial insurance covers individual and aggregate claims up to $5.0 million. This insurance may not cover all claims, and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our cleared products as well as our products under development, if and when those products are cleared or approved. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we develop. If our technologies or products become obsolete or uncompetitive, our related product sales would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

Avenova faces substantial competition in the eye care markets in which we operate.

We face intense competition in the eye care market, which is focused on cost-effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation. Avenova faces substantial competition in the eye care market from companies of all sizes in the United States and abroad, including, among others, large companies such as Allergan plc and Shire plc, against products such as Restasis, Xiidra, eye wipes, baby shampoo and soap. There are also over-the-counter products that contain hypochlorous acid that compete with Avenova. Competition may increase further as existing competitors enhance their offerings or additional companies enter our markets or modify their existing products to compete directly with our products. Many of our competitors have substantially more resources and a greater marketing scale than we do. We may not be able to sustain our current levels of growth as competitive pressures, including pricing pressure from competitors, increase. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements, our products may be rendered obsolete or non-competitive. In addition, if our competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization than we do, our operating results will materially suffer.

We may not be able to enhance the capabilities of our current and new products to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend significantly on our ability to keep pace with technological developments and evolving industry standards as well as respond to changes in customer needs. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we currently sell, Avenova in particular, and products that we plan to sell. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

Demands of third-party payors, cost reduction pressures among our customers, restrictive reimbursement practices, and cost-saving and other financial measures may adversely affect our business.

Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate that they will be reimbursed by such programs in the future. Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or group purchasing organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced fees or other concessions or to delay payment. In addition, third-party payors may reduce or limit reimbursement for our products in the future, such as by withdrawing their coverage policies, canceling any future contracts with us, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers, lower pricing for our products to new customers, or limitations or reductions in reimbursement could have a material adverse effect on our financial position, cash flows and results of operations.

Federal and state healthcare reform legislation, including the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the "Affordable Care Act," may also adversely affect our business. The Affordable Care Act contains provisions aimed at improving quality and decreasing costs in the Medicare program, such as value-based payment programs and reduced hospital payments for avoidable readmissions and hospital acquired conditions. The Affordable Care Act has been, and continues to be, subject to judicial and legislative challenges seeking to modify, limit, replace, or repeal the legislation. While we cannot predict what additional healthcare programs and regulations will be implemented at the federal or state level, or the effect of any future legislation or regulation on our business, any changes that lower potential reimbursement for our products, impose additional costs, reduce the potential number of people eligible for reimbursement for the use of our products, or otherwise reduce demand for our products, could adversely affect our business, financial condition and results of operations.

The pharmaceutical and biopharmaceutical industries are characterized by patent litigation, and any litigation or claim against us may impose substantial costs on us, place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain six months of exclusivity as a generic product under the Hatch-Waxman Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position, and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may be issued to third parties which our technology may infringe. Because patent applications can take many years to issue and because patent applications are not published for a period of time, or in some cases at all, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, would divert management's attention from our business and could have a material negative effect on our business, operating results or financial condition. If a dispute involving our proprietary technology were resolved against us, it could mean the earlier entry of some or all third parties seeking to compete in the marketplace for a given product, and a consequent significant decrease in the price we could charge for our product. If such a dispute alleging that our technology or operations infringed third party patent rights were to be resolved against us, we might be required to pay substantial damages, including treble damages and attorney's fees if we were found to have willfully infringed a third party's patent, to the party claiming infringement, to develop non-infringing technology, to stop selling any products we develop, to cease using technology that contains the allegedly infringing intellectual property or to enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

If product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities.

Despite all reasonable efforts to ensure safety, it is possible that we or our distributors will sell Avenova, CelleRx, NeutroPhase or KN95 Masks or products that we currently do not sell but may sell in the future such as intelli-Case or the Test Kits, which are defective, to which patients/customers react in an unexpected manner, or which are alleged to have side effects or otherwise not work for the product's intended purpose. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention, and could have a material adverse effect on our financial condition, business and results of operations.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources.

If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the U.S. and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

There is no assurance that any patents issued to us, or in-licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted thereunder will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute, obtain or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know-how may become known or be independently discovered by competitors.

We operate in the State of California. California law prevents us from imposing a delay before an employee, who may have access to trade secrets and proprietary know-how, can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damage has been done to our Company.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

Our current patent portfolio could leave us vulnerable to larger companies who have the resources to develop and market competing products.

We aggressively protect and enforce our patent rights worldwide. However, certain risks remain. There is no assurance that patents will be issued from any of our applications or, for those patents we have or that do issue, that the claims will withstand an invalidity challenge or be sufficiently broad to protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the Neutrox composition. This relatively weak patent portfolio leaves us vulnerable to competitors who wish to compete in the same marketplace with similar products. If a potential competitor introduces a formulation similar to Avenova, CelleRx or NeutroPhase with a similar composition that does not fall within the scope of the method of treatment/manufacture claims, then we or a potential marketing partner would be unable to rely on the allowed claims to protect its market position for the method of using the Avenova, CelleRx or NeutroPhase composition, and any revenues arising from such protection would be adversely impacted.

If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA has cleared or approves products that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- published studies demonstrating the cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or commercial payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

Failure to comply with laws and regulations governing the sales and marketing of our products could materially impact our revenues.

We engage in various marketing, promotional and educational activities pertaining to, as well as the sale of, pharmaceutical products and/or medical devices in the United States and in certain other jurisdictions outside of the United States. The promotion, marketing and sale of pharmaceutical products and medical devices is highly regulated and the sales and marketing practices of market participants, such as us, have been subject to increasing supervision by governmental authorities, and we believe that this trend will continue.

In the United States, our sales and marketing activities are regulated by a number of regulatory authorities and law enforcement agencies, including the U.S. Department of Health and Human Services, the FDA, the Federal Trade Commission, the U.S. Department of Justice, the SEC, and state regulatory authorities. These authorities and agencies and their equivalents in countries outside the United States have broad authority to investigate market participants for potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products and medical devices, including the False Claims Act, the Anti-Kickback Statute, the UK Bribery Act of 2010 and the Foreign Corrupt Practices Act, and their state equivalents, among others, for alleged improper conduct, including corrupt payments to government officials, improper payments, inducements, and financial relationships with and to medical professionals, patients, and sales personnel, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies and providers may also be subject to enforcement actions or prosecution for such improper conduct. Any inquiries or investigations into our operations, or enforcement or other regulatory action against us, by such authorities could result in significant defense costs, fines, penalties and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or us, from government reimbursement programs or subject us to regulatory controls or government monitoring of our activities in the future.

Failure to obtain and/or maintain required licenses or registrations could reduce revenue.

Our business is subject to a variety of licensing or registration requirements by the FDA, certain states and foreign jurisdictions where our products are distributed. Failure to obtain or maintain required licenses could result in the termination of the sale of certain products in the application states or foreign jurisdictions, or the termination of such products. We may also be subject to fines and other penalties imposed by the relevant government authorities for non-compliance.

The process for obtaining licenses or registrations can be lengthy and expensive and the results sometimes are unpredictable. If we are unable to obtain licenses or registrations needed to produce, market and sell our products in a timely fashion, or at all, our revenues could be materially and adversely affected.

We are subject to U.S. healthcare fraud and abuse and health information privacy and security laws, and the failure to comply with such laws may adversely affect our business.

We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The U.S. laws that may affect our ability to operate include, but are not limited to: (i) the federal Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies, and relationships with healthcare providers or other persons and entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third party payers that are false or fraudulent, and from offering or transferring remuneration to a Medicare or state healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state healthcare program; (iii) the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which, among other things, created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and places restrictions on the use of such information for marketing communications; (v) the Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to “payments or other transfers of value” made to physicians and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members; (vi) the government pricing rules and price reporting laws applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, and the TRICARE program; and (vii) state and foreign law equivalents of each of the above laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, and state and foreign price and payment reporting and disclosure laws, many of which differ from each other in significant ways and often are not preempted by their federal counterparts, thus complicating compliance efforts. Violations of the health information privacy and fraud and abuse laws may result in severe penalties against us and/or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Defense of litigation claims and government investigations can be costly, time consuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. Certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with health information privacy or fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that may govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. Due to the breadth of these statutory provisions, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the U.S. Department of Justice, and other agencies have increased their enforcement activities and scrutiny with respect to sales, marketing, research, financial relationships with healthcare providers, rebate or copay arrangements, discounts, and similar activities and relationships of pharmaceutical and medical device companies in recent years, and many companies have been subject to government investigations related to these practices and relationships. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacture and/or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs, and other sanctions.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audit reports to stockholders causes our expenses to be higher than they would be if we were a privately-held company. The increased costs associated with operating as a public company may decrease our net income or increase our net loss, and may cause us to reduce costs in other areas of our business or increase the prices of our product to offset the effect of such increased costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations.

A failure of our internal control over financial reporting could materially impact our business or stock price.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. An internal control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system 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 all internal control systems, internal control over financial reporting may not prevent or detect misstatements. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud and could expose us to litigation or adversely affect the market price of our common stock.

Significant disruptions of information technology systems or breaches of information security could adversely affect our businesses.

We rely to a large extent upon information technology systems to operate our businesses. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

ITEM 6. EXHIBITS

The following exhibits are filed with or incorporated by reference into this report.

EXHIBIT INDEX

The following exhibits are filed with or incorporated by reference into this report.

		Incorporation by Reference				Filed Herewith
Exhibit Number	**Exhibit Description**	**Form**	**File Number**	**Exhibit/ Form 8-K Item Reference**	**Filing Date**	
3.1	Amended and Restated Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	10-K	001-33678	3.1	3/21/2018	
3.2	Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-33678	3.1	6/04/2018	
3.3	Amendment to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-33678	3.1	5/28/2020	
3.4	Bylaws	8-K	001-33678	3.2	6/29/2010	
4.1	Form of Warrant issued in October 2015 offering, as amended	10-K	001-33678	4.5	3/23/2017	
4.2	Form of 2019 Domestic Warrant issued in August 2019	8-K	001-33678	4.1	8/9/2019	
4.3	Form of 2019 Foreign Warrant issued in August 2019	8-K	001-33678	4.2	8/9/2019	
4.4	Form of Warrant in June 2019 offering	8-K	001-33678	4.2	6/19/2019	
4.5	Form of Warrant pursuant to the International Distribution Agreement with Shenzhen Microprofit Biotech Co., Ltd., dated April 16, 2020	8-K	001-33678	4.1	4/20/2020	
4.6	Form of Warrant pursuant to the Services Agreement with TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	4.1	5/18/2020	
4.7	Form of New Warrant	8-K	001-33678	4.1	07/21/2020	
10.1+	Indemnity Agreement (Form of Indemnity Agreement between the Company and its Directors and Officers)	10-Q	001-33678	10.1	08/06/2020	
10.2+	NovaCal Pharmaceuticals, Inc. 2005 Stock Option Plan	S-1 as amended	333-140714	10.2	3/30/2007	
10.3+	NovaBay Pharmaceuticals, Inc. 2007 Omnibus Incentive Plan (as amended and restated)	S-8	333-215680	99.1	1/24/2017	

10.4+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan	S-8	333-218469	99.1	6/02/2017	
10.5+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan (Form Agreements to the 2017 Omnibus Incentive Plan)	S-8	333-218469	99.2	6/02/2017	
10.6+	Non-Employee Director Compensation Plan	8-K	001-33678	10.1	10/11/2018	
10.7+	Executive Employment Agreement (Employment Agreement of Justin M. Hall)	8-K	001-33678	10.1	2/6/2020	
10.8+	Executive Employment Agreement (Employment Agreement of Andrew D. Jones)	8-K	001-33678	10.1	5/5/2020	
10.9	Office Lease between EmeryStation Associates II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North	S-1, as amended	333-140714	10.10	3/30/2007	
10.10	Fifth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.20	3/14/2008	
10.11	Sixth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q, as amended	001-33678	10.1	11/14/2008	
10.12	Seventh Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q	001-33678	10.2	8/09/2012	
10.13	Eighth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.19	3/04/2016	
10.14	Ninth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q	001-33678	10.14	08/06/2020	
10.15	Office Lease (between the Company and KBSIII Towers at Emeryville, LLC)	8-K	001-33678	10.1	8/26/2016	
10.16	Sublease Agreement by and between NovaBay Pharmaceuticals, Inc. and Zymergen, Inc., dated July 11, 2016	8-K	001-33678	10.1	7/15/2016	
10.17	Sublease Termination Agreement by and between the Company and Zymergen, Inc.	10-Q	001-33678	10.17	08/06/2020	
10.18†	Collaboration and License Agreement by and between NovaBay Pharmaceuticals, Inc. and Galderma S.A.	10-Q, as amended	001-33678	10.2	8/04/2009	
10.19†	Amendment No. 1 to the Collaboration and License Agreement	10-K	001-33678	10.18	3/30/2010	
10.20†	Amendment No. 2 to the Collaboration and License Agreement	10-K	001-33678	10.24	3/10/2011	
10.21†	International Distribution Agreement (by and between the Company and Pioneer Pharma Co. Ltd.)	10-K	001-33678	10.18	3/27/2012	
10.22	Promissory Note Payable to Pioneer Pharma (Hong Kong) Company Limited, dated February 27, 2019	8-K	001-33678	10.1	3/01/2019	
10.23	First Amendment to the Promissory Note (payable to Pioneer Pharma (Hong Kong) Company Limited), dated June 25, 2019	8-K	001-33678	10.1	6/26/2019	
10.24	Second Amendment to the Promissory Note (payable to Pioneer Pharma (Hong Kong) Company Limited), dated May 14, 2020	8-K	001-33678	10.1	5/15/2020	
10.25	Security Agreement with China Kington Asset Management Co. Ltd., dated February 27, 2019 (in connection with the Promissory Note of the same date)	8-K	001-33678	10.2	3/01/2019	
10.26	Securities Purchase Agreement between the Company and Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.2	3/28/2019	
10.27	Secured Convertible Promissory Note from the Company to Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.3	3/28/2019	

10.28	Security Agreement between the Company and Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.4	3/28/2019	
10.29*	International Distribution Agreement between the Company and Shenzhen Microprofit Biotech Co., Ltd., dated April 16, 2020	8-K	001-33678	10.1	4/20/2020	
10.30*	Intermediary Distribution Agreement between the Company and Chongqing Pioneer Pharma Holdings Limited, dated April 16, 2020	8-K	001-33678	10.2	4/20/2020	
10.31*	First Amendment to Intermediary Distribution Agreement between the Company and Chongqing Pioneer Pharma Holdings Limited, dated June 29, 2020	10-Q	001-33678	10.31	08/06/2020	
10.32	At the Market Offering Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated April 27, 2020	8-K	001-33678	1.1	4/27/2020	
10.33	Paycheck Protection Program Promissory Note and Agreement, dated May 3, 2020, between the Company and Wells Fargo Bank, N.A.	10-Q	001-33678	10.28	5/7/2020	
10.34	Services Agreement between the Company and TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	10.1	5/18/2020	
10.35†	First Amendment to Services Agreement between the Company and TLF Bio Innovation Lab, LLC, dated September 4, 2020	8-K	001-33678	10.1	09/10/2020	
10.36	Securities Purchase Agreement between the Company and TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	10.2	5/18/2020	
10.37	Form of Exercise Agreement with Holders of 2019 Domestic Warrants	8-K	001-33678	10.1	7/21/2020	
10.38	Form of Exercise Agreement with Holders of 2019 Foreign Warrants	8-K	001-33678	10.2	7/21/2020	
10.39	Form of Reprice Agreement with Ladenburg	8-K	001-33678	10.3	7/21/2020	
31.1	Certification of the Principal Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)					X
31.2	Certification of the Principal Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)					X
32.1	Certification by the Chief Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)					X
32.2	Certification by the Chief Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

+ Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

* Certain confidential portions of this exhibit were omitted by means of marking such portions with brackets because the confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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.

Date: November 12, 2020

NOVABAY PHARMACEUTICALS, INC.

/s/ Justin Hall
Justin Hall
President and Chief Executive Officer
(principal executive officer)

Date: November 12, 2020

/s/ Andrew Jones
Andrew Jones
Chief Financial Officer
(principal financial officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Justin Hall, certify that:

1. I have reviewed this Form 10-Q of NovaBay 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

/s/ Justin Hall
Justin Hall
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Jones, certify that:

1. I have reviewed this Form 10-Q of NovaBay 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

/s/ Andrew Jones
Andrew Jones
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-Q for the quarter ended September 30, 2020 (the Report), I, Justin Hall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2020

/s/ Justin Hall
Justin Hall
President and Chief Executive Officer

This Certification is made solely for the purpose of 18 USC Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-Q for the quarter ended September 30, 2020 (the Report), I, Andrew Jones, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2020

/s/ Andrew Jones
Andrew Jones
Chief Financial Officer

This Certification is made solely for the purpose of 18 USC Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.