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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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 001-37880

Novan, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**20-4427682**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4020 Stirrup Creek Drive, Suite 110 **Durham, North Carolina**	**27703**
(Address of principal executive offices)	(Zip Code)

(919) 485-8080
(Registrant's telephone number, including area code)

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, $0.0001 par value	NOVN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 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 X No ☐

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

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

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

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

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

As of November 4, 2022, there were 24,462,228 shares of the registrant's Common Stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

NOVAN, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,903	$ 47,085
Accounts receivable, net	14,882	4,473
Inventory, net	1,178	—
Prepaid expenses and other current assets	3,664	2,572
Total current assets	34,627	54,130
Restricted cash	583	583
Property and equipment, net	13,921	12,201
Intangible assets, net	27,963	75
Other assets	259	278
Right-of-use lease assets	1,794	1,693
Goodwill	4,123	—
Total assets	$ 83,270	$ 68,960
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,074	$ 2,170
Accrued expenses	27,626	4,988
Deferred revenue, current portion	2,586	2,586
Research and development service obligation liability, current portion	649	1,406
Contingent consideration liability, current portion	438	—
Operating lease liabilities, current portion	254	—
Total current liabilities	35,627	11,150
Deferred revenue, net of current portion	8,726	10,665
Operating lease liabilities, net of current portion	3,801	3,613
Research and development service obligation liability, net of current portion	48	142
Research and development funding arrangement liability	25,000	25,000
Contingent consideration liability, net of current portion	2,942	—
Other long-term liabilities	366	71
Total liabilities	76,510	50,641
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock $0.0001 par value; 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 24,463,178 and 18,816,842 shares issued as of September 30, 2022 and December 31, 2021, respectively; 24,462,228 and 18,815,892 shares outstanding as of September 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	314,170	297,441
Treasury stock at cost, 950 shares as of September 30, 2022 and December 31, 2021	(155)	(155)
Accumulated deficit	(307,257)	(278,969)
Total stockholders' equity	6,760	18,319
Total liabilities and stockholders' equity	$ 83,270	$ 68,960

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

NOVAN, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net product revenues	$ 4,605	$ —	$ 11,131	$ —
License and collaboration revenues	492	680	2,010	2,174
Government research contracts and grants revenue	18	57	60	129
Total revenue	5,115	737	13,201	2,303
Operating expenses:				
Product cost of goods sold	1,440	—	4,259	—
Research and development	4,288	4,251	12,265	15,926
Selling, general and administrative	8,562	2,969	27,151	8,086
Amortization of intangible assets	443	—	1,112	—
Change in fair value of contingent consideration	186	—	(268)	—
Impairment loss on long-lived assets	—	—	—	114
Total operating expenses	14,919	7,220	44,519	24,126
Operating loss	(9,804)	(6,483)	(31,318)	(21,823)
Other income (expense), net:				
Interest income	38	4	56	10
Interest expense	(635)	—	(1,375)	—
Gain on debt extinguishment	4,340	—	4,340	956
Other income (expense)	31	(5)	9	(602)
Total other income (expense), net	3,774	(1)	3,030	364
Net loss and comprehensive loss	$ (6,030)	$ (6,484)	$ (28,288)	$ (21,459)
Net loss per share, basic and diluted	$ (0.25)	$ (0.34)	$ (1.33)	$ (1.30)
Weighted-average common shares outstanding, basic and diluted	24,462,228	18,813,653	21,189,799	16,476,235

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

NOVAN, INC.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

	Nine Months Ended September 30, 2022					
	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2021	18,815,892	$ 2	$ 297,441	$ (155)	$ (278,969)	$ 18,319
Stock-based compensation	—	—	381	—	—	381
Common stock issued pursuant to equity distribution agreement (at-the-market facility)	164,230	—	562	—	—	562
Net loss	—	—	—	—	(13,380)	(13,380)
Balance as of March 31, 2022	18,980,122	$ 2	$ 298,384	$ (155)	$ (292,349)	$ 5,882
Stock-based compensation	—	—	453	—	—	453
Common stock and pre-funded warrants issued pursuant to the June 2022 registered direct offering, net	2,080,696	—	14,020	—	—	14,020
Common stock issued pursuant to equity distribution agreement (at-the-market facility)	220,795	—	772	—	—	772
Net loss	—	—	—	—	(8,878)	(8,878)
Balance as of June 30, 2022	21,281,613	$ 2	$ 313,629	$ (155)	$ (301,227)	$ 12,249
Stock-based compensation	—	—	509	—	—	509
Exercise of pre-funded warrants related to the June 2022 registered direct offering	3,180,615	—	32	—	—	32
Net loss	—	—	—	—	(6,030)	(6,030)
Balance as of September 30, 2022	24,462,228	$ 2	$ 314,170	$ (155)	$ (307,257)	$ 6,760

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

NOVAN, INC.
Condensed Consolidated Statements of Stockholders' Equity, continued
(unaudited)
(in thousands, except share amounts)

Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2020	14,570,009	$ 1	$ 252,408	$ (155)	$ (249,277)	$ 2,977
Stock-based compensation	—	—	36	—	—	36
Exercise of common stock warrants	99,651	—	442	—	—	442
Common stock issued pursuant to common stock purchase agreement	493,163	1	6,333	—	—	6,334
Exercise of stock options	2,492	—	13	—	—	13
Net loss	—	—	—	—	(8,952)	(8,952)
Balance as of March 31, 2021	15,165,315	$ 2	$ 259,232	$ (155)	$ (258,229)	$ 850
Stock-based compensation	—	—	215	—	—	215
Common stock issued pursuant to public offering, net	3,636,364	—	37,236	—	—	37,236
Exercise of common stock warrants	3,900	—	19	—	—	19
Exercise of stock options	6,150	—	29	—	—	29
Extinguishment of fractional shares resulting from reverse stock split	(37)	—	—	—	—	—
Net loss	—	—	—	—	(6,023)	(6,023)
Balance as of June 30, 2021	18,811,692	$ 2	$ 296,731	$ (155)	$ (264,252)	$ 32,326
Stock-based compensation	—	—	327	—	—	327
Exercise of stock options	3,450	—	16	—	—	16
Net loss	—	—	—	—	(6,484)	(6,484)
Balance as of September 30, 2021	18,815,142	$ 2	$ 297,074	$ (155)	$ (270,736)	$ 26,185

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

NOVAN, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash flow from operating activities:		
Net loss	$ (28,288)	$ (21,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	812	242
Impairment loss on long-lived assets	—	114
Amortization of intangible assets	1,112	—
Accretion of debt discount	635	—
Change in fair value of contingent consideration	(268)	—
Stock-based compensation	1,343	(84)
Foreign currency transaction loss	—	676
Gain on debt extinguishment	(4,340)	(956)
Changes in operating assets and liabilities:		
Accounts receivable	9,674	4,399
Inventory	122	—
Prepaid expenses and other current assets	2,600	2,137
Accounts payable	990	(45)
Accrued expenses	(1,110)	820
Deferred revenue	(1,939)	(2,174)
Research and development service obligation liabilities	(851)	93
Other long-term assets and liabilities	(266)	201
Net cash used in operating activities	(19,774)	(16,036)
Cash flow from investing activities:		
Purchases of property and equipment	(3,209)	(4,515)
Landlord reimbursement of tenant improvement allowance	508	1,015
Payment for EPI Health Acquisition	(15,093)	—
Net cash used in investing activities	(17,794)	(3,500)
Cash flow from financing activities:		
Proceeds from issuance of common stock and issuance and exercise of pre-funded warrants, net of underwriting fees and commissions	14,252	37,600
Proceeds from exercise of common stock warrants	—	461
Proceeds from issuance of common stock under common stock purchase agreement	—	6,334
Payment of note payable	(10,000)	—
Proceeds from common stock issued pursuant to equity distribution agreement (at-the-market facility)	1,334	—
Payments related to offering costs	(200)	(364)
Proceeds from exercise of stock options	—	58
Net cash provided by financing activities	5,386	44,089
Net (decrease) increase in cash, cash equivalents and restricted cash	(32,182)	24,553
Cash, cash equivalents and restricted cash as of beginning of period	47,668	35,879
Cash, cash equivalents and restricted cash as of end of period	$ 15,486	$ 60,432
Supplemental disclosure for cash flow information:		
Interest paid	$ 339	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment with accounts payable and accrued expenses	$ 694	$ 3,892
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 1,343
Non-cash gain on debt extinguishment	$ 4,340	$ 956
Deferred offering costs reclassified to additional paid-in capital	$ —	$ 364
Contingent consideration related to EPI Health Acquisition	$ 3,648	$ —
Note payable issued for EPI Health Acquisition	$ 13,305	$ —
Reconciliation to condensed consolidated balance sheets:		
Cash and cash equivalents	$ 14,903	$ 59,960
Restricted cash included in noncurrent assets	583	472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 15,486	$ 60,432

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

NOVAN, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(dollar values in thousands, except per share data)

Note 1: Organization and Significant Accounting Policies

Business Description

Novan, Inc. ("Novan" and together with its subsidiaries, the "Company") is a medical dermatology company focused primarily on researching, developing and commercializing innovative therapeutic products for skin diseases. Its goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. The Company is developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. On March 11, 2022, the Company acquired EPI Health, LLC, a specialty pharmaceutical company focused on medical dermatology ("EPI Health"), from Evening Post Group, LLC, a South Carolina limited liability company ("EPG" or the "Seller"). The acquisition of EPI Health (the "EPI Health Acquisition") has provided the Company with a commercial infrastructure to sell a marketed portfolio of therapeutic products for skin diseases. Subsequent to the acquisition, the Company sells various medical dermatology products for the treatments of plaque psoriasis, rosacea, acne and dermatoses.

Novan was incorporated in January 2006 under the state laws of Delaware. In 2015, Novan Therapeutics, LLC, was organized as a wholly owned subsidiary under the state laws of North Carolina; in March 2019, the Company completed registration of a wholly owned Ireland-based subsidiary, Novan Therapeutics, Limited; and in March 2022, the Company acquired its wholly owned subsidiary, EPI Health, a South Carolina limited liability company. In August 2022, EPI Health, as sole equity member, formed and organized a new Delaware single member LLC.

See Note 2—"Acquisition of EPI Health" for further information regarding the EPI Health Acquisition. The post-acquisition operating results of EPI Health are reflected within the Company's condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2022, specifically from March 11, 2022 through September 30, 2022.

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The December 31, 2021 year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP for annual financial statements. Additionally, the Company's independent registered public accounting firm's report on the December 31, 2021 financial statements included an explanatory paragraph indicating that there was substantial doubt about the Company's ability to continue as a going concern.

Basis of Consolidation

The accompanying condensed consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Reverse Stock Split

On May 25, 2021, the Company amended its restated certificate of incorporation effecting a 1-for-10 reverse stock split of its outstanding shares of capital stock (the "Reverse Stock Split"). The Reverse Stock Split did not change the number of authorized shares of capital stock of the Company or cause an adjustment to the par value of the Company's capital stock. As a result of the Reverse Stock Split, the Company adjusted (i) the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, warrants to purchase shares of common stock and stock appreciation rights, (ii) the share price targets of the Company's Tangible Stockholder Return Plan and (iii) the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would have otherwise held a fractional share of capital stock received a cash payment for any fractional share resulting from the Reverse Stock Split in an amount equal to such fraction multiplied by the closing sales price of the common stock as reported on the Nasdaq Stock Market on May 25, 2021, the last trading day immediately prior to the effectiveness of the Reverse Stock Split. See Note 11—"Stockholders' Equity" for further information regarding the Reverse Stock Split.

All disclosures of shares and per share data in the condensed consolidated financial statements and related notes have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

Liquidity and Ability to Continue as a Going Concern

The Company's condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company has evaluated principal conditions and events, in the aggregate, that may raise substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The Company identified the following conditions:

- The Company has reported a net loss in all fiscal periods since inception and, as of September 30, 2022, the Company had an accumulated deficit of $307,257.
- As of September 30, 2022, the Company had a total cash and cash equivalents balance of $14,903.
- The Company anticipates that it will continue to generate losses for the foreseeable future, and it expects the losses to increase as it continues the development of, and seeks regulatory approvals for, its product candidates and begins activities to prepare for potential commercialization of SB206, if approved.
- The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company, coupled with its current forecasts, including costs associated with implementing the SB206 prelaunch strategy and commercial preparation, raise substantial doubt about its ability to continue as a going concern.

This evaluation is also based on other relevant conditions that are known or reasonably knowable at the date that the financial statements are issued, including ongoing liquidity risks faced by the Company, the Company's conditional and unconditional obligations due or anticipated within one year, the funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows, and other conditions and events that, when considered in conjunction with the above, may adversely affect the Company's ability to meet its obligations. The Company will continue to evaluate this going concern assessment in connection with the preparation of its quarterly and annual financial statements based upon relevant facts and circumstances, including, but not limited to, its cash and cash equivalents balance and its operating forecast and related cash projection.

The Company believes that its existing cash and cash equivalents as of September 30, 2022, plus expected receipts associated with product sales from its commercial product portfolio, will provide it with adequate liquidity to fund its planned operating needs into the beginning of 2023. Variability in its operating forecast, driven primarily by (i) commercial product sales, (ii) timing of operating expenditures, and (iii) unanticipated changes in net working capital, will impact the Company's cash runway. This operating forecast and related cash projection includes (i) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum, including studies enabling submission of a new drug application ("NDA") for SB206, (ii) costs associated with the readiness and operation of the Company's new manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party CMOs, (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution, and supportive activities, related to its portfolio of therapeutic products for skin diseases acquired with the EPI Health Acquisition, and (v) initial efforts to support potential commercialization of SB206, but excludes additional operating costs that could occur between a potential NDA submission for SB206 through NDA approval, including, but not limited to, marketing and commercialization efforts to achieve potential launch of SB206. The Company does not currently have sufficient funds to complete commercialization of any of its product candidates that are under development, and its funding needs will largely be determined by its commercialization strategy for SB206, subject to the targeted submission timing for the NDA relating to SB206 and the regulatory approval process and outcome, and the operating performance of its commercial product portfolio.

The inability of the Company to generate sufficient net revenues to fund its operations or obtain significant additional funding on acceptable terms in the near term, could have a material adverse effect on the Company's business and cause the Company to alter or reduce its planned operating activities, including, but not limited to, delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve its cash and cash equivalents. The Company has pursued and may continue to pursue additional capital through equity or debt financings or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. The Company's anticipated expenditure levels may change as it adjusts its current operating plan. Such actions could delay development timelines and have a material adverse effect on its business, results of operations, financial condition and market valuation.

The Company may also explore the potential for additional strategic transactions, such as strategic acquisitions or in-licenses, sales, out-licenses or divestitures of some of its assets, or other potential strategic transactions, which could include a sale of the Company. If the Company were to pursue such a transaction, it may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to the Company. Alternatively, if the Company is unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, it could instead determine to dissolve and liquidate its assets or seek protection under the bankruptcy laws. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company would be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Business Acquisitions

The Company accounts for business acquisitions using the acquisition method of accounting in accordance with Accounting Standards Codification ("ASC") 805, *Business Combinations* ("ASC 805"). ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, *Fair Value Measurements* ("ASC 820"), as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

COVID-19

The extent to which COVID-19, and its variant strains, and domestic and global efforts to contain its spread along with lingering effects of the foregoing will impact the Company's business, including its operations, preclinical studies, clinical trials, and financial condition, will depend on future developments, which are highly uncertain and cannot be predicted, and include the duration, severity and scope of the pandemic and its lingering impacts, the availability and effectiveness of vaccines in preventing the spread of COVID-19 (and its variants), and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19 and its variants.

During the pandemic, the timetable for development of the Company's product candidates has been impacted and may face further disruption and the Company's business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of the Company's B-SIMPLE4 Phase 3 study and was a factor influencing the Company's previous adjustment of its targeted SB206 NDA submission timing, currently planned for around the end of 2022.

In addition, certain factors from the COVID-19 pandemic may delay or otherwise adversely affect the Company's generation of product revenues from its portfolio of therapeutic products for skin diseases, as well as adversely impact the Company's business generally, including (i) changes in buying patterns caused by lack of normal access by patients to the healthcare system and concern about the supply of medications, (ii) adverse impacts on the Company's manufacturing operations, supply chain and distribution processes, which may impact its ability to procure, produce and distribute its products or product candidates, (iii) the inability of third parties to fulfill their obligations to the Company due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, (iv) the risk of shutdown in countries where the Company relies on CMOs to provide commercial manufacture of its products or clinical batch manufacturing of its product candidates, (v) the ability to procure raw materials needed for the production of the Company's active pharmaceutical ingredient ("API") and other manufacturing components for the Company's product candidates, (vi) the possibility that third parties on which the Company may rely for certain functions and services, including CMOs, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from the COVID-19 pandemic, which could cause the Company to experience delays or to incur additional costs, and (vii) the risk that the COVID-19 pandemic may intensify other risks inherent in the Company's business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. The Company reviews all significant estimates affecting the condensed consolidated financial statements on a recurring basis and records the effects of any necessary adjustments prior to their issuance.

Significant estimates made by management include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of contingent consideration and contingencies.

Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and applicable rules and regulations of the Securities and Exchange Commission's ("SEC") Rule 10-01 of Regulation S-X for interim financial information. The condensed consolidated financial statements were prepared on the same basis as the audited consolidated financial statements and in the opinion of management, reflect all adjustments of a normal, recurring nature that are necessary for the fair statement of the Company's financial position and its results of operations and cash flows. The results of operations for interim periods are not necessarily indicative of the results expected for the full fiscal year or any future period. These interim financial statements should be read in conjunction with the consolidated financial statements and notes set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 18, 2022.

Reclassifications

Certain amounts in the Company's consolidated balance sheet as of December 31, 2021 have been reclassified to conform to the current presentation. Prepaid insurance in the amount of $1,697 and other current assets related to leasing arrangement, net in the amount of $109 has been reclassified to prepaid expenses and other current assets. In addition, certain current liabilities totaling $2,164, which were previously classified as accrued compensation, accrued outside research and development services, and accrued legal and professional fees, have been reclassified to all be included in accrued expenses to conform with the current presentation.

These reclassifications had no impact on the Company's consolidated current assets, current liabilities or on the consolidated statements of operations and comprehensive loss or cash flows as of and for the year ended December 31, 2021.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the three and nine months ended September 30, 2022 and 2021, comprehensive loss was equal to net loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Basic shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which requires little or no consideration for the delivery of shares of common stock.

Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are anti-dilutive for all periods presented.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding for the three and nine months ended September 30, 2022 and September 30, 2021 because the effect is anti-dilutive due to the net loss reported in each of those periods. All share amounts presented in the table below represent the total number outstanding as of the end of each period.

	September 30,	
	2022	2021
Warrants to purchase common stock (Note 11)	5,535,637	1,274,176
Stock options outstanding under the 2008 and 2016 Plans (Note 16)	1,044,753	392,058
Nonvested restricted stock units (Note 16)	464,206	—
Stock appreciation rights outstanding under the 2016 Plan (Note 16)	60,000	60,000
Inducement stock options outstanding (Note 16)	1,250	1,250

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker. The Company's chief operating decision maker reviews financial information on a disaggregated basis for purposes of allocating resources and evaluating financial performance. See Note 18—"Segment Information" for further information on reportable segments.

Revenue Recognition

The Company accounts for revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company (i) identifies the contract with a customer, (ii) identifies the performance obligations within the contract, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations in the contract, and (v) recognizes revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Upon occurrence of a contract modification, the Company conducts an evaluation pursuant to the modification framework in ASC 606 to determine the appropriate revenue recognition. The framework centers around key questions, including (i) whether the modification adds additional goods and services, (ii) whether those goods and services are distinct, and (iii) whether the contract price increases by an amount that reflects the standalone selling price for the new goods or services. The resulting conclusions will determine whether the modification is treated as a separate, standalone contract or if it is combined with the original contract and accounted for in that manner. In addition, some modifications are accounted for on a prospective basis and others on a cumulative catch-up basis.

The Company currently has the following types of revenue generating arrangements:

Net Product Revenues

Net product revenues encompass sales recognized resulting from transferring control of products to the customer, excluding amounts collected on behalf of third parties and sales taxes. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when legal transfer of title has occurred, based on shipping terms. The Company records a reduction to the transaction price for estimated chargebacks, rebates, coupons, trade and cash discounts and sales returns. A liability is recognized for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present as the typical payment terms are less than one year. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. The Company recognizes provisions at the time of sale and adjusts them if the actual amounts differ from the estimated provisions. The following describes the nature of each deduction and how provisions are estimated:

Chargebacks – The Company has arrangements with various third-party wholesalers that require the Company to issue a credit to the wholesaler for the difference between the invoice price to the wholesaler and the customer's contract price. Provisions for chargebacks involve estimates of the contract prices within multiple contracts with multiple wholesalers. The provisions for chargebacks vary in relation to changes in product mix, pricing and the level of inventory at the wholesalers and, in addition, fluctuate in proportion to an increase or decrease in sales. Provisions for estimated chargebacks are calculated using the historical chargeback experience and expected chargeback levels for new products and anticipated pricing changes. Chargeback provisions are compared to externally obtained distribution channel reports for reasonableness. The Company regularly monitors the provisions for chargebacks and makes adjustments when the Company believes that actual chargebacks may differ from estimated provisions.

Rebates – Rebates include managed care services, fee for service and Medicaid rebate programs. Rebates are primarily related to volume-based incentives and are offered to key customers to promote loyalty. Customers receive rebates upon the attainment of a pre-established volume or the attainment of revenue milestones for a specified period. Since rebates are contractually agreed upon, provisions are estimated based on the specific terms in each agreement based on historical trends and expected sales.

Returns – Returns primarily relate to customer returns of expired products that the customer has the right to return up to one year following the product's expiration date. Such returned products are destroyed and credits and/or refunds are issued to the customer for the value of the returns. Accordingly, no returned assets are recorded in connection with those products. The returns provision is estimated by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Revenue subject to returns is estimated based on the lag time from time of sale to date of return. The estimated lag time is developed by analyzing historical experience. Additionally, the Company considers specific factors, such as levels of inventory in the distribution channel, product dating and expiration, size and maturity of launch, entrance of new competitors, changes in formularies or packaging and any changes to customer terms, in determining the overall expected levels of returns.

Prompt pay discounts – Prompt pay discounts are offered to most customers to encourage timely payment. Discounts are estimated at the time of invoice based on historical discounts in relation to sales. Prompt pay discounts are almost always utilized by customers. As a result, the actual discounts typically do not vary significantly from the estimated amount.

Coupons – The Company offers coupons to market participants in order to stimulate product sales. The redemption cost of consumer coupons is based on historical redemption experience by product and value.

Sales and other taxes the Company collects concurrent with revenue-producing activities are excluded from revenue. Shipping and handling costs are accounted for as a fulfillment cost and are recorded as cost of revenue. Incidental items that are immaterial in the context of the contract are recognized as expense. Costs incurred to obtain a contract will be expensed as incurred when the amortization period is less than a year.

There can be a lag between the Company's establishment of an estimate and the timing of the invoicing or claim. The Company believes it has made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated.

License and Collaboration Revenues

The Company has entered into various types of agreements that either license the Company's intellectual property to a third party or acquire license rights to intellectual property of a third party, or both.

Agreements where the Company licenses its intellectual property to a third party for development and commercialization in a licensed territory. If the applicable license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company's management utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. The Company re-evaluates the estimated performance period and measure of progress each reporting period and, if necessary, adjusts related revenue recognition accordingly. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, the Company does not recognize any contingent payments until after regulatory approval has been achieved.

Agreements where the Company acquires licensed rights to, or otherwise accesses, a third party's intellectual property for commercialization of the third party's product in a licensed territory. The Company also enters into various types of arrangements to commercialize products. The Company's services provided to the third party under such arrangements, in exchange for compensation that may take the form of cost reimbursements, may include promoting, marketing, selling and distributing the third party's developed drugs, and may also involve certain license rights granted to the parties for use of the other party's intellectual property while providing defined services under the arrangements. The Company assesses the nature of each such arrangement and the various rights granted and services performed thereunder, and determines the applicable accounting standard, which may include ASC 808*, Collaborative Arrangements* ("ASC 808") or ASC 606.

Royalty revenue from licenses provided to the Company's collaboration partners, which is based on sales to third parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied. This royalty revenue is included in license and collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive loss.

When the Company performs and incurs marketing and promotional services expense under an arrangement that is determined to be within the scope of ASC 808, and where such services are on behalf of a collaboration partner that is not considered a customer under ASC 606, the Company recognizes a contra-expense that reflects the value of the cost reimbursement to which the Company is expected to be entitled in exchange for those services.

Such contractually required reimbursements are reported as a liability or an asset within the accompanying condensed consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

Government research contracts and grants revenue

Under the terms of the contracts and grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts. Revenues from development and support activities under government research contracts and grants are recorded in the period in which the related costs are incurred. Associated expenses are recognized when incurred as research and development expense. Revenue recognized in excess of amounts collected from funding sources is recorded as accounts receivable. Any of the funding sources may, at their discretion, request reimbursement for expenses or return of funds, or both, as a result of noncompliance by the Company with the terms of the grants. No reimbursement of expenses or return of funds has been requested or made since inception of the contracts and grants.

Product Cost of Goods Sold

Product cost of goods sold includes the direct costs attributable to the Company's product revenue. It includes the cost of the purchased finished goods, shipping and storage costs related to the Company's marketed drug products, sales based royalty and milestone expenses, and certain third-party intellectual property licensing costs.

Advertising Costs

Promotion, marketing and advertising costs are expensed as incurred. Promotion, marketing and advertising costs for the three and nine months ended September 30, 2022, were approximately $710 and $1,288, respectively. There were no costs for the three and nine months ended September 30, 2021. The costs are included in selling, general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

Income Taxes

Deferred tax assets and liabilities are determined based on the temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. In estimating future tax consequences, all expected future events are considered other than enactment of changes in the tax law or rates.

The Company did not record a federal or state income tax benefit for the three and nine months ended September 30, 2022 or 2021 due to its conclusion that a full valuation allowance is required against the Company's deferred tax assets.

The determination of recording or releasing a tax valuation allowance is made, in part, pursuant to an assessment performed by management regarding the likelihood that the Company will generate future taxable income against which benefits of its deferred tax assets may or may not be realized. This assessment requires management to exercise judgment and make estimates with respect to its ability to generate taxable income in future periods.

Restricted Cash

Restricted cash as of September 30, 2022 and December 31, 2021 includes funds maintained in a deposit account to secure a letter of credit for the benefit of the lessor of the Company's headquarters. See Note 6—"Leases" for further information regarding the letter of credit.

Accounts Receivable, net

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables. An account receivable is considered to be past due if any portion of the receivable balance is outstanding beyond the agreed-upon due date.

The Company records an allowance for credit losses, which includes a provision for expected losses based on historical write-offs, adjusted for current conditions as deemed necessary, reasonable and supportable forecasts about future conditions that affect the expected collectability of the reported amount of the financial asset, as well as a specific reserve for accounts deemed at risk. The allowance is the Company's estimate for accounts receivable as of the balance sheet date that ultimately will not be collected. Any changes in the allowance are reflected in the results of operations in the period in which the change occurs. No allowance for credit losses was recorded as of September 30, 2022 or December 31, 2021 as all amounts included in accounts receivable are expected to be collected.

Account balances are written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Recoveries of receivables previously written off are recorded when received. The Company does not charge interest on accounts receivable.

As part of the EPI Health Acquisition, accounts receivable, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

Inventory, net

The Company maintains inventory consisting of for-sale pharmaceuticals related to its marketed product portfolio. The Company measures inventory using the first-in, first-out method and values inventory at the lower of cost or net realizable value. Net realizable value represents the estimated selling price for inventories less all estimated costs to sell.

The Company performs an analysis and records a provision for potentially obsolete inventory. The reserve for obsolescence is generally an estimate of the amount of inventory held at period end that is expected to expire in the future based on projected sales volume and expected product expiration or sell-by dates. These assumptions require the Company to analyze the aging of and forecasted demand for its inventory and make estimates regarding future product sales.

Property and Equipment, net

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the shorter of the life of the lease or the useful life of the improvements. Expenditures for maintenance and repairs are expensed as incurred. Improvements and betterments that add new functionality or extend the useful life of an asset are capitalized. Leases for real estate often include tenant improvement allowances, which the Company assesses according to applicable accounting guidance to determine the appropriate owner, and capitalizes such tenant improvement assets accordingly.

Intangible Assets, net and Goodwill

Intangible assets represent certain identifiable intangible assets, including pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term of the agreement and the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, then management compares the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being determined for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, such as goodwill and the cost to obtain and register the Company's internet domain, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at September 30 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test.

A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in the Company's stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Key assumptions used in the annual goodwill impairment test are highly judgmental. Any change in these indicators or key assumptions could have a significant negative impact on the Company's financial condition, impact the goodwill impairment analysis or cause the Company to perform a goodwill impairment analysis more frequently than once per year.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to the EPI Health Acquisition. The estimated fair value of contingent consideration was determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration. See Note 2—"Acquisition of EPI Health" for further information regarding purchase consideration.

Contingent consideration is remeasured at each reporting date and any changes in the liability are recorded within the consolidated statement of operations and comprehensive loss. See Note 17—"Fair Value" for further information.

Classification of Warrants Issued in Connection with Offerings of Common Stock

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and remeasured each balance sheet date thereafter. Changes in the estimated fair value of the liability-classified warrants are recognized as a non-cash gain or loss in the accompanying condensed consolidated statements of operations and comprehensive loss.

Related Parties

Members of the Company's board of directors held 124,497 and 100,497 shares of the Company's common stock as of September 30, 2022 and December 31, 2021, respectively.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which is designed to provide financial statement users with more information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. When determining such expected credit losses, the guidance requires companies to apply a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The adoption of this new accounting guidance, as of January 1, 2022, did not have a material impact on the Company's condensed consolidated financial statements.

Note 2: Acquisition of EPI Health

On March 11, 2022, the Company completed the EPI Health Acquisition, in which the Company acquired all of the issued and outstanding units of membership interest of EPI Health from EPG for an estimated fair value of purchase consideration of $32,046. EPI Health is an integrated medical dermatology company providing the Company with a commercial infrastructure to support the commercialization of products. Subsequent to the EPI Health Acquisition, the Company sells various dermatological products for the treatments of plaque psoriasis, rosacea, acne and dermatoses.

At closing, the Company paid or committed to pay non-contingent consideration totaling $27,500, as adjusted for cash, indebtedness, net working capital estimates and other contractually defined adjustments (the "Closing Purchase Price"). The Closing Purchase Price consisted of (i) $11,000 paid in cash, (ii) a secured promissory note issued to EPG in the principal amount of $16,500 (the "Seller Note"), and (iii) a $993 payment representing an adjustment for estimated net working capital. See Note 9—"Notes Payable" for additional detail regarding the Seller Note and its related terms.

The purchase agreement entered into in connection with the EPI Health Acquisition (the "EPI Heath Purchase Agreement") included the potential payment of additional contingent consideration totaling up to $23,500 upon achievement of certain milestones, as follows:

a. $1,000, as a one-time cash payment, upon EPG's performance of transition services and the successful completion of the transition provided under the transition services agreement between the Company and EPG;

b. $3,000, as a one-time payment, payable in cash or the Company's common stock, at the discretion of the Company, upon net sales of certain of EPI Health's legacy products exceeding $30,000 during the period from April 1, 2022 through March 31, 2023;

c. up to $2,500, paid in quarterly installments in cash or the Company's common stock at the discretion of the Company, upon net sales of Wynzora Cream ("Wynzora") exceeding certain quarterly thresholds or an annual threshold of $12,500 during the period from April 1, 2022 through March 31, 2023;

d. $5,000, as a one-time payment, payable in cash or the Company's common stock at the discretion of the Company, upon the first occurrence of post-closing net sales of certain of EPI Health's legacy products exceeding $35,000 during any twelve-month period from April 1, 2023 through March 31, 2026; and

e. up to $12,000 based on receipt by EPI Health of regulatory and net sales milestones related to Sitavig from EPI Health's OTC Switch License Agreement with Bayer.

Certain of the above milestone payments will accelerate and become immediately payable upon certain specified events during the applicable milestone periods, including a sale of all or substantially all of the assets with respect to certain of EPI Health's legacy products. The EPI Health Purchase Agreement provides that payment of any additional consideration may be made in cash or in shares of the Company's common stock, so long as the number of shares that may be issued pursuant to the EPI Health Purchase Agreement or otherwise in connection with the EPI Health Acquisition is limited to no more than 19.99% of the Company's outstanding shares of common stock immediately prior to the closing, unless stockholder approval is obtained to issue more than 19.99%.

The EPI Health Acquisition is being accounted for as a business combination using the acquisition method in accordance with ASC 805. Under this method of accounting the fair value of the consideration transferred is allocated to the assets acquired and liabilities assumed based upon their estimated fair values on the date of the EPI Health Acquisition. Any excess of the purchase price over the fair value of identified assets acquired and liabilities assumed is recognized as goodwill.

For the nine months ended September 30, 2022, the Company incurred costs related to the EPI Health Acquisition of $4,811 recognized in selling, general and administrative expenses within the condensed consolidated statements of operations and comprehensive loss.

From the EPI Health Acquisition date through September 30, 2022, $11,202 of total net revenue and a net loss of $3,461 associated with EPI Health's operations are included in the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2022.

Purchase Consideration

The following table presents the estimated fair value of purchase consideration as of each interim reporting period end date since the EPI Health Acquisition date, including measurement period adjustments made during each interim period. The estimated fair value of purchase consideration is then allocated to the estimated fair values of the net assets acquired at the EPI Health Acquisition date, as described further following the table under the section entitled *Provisional Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired.*

	As of March 11, 2022	Measurement Period Adjustments		As of June 30, 2022	Measurement Period Adjustments		As of September 30, 2022
Initial cash consideration to Seller	$ 11,000	$ —		$ 11,000	$ —		$ 11,000
Secured promissory note issued to Seller	16,500	—		16,500	(3,195)	**(B)**	13,305
Closing date fair value of contingent consideration liability	3,773	—		3,773	(125)	**(C)**	3,648
Remaining working capital adjustment to be paid	4,069	(969)	**(A)**	3,100	—		3,100
Working capital adjustment paid at close	993	—		993	—		993
Total estimated purchase consideration	$ 36,335	$ (969)		$ 35,366	$ (3,320)		$ 32,046

A. On July 7, 2022, the Company and EPG agreed to the final net working capital adjustment amount (the "Total Adjustment Amount"), as defined in the EPI Health Purchase Agreement, as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The Total Adjustment Amount was determined to be positive and in the amount of $3,100, which was paid to EPG on July 7, 2022. As of March 31, 2022, the Company had previously estimated that the Total Adjustment Amount would be $4,069. Therefore, the Company has reflected a $969 measurement period adjustment to the estimated fair value of total purchase consideration. As this adjustment related to the estimated fair value of purchase consideration and did not affect the fair value of any assets acquired or liabilities assumed, it resulted in a reduction of goodwill.

B. During the third quarter of 2022, the Company, with the assistance of a third-party valuation specialist, continued to conduct a fair value assessment of the Seller Note as of the EPI Health Acquisition date of March 11, 2022. The Company completed the fair value assessment and updated the Seller Note fair value estimate as of March 11, 2022 to $13,305 via a downward measurement period adjustment of $3,195 during the interim quarterly period ended September 30, 2022. See Note 9—"Notes Payable" to these condensed consolidated interim financial statements for further discussion regarding the Seller Note, including its repayment and termination during the third quarter of 2022.

C. During the third quarter of 2022, the Company, with the assistance of a third-party valuation specialist, continued to conduct a fair value assessment of the contingent consideration liability as of the EPI Health Acquisition date of March 11, 2022. The Company updated the contingent consideration provisional fair value estimate as of March 11, 2022 to $3,648 via a downward measurement period adjustment of $125 during the interim quarterly period ended September 30, 2022, based on progression of the fair value assessment procedures conducted to date.

Provisional Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired

ASC 805 requires, among other things, that the assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. Further, ASC 805 requires any consideration transferred or paid in a business combination in excess of the fair value of the assets acquired and liabilities assumed should be recognized as goodwill.

The total estimated purchase consideration was provisionally allocated to the estimated fair values of the assets acquired and liabilities assumed as of March 11, 2022 as follows:

	As of March 11, 2022	Measurement Period Adjustments		As of June 30, 2022	Measurement Period Adjustments		As of September 30, 2022
Assets acquired and liabilities assumed:							
Accounts receivable	$ 20,083	$ —		$ 20,083	$ —		$ 20,083
Inventory	1,710	—		1,710	(410)	(B)	1,300
Prepaid expenses and other current assets	3,692	—		3,692	—		3,692
Property and equipment	100	—		100	—		100
Intangible assets	33,000	—		33,000	(4,000)	(C)	29,000
Other assets	27	—		27	—		27
Right-of-use lease assets	400	—		400	—		400
Total assets	$ 59,012	$ —		$ 59,012	$ (4,410)		$ 54,602
Accounts payable	$ 947	$ —		$ 947	$ —		$ 947
Accrued expenses	24,892	—		24,892	—		24,892
Operating lease liabilities, current portion	208	—		208	—		208
Operating lease liabilities, net of current portion	342	—		342	—		342
Other long-term liabilities	290	—		290	—		290
Total liabilities	$ 26,679	$ —		$ 26,679	$ —		$ 26,679
Total identifiable net assets acquired	$ 32,333	$ —		$ 32,333	$ (4,410)		$ 27,923
Goodwill	4,002	(969)	(A)	3,033	1,090	(D)	4,123
Total estimated purchase consideration	$ 36,335	$ (969)		$ 35,366	$ (3,320)		$ 32,046

A. On July 7, 2022, the Company and EPG agreed to the final net working capital adjustment amount (the "Total Adjustment Amount"), as defined in the EPI Health Purchase Agreement, as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The Total Adjustment Amount was determined to be positive and in the amount of $3,100, which was paid to EPG on July 7, 2022. As of March 31, 2022, the Company had previously estimated that the Total Adjustment Amount would be $4,069. Therefore, the Company has reflected a $969 measurement period downward adjustment to the estimated fair value of total purchase consideration. As this adjustment related to the estimated fair value of purchase consideration and did not affect the fair value of any assets acquired or liabilities assumed, it resulted in a reduction of goodwill.

B. During the third quarter of 2022, the Company, with the assistance of a third-party valuation specialist, continued to conduct a fair value assessment of the trade inventory on hand as of the EPI Health Acquisition date of March 11, 2022. The Company updated the trade inventory's provisional fair value estimate as of March 11, 2022 to $1,300 via a downward measurement period adjustment of $410 during the interim quarterly period ended September 30, 2022, based on progression of the fair value assessment procedures conducted to date.

C. During the third quarter of 2022, the Company, with the assistance of a third-party valuation specialist, continued to conduct a fair value assessment of the acquired definite-lived intangible product rights assets as of the EPI Health Acquisition date of March 11, 2022, which included further analysis of the forecasts used in the initial preliminary valuation. This downward measurement period adjustment also resulted in the recognition of $192 of additional amortization expense during the interim quarterly period ended September 30, 2022.

D. The aforementioned measurement period adjustments made to the acquired assets and assumed liabilities, as well as the measurement period adjustments made to the estimated fair value of purchase consideration in the preceding section entitled *Purchase Consideration*, result in an updated goodwill balance of $4,123 as of September 30, 2022 based on a net upward adjustment of $1,090 during the interim quarterly period ended September 30, 2022.

The Company determined the estimated fair value of the acquired intangible assets as of the closing date using the income approach. This is a valuation technique that is based on the market participant's expectations of the cash flows that the intangible assets are forecasted to generate. The projected cash flows from these intangible assets were based on various assumptions, including estimates of revenues, expenses, and operating profit, and risks related to the viability of and commercial potential for alternative treatments. The cash flows were discounted at a rate commensurate with the level of risk associated with the projected cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

Goodwill was determined on the basis of the provisional fair values of the assets and liabilities identified at the time of the EPI Health Acquisition. The estimated provisional allocation of purchase consideration will be adjusted, within a period of no more than 12 months from the EPI Health Acquisition date, if these fair values change further as a result of circumstances existing at the acquisition date. These measurement period adjustments may arise with regard to amounts recorded as assets and liabilities upon verification of such amounts or upon finalization of the required valuations of intangible assets identified. The amounts of reserves and provisions may also be adjusted as a result of ongoing procedures to identify and measure liabilities, including tax, environmental risks and litigation. The purchase consideration may also be adjusted further in connection with finalizing the valuation procedures for the contingent consideration liability and any potential changes in the fair value of the Seller Note. Any further adjustments to amounts may impact the valuation of the consideration or the amounts recorded as goodwill.

Goodwill was calculated as the excess of the consideration paid consequent to completing the acquisition, compared to the net assets recognized. Goodwill represents the future economic benefits arising from the other acquired assets, which could not be individually identified and separately valued. Goodwill is primarily attributable to the acquired commercial platform and infrastructure, including personnel, and expected synergies related to the commercialization of product candidates.

Pro forma Information

The following pro forma information presents the combined results of operations for the three and nine months ended September 30, 2022 and 2021, as if the Company had completed the EPI Health Acquisition at the beginning of the periods presented. The pro forma financial information is provided for comparative purposes only and is not indicative of what actual results would have been had the EPI Health Acquisition occurred at the beginning of the periods presented, nor does it give effect to synergies, cost savings, fair market value adjustments, and other changes expected to result from the EPI Health Acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs.

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Total revenue	$ 5,115	$ 4,292	$ 17,220	$ 14,182
Net loss and comprehensive loss	(6,030)	(21,029)	(29,342)	(42,034)
Net loss per share, basic and diluted	$ (0.25)	$ (1.12)	$ (1.38)	$ (2.55)

Note 3: Inventory, net

The major components of inventory, net, were as follows:

	September 30, 2022
Finished goods available for sale	$ 1,190
Reserve for obsolescence	(12)
Inventory, net	$ 1,178

As part of the EPI Health Acquisition, inventory, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

Note 4: Prepaid Expenses and Other Current Assets

The following table represents the components of prepaid expenses and other current assets as of:

	September 30, 2022	December 31, 2021
Inventory and raw material deposits	$ 1,190	$ —
Prepaid service contracts	294	—
Prepaid insurance	619	1,697
Product samples	1,012	—
Other current assets related to leasing arrangement	—	109
Prepaid expenses and other current assets	549	766
Total prepaid expenses and other current assets	$ 3,664	$ 2,572

Note 5: Property and Equipment, net

Property and equipment consisted of the following:

	September 30, 2022	December 31, 2021
Computer equipment	$ 101	$ 58
Furniture and fixtures	100	23
Laboratory equipment	5,865	4,134
Office equipment	177	177
Leasehold improvements	10,072	9,391
Property and equipment, gross	16,315	13,783
Less: Accumulated depreciation and amortization	(2,394)	(1,582)
Total property and equipment, net	$ 13,921	$ 12,201

Depreciation and amortization expense was $468 and $812 for the three and nine months ended September 30, 2022, respectively, and $104 and $242 for the three and nine months ended September 30, 2021, respectively.

Corporate and Manufacturing Facility

As of September 30, 2022 and December 31, 2021, the Company had construction in progress amounts related to leasehold improvements of $160 and $7,485, respectively.

See Note 6—"Leases" for details regarding the TBC Lease (as defined below) and the Company's corporate and manufacturing facility.

Note 6: Leases

The Company leases office space and certain equipment under non-cancelable lease agreements.

In accordance with ASC 842, *Leases*, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease, if available, or otherwise at the Company's incremental borrowing rate. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elected, and has in practice, historically combined lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

Office Lease at Triangle Business Center, Durham, North Carolina

On January 18, 2021, the Company entered into a lease with an initial term expiring in 2032, as amended for 19,265 rentable square feet, located in Durham, North Carolina. This lease dated as of January 18, 2021, as amended (the "TBC Lease"), is by and between the Company and Copper II 2020, LLC (the "TBC Landlord"), pursuant to which the Company is leasing space serving as its corporate headquarters and small-scale manufacturing site (the "Premises") located within the Triangle Business Center. The lease executed on January 18, 2021, as amended, was further amended on November 23, 2021 to expand the Premises by approximately 3,642 additional rentable square feet from 15,623 rentable square feet.

The Premises serves as the Company's corporate headquarters and supports various cGMP activities, including research and development and small-scale manufacturing capabilities. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a primary, or secondary backup, component of a potential future commercial supply chain.

The TBC Lease commenced on January 18, 2021 (the "Lease Commencement Date"). Rent under the TBC Lease commenced in October 2021 (the "Rent Commencement Date"). The term of the TBC Lease expires on the last day of the one hundred twenty-third calendar month after the Rent Commencement Date. The TBC Lease provides the Company with one option to extend the term of the TBC Lease for a period of five years, which would commence upon the expiration of the original term of the TBC Lease, with base rent of a market rate determined according to the TBC Lease; however, the renewal period was not included in the calculation of the lease obligation as the Company determined it was not reasonably certain to exercise the renewal option.

The monthly base rent for the Premises is approximately $40 for months 1-10 and approximately $49 for months 11-12, per the second amendment to the primary lease. Beginning with month 13 and annually thereafter, the monthly base rent will be increased by 3%. Subject to certain terms, the TBC Lease provides that base rent will be abated for three months following the Rent Commencement Date. The Company is obligated to pay its pro-rata portion of taxes and operating expenses for the building as well as maintenance and insurance for the Premises, all as provided for in the TBC Lease.

The TBC Landlord has agreed to provide the Company with a tenant improvement allowance in an amount not to exceed $130 per rentable square foot, totaling approximately $2,450, per the primary lease, inclusive of the first amendment, and $115 per rentable square foot, totaling $419, per the second amendment to the TBC Lease. The tenant improvement allowance will be paid over four equal installments corresponding with work performed by the Company. Pursuant to the terms of the TBC Lease, the Company delivered to the TBC Landlord a letter of credit in the amount of $583, as amended, as collateral for the full performance by the Company of all of its obligations under the TBC Lease and for all losses and damages the TBC Landlord may suffer as a result of any default by the Company under the TBC Lease. Cash funds maintained in a separate deposit account at the Company's financial institution to fully secure the letter of credit are presented as restricted cash in non-current assets on the accompanying condensed consolidated balance sheets.

Office Lease at Meeting Street, Charleston, South Carolina

On March 3, 2022 EPI Health entered into a sublease agreement with EPG (the "Meeting Street Lease") for office space at 174 Meeting Street in Charleston, South Carolina for approximately 6,000 rentable square feet.

The term of the Meeting Street Lease was initially through September 30, 2024, and EPI Health had the right to terminate the Meeting Street Lease with prior notice. On August 31, 2022, EPI Health notified EPG of its termination of the sublease effective February 28, 2023. The monthly base rent for the Meeting Street Lease is $20 for months 1-12, inclusive of taxes and operating expenses such as maintenance and insurance.

TBC Lease and Meeting Street Lease

Rent expense, including both short-term and variable lease components associated with the TBC Lease and the Meeting Street Lease, as applicable, was $140 and $425 for the three and nine months ended September 30, 2022, respectively. Rent expense was $100 and $356 for the three and nine months ended September 30, 2021, respectively.

The remaining lease term for the TBC Lease and the Meeting Street Lease are 9.42 years and 0.42 years, respectively, as of September 30, 2022. The weighted average discount rate for both leases was 8.35% as of September 30, 2022.

Future net minimum lease payments, net of amounts expected to be received related to the tenant improvement allowance, as of September 30, 2022 were as follows:

Maturity of Lease Liabilities		**Operating Lease**
2022	$	210
2023		229
2024		626
2025		645
2026		665
2027 and beyond		3,700
Total future undiscounted lease payments	$	6,075
Less: imputed interest		(2,020)
Total reported lease liability	$	4,055

The table above reflects payments for an operating lease with a remaining term of one year or more, but does not include obligations for short-term leases. In addition, the net cash outflows related to the 2022 and 2023 fiscal years presented above includes the expected timing of the remaining balance of the total tenant improvement allowance of $2,450 being funded by the TBC Landlord, which the Company reasonably expects to receive within the next twelve months. During the year ended December 31, 2021, the Company received $2,031 related to payments as part of the total TBC Landlord funded tenant improvement allowance.

Components of lease assets and liabilities as of September 30, 2022 were as follows:

		September 30, 2022
Assets		
Right-of-use lease assets	$	1,794
Total lease assets	$	1,794
Liabilities		
Operating lease liabilities, current portion	$	254
Operating lease liabilities, net of current portion		3,801
Total lease liabilities	$	4,055

Note 7: Goodwill and Intangible Assets, net

Goodwill

The Company's goodwill balance as of September 30, 2022 was $4,123. The entire goodwill balance relates to the EPI Health Acquisition during the nine months ended September 30, 2022. None of the goodwill is expected to be deductible for income tax purposes.

Intangible Assets

The following table presents both definite and indefinite lived intangible assets as of September 30, 2022, comprised primarily of acquired product rights related to the EPI Health Acquisition:

	Initial Carrying Value	Accumulated Amortization	Net Book Value	Remaining Useful Life (Years)
Rhofade	$ 15,500	$ 575	$ 14,925	14.5
Wynzora	2,000	74	1,926	14.5
Minolira	8,500	315	8,185	14.5
Cloderm	1,000	37	963	14.5
Sitavig	2,000	111	1,889	9.5
Website domain	75	—	75	—
Total intangible assets	$ 29,075	$ 1,112	$ 27,963	

The Company amortizes the product rights related to its commercial product portfolio over their estimated useful lives. As part of the EPI Health Acquisition, product rights were recorded at fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

The following table represents annual amortization of definite lived intangible assets for the next five fiscal years, and thereafter:

2022	$ 505
2023	2,000
2024	2,005
2025	2,000
2026	2,000
Thereafter	19,378
Total amortization	$ 27,888

Note 8: Accrued Expenses

The following table represents the components of accrued expenses as of September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
Accrued rebates, discounts and chargebacks	$ 13,066	$ —
Accrued returns	4,320	—
Accrued compensation	3,013	1,543
Accrued outside research and development services	175	194
Accrued legal and professional fees	451	—
Accrued royalties	714	—
Accrued construction in process	276	1,020
Accrued SB206 pre-commercial and marketing	107	—
Accrued Wynzora payments due to collaborator	267	—
Accrued MC2 collaboration deposit	2,799	—
Accrued other expenses	2,438	2,231
Total accrued expenses	$ 27,626	$ 4,988

Note 9: Notes Payable

Seller Note with Evening Post Group

On March 11, 2022, at the closing of the EPI Health Acquisition, the Company entered into a secured promissory note and security agreement with EPG. The Company entered into the Seller Note with EPG to finance a portion of the Closing Purchase Price related to the EPI Health Acquisition.

The Seller Note had a principal amount of $16,500 with interest-only payments due over the course of the 24-month term of the Seller Note. The Seller Note bore interest at the rate of 5.0% per annum for the first 90 days after the closing date, 15.0% per annum for the following 12 months, and 18.0% per annum for the remainder of the term. The non-amortizing principal of the Seller Note was to be paid in full at maturity and was secured by the membership interests of EPI Health held by the Company. EPI Health was a guarantor of the Seller Note. There was no penalty for repaying the Seller Note prior to the end of the term. Based on the escalating interest rate over the term of the Seller Note, the Company recorded interest expense using the effective interest method.

During the three and nine months ended September 30, 2022, the Company recorded interest expense of $635 and $1,375, respectively, related to the Seller Note, of which $635 related to accretion of the debt discount which was recorded as part of the measurement period adjustment in the current period to the Seller Note’s fair value estimate.

On July 13, 2022, the Company reached agreement with EPG regarding payment and termination of the Seller Note. Upon the Company’s payment to EPG of $10,000, or an approximate 39% discount on the original principal amount of the Seller Note, the Seller Note and all related security agreements were terminated.

Pursuant to the terms of the Seller Note, there was no penalty for repaying the Seller Note prior to the end of the term. In connection with the repayment of the Seller Note, the guaranty agreement between EPG and EPI Health, dated March 11, 2022, was terminated as of July 13, 2022. Accordingly, the liens on the membership interests and assets of EPI Health were also terminated such that no obligations with respect to the Seller Note and related securities agreement or the underlying loan remain outstanding.

Upon repayment and termination of the Seller Note, the Company recognized a $4,340 gain on debt extinguishment within the condensed consolidated statements of operations and comprehensive loss. This gain represents (i) the $3,939 difference between the Seller Note’s $10,000 termination and settlement value and its $13,939 carrying value at the date of termination; and (ii) a $401 write-off of accrued interest outstanding upon termination of the Seller Note.

See Note 2—"Acquisition of EPI Health” for additional detail regarding the Seller Note as it relates to the EPI Health purchase consideration and its estimated fair value and measurement period adjustments.

Note 10: Commitments and Contingencies

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for any such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. See the section entitled *Legal Proceedings* below for further discussion of pending legal claims.

The Company has entered into, and expects to continue to enter into, contracts in the normal course of business with various third parties that support its clinical trials, preclinical research studies, development services, and commercial sales and marketing activities in addition to potential third-party manufacturers for both the manufacture of the Company's product candidates and procurement of its commercial finished good products. The scope of the services under these agreements can generally be modified at any time, and these agreements can generally be terminated by either party after a period following written notice.

In connection with entering into the Equity Distribution Agreement with Oppenheimer discussed in Note 11—"Stockholders' Equity," the Company terminated its common stock purchase agreement with Aspire Capital on March 10, 2022. Other than such termination and the repayment and termination of the Seller Note discussed in Note 9—"Notes Payable," there have been no material contract terminations as of September 30, 2022.

Also, see Note 11—"Stockholders' Equity" regarding outstanding common stock warrants and pre-funded warrants.

Contingent Payment Obligations Related to the Purchase of EPI Health

See Note 2—"Acquisition of EPI Health" for certain contingent payments related to consideration due to EPG upon achievement of certain milestones by EPI Health.

Contingent Payment Obligations from Historical Acquisitions by EPI Health

EPI Health has in the past acquired certain rights to pharmaceutical products and such arrangements have typically included requirements that EPI Health make certain contingent payments to the applicable seller as discussed below.

Rhofade. On October 10, 2019, EPI Health entered into an agreement whereby it acquired certain assets related to Rhofade (the "Rhofade Acquisition Agreement"). In connection with the Rhofade Acquisition Agreement, EPI Health is required to make the following milestone payments to the seller upon reaching the following net sales thresholds during any calendar year following the closing date, as defined in the Rhofade Acquisition Agreement:

Calendar Year Net Sales Threshold	Milestone Payment
$ 50,000	$ 5,000
$ 75,000	$ 5,000
$ 100,000	$ 10,000

Under the terms of the Rhofade Acquisition Agreement, EPI Health assumed certain liabilities of the prior licensees of the product Rhofade. In particular, EPI Health is required to pay certain earnout payments pursuant to historic acquisition agreements for Rhofade upon the achievement of net sales thresholds higher than those set forth above. However, the Company has not recognized a liability for such Rhofade milestones based on current and historical sales figures and management's estimates of future sales.

Cloderm. On September 28, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Cloderm. EPI Health is required to pay a low double-digit royalty once cumulative net sales of Cloderm reach $20,833, until $6,500 of royalty payments have been made by EPI Health.

Minolira. On August 20, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Minolira. In connection with the agreement, EPI Health is required to make the following milestone payments to the seller upon reaching cumulative net sales thresholds as defined in the acquisition agreement:

Cumulative Net Sales Threshold	Milestone Payment
$ 10,000	$ 1,000
$ 20,000	$ 1,000
Each additional $ 20,000	$ 1,500

See Note 12—"Licensing and Collaboration Arrangements" for certain obligations and contingent payments related to license agreements, including those related to the Company's commercial product portfolio.

Also, see Note 15—"Research and Development Agreements" for certain obligations regarding the Company's research and development license agreements, including the Reedy Creek Purchase Agreement and the Ligand Funding Agreement (each as defined below).

For the three and nine months ended September 30, 2022, the Company recorded $1,060 and $2,696, respectively, of expense related to royalties on net sales and accruals of certain cumulative sales-based milestones related to its commercial product portfolio, described above, including Wynzora residual net sales royalty payments due to the collaboration partner. As of September 30, 2022 the Company had (i) accrued royalties of $714 and accrued Wynzora royalty payments of $267, and (ii) accrued milestones of $366 presented within accrued expenses and other long-term liabilities, respectively, in its condensed consolidated balance sheets.

Development Services Agreement

In July 2021, the Company entered into a development services agreement with a third-party full-scale API manufacturer for certain manufacturing process feasibility services including process familiarization, safety assessments, preliminary engineering studies, and initial process and analytical methods determination. Following the successful completion of certain preliminary activities with this third-party API manufacturer and other preparatory activities, the Company would then proceed with the third-party API manufacturer beyond the initial stages noted above, in which case the Company expects to incur substantial costs associated with technical transfer efforts, capital expenditures, manufacturing capabilities, and certain quantities of its drug substance.

Legal Proceedings

The Company is not currently a party to any material legal proceedings and is not aware of any claims or actions pending against the Company that the Company believes could have a material adverse effect on the Company's business, operating results, cash flows or financial statements. In the future, the Company might from time to time become involved in litigation relating to claims arising from its ordinary course of business.

Compensatory Obligations

The Company enters into employment agreements with certain officers and employees. These agreements are in the normal course of business and contain certain customary Company controlled termination provisions which, if triggered, could result in future severance payments.

See Note 16—"Stock-Based Compensation" regarding stock options, stock appreciation rights and the Tangible Stockholder Return Plan.

Note 11: Stockholders' Equity

Capital Structure

In conjunction with the completion of the Company's initial public offering in September 2016, the Company amended its restated certificate of incorporation and amended and restated its bylaws. The amendment to the Company's certificate of incorporation provided for 210,000,000 authorized shares of capital stock, of which 200,000,000 shares are designated as $0.0001 par value common stock and 10,000,000 shares are designated as $0.0001 par value preferred stock.

At the Company's Annual Meeting of Stockholders held on July 28, 2020 (the "2020 Annual Meeting"), the Company's stockholders approved an amendment to the Company's restated certificate of incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio of not less than one-for-two and not more than one-for-fifteen, with such ratio and the implementation and timing of such reverse stock split to be determined by the Company's board of directors in its sole discretion. On May 18, 2021, the Company's board of directors approved a one-for-ten reverse stock split of the Company's issued and outstanding common stock. On May 24, 2021, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Restated Certification of Incorporation of the Company in order to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on May 25, 2021, and the Company's common stock began trading on a split-adjusted basis on May 26, 2021. As a result of the Reverse Stock Split, on the effective date thereof, each outstanding ten (10) shares of common stock combined into and became one (1) share of common stock, and the number of the Company's issued and outstanding shares of common stock was reduced to 15,170,678. The accompanying condensed consolidated financial statements and related notes give retroactive effect to the Reverse Stock Split.

Common Stock

The Company’s common stock has a par value of $0.0001 per share and consists of 200,000,000 authorized shares as of September 30, 2022 and December 31, 2021. There were 24,462,228 and 18,815,892 shares of voting common stock outstanding as of September 30, 2022 and December 31, 2021, respectively.

The Company had reserved shares of common stock for future issuance as follows:

	September 30, 2022	December 31, 2021
Outstanding warrants to purchase common stock	5,535,637	1,274,176
Outstanding stock options (Note 16)	1,046,003	518,553
Outstanding stock appreciation rights (Note 16)	60,000	60,000
Nonvested restricted stock units (Note 16)	464,206	—
For possible future issuance under the 2016 Stock Plan (Note 16)	221,568	1,213,224
	7,327,414	3,065,953

Preferred Stock

The Company’s restated certificate of incorporation provides the Company’s board of directors with the authority to issue $0.0001 par value preferred stock from time to time in one or more series by adopting a resolution and filing a certificate of designations. Voting powers, designations, preferences, dividend rights, conversion rights and liquidation preferences shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and no shares outstanding as of September 30, 2022 and December 31, 2021.

March 2022 Equity Distribution Agreement – At-the-Market Facility

On March 11, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement”) with Oppenheimer & Co. Inc. ("Oppenheimer”). Pursuant to the Equity Distribution Agreement, the Company may from time to time issue and sell to or through Oppenheimer, acting as the Company’s sales agent, shares of the Company’s common stock, par value $0.0001 per share having an aggregate offering price of up to $50,000. Sales of the shares, if any, will be made by any method permitted by law deemed to be an "at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933 ("Securities Act”), or, if expressly authorized by the Company, in privately negotiated transactions. As sales agent, Oppenheimer will offer the shares at prevailing market prices and will use its commercially reasonable efforts, consistent with its sales and trading practices, to sell on the Company’s behalf all of the shares requested to be sold by the Company, subject to the terms and conditions of the Equity Distribution Agreement. The Company or Oppenheimer may suspend the offering of the shares upon proper notice to the other party. The offering of the shares pursuant to the Equity Distribution Agreement will terminate upon the sale of shares in an aggregate offering amount equal to $50,000, or sooner if either the Company or Oppenheimer terminates the Equity Distribution Agreement as permitted by its terms.

The Company will pay Oppenheimer a commission equal to 3.0% of the aggregate gross proceeds from the sale of the shares sold pursuant to the Equity Distribution Agreement and will reimburse Oppenheimer for certain expenses incurred in connection with its services under the Equity Distribution Agreement. The foregoing rate of compensation will not apply when Oppenheimer acts as principal, in which case the Company may sell the shares to Oppenheimer as principal at a price agreed upon among the parties.

During the nine months ended September 30, 2022, the Company sold 385,025 shares of its common stock at an average price of approximately $3.58 per share for total net proceeds of $1,334 under the Equity Distribution Agreement.

In relation to the June 2022 Registered Direct Offering (as defined and described below), the Company agreed not to issue any additional securities in any variable rate transaction (as defined in the related securities purchase agreement), including under the Equity Distribution Agreement, until December 13, 2022, unless, on or after September 11, 2022, the VWAP (as defined in the related securities purchase agreement) for the trading day prior to the date of the transaction is greater than 50% above the exercise price for the June 2022 Common Warrants.

Outstanding Common Stock Warrants and Pre-funded Warrants

The Company has historically entered into certain equity offerings with underwriters and placement agents, such as the June 2022 Registered Direct Offering, the March 2020 Public Offering, the March 2020 Registered Direct Offering and the January 2018 Offering, that included certain common stock warrant and pre-funded warrant issuances.

The following table presents the Company’s outstanding warrants to purchase common stock and pre-funded warrants for the periods indicated.

	September 30, 2022	December 31, 2021	Exercise Price Per Share
Warrants to purchase common stock issued in the January 2018 Offering	—	999,850	$ 46.60
Warrants to purchase common stock issued in the June 2022 Registered Direct Offering	5,261,311	—	2.851
Warrants to purchase common stock issued in the March 2020 Public Offering	252,417	252,417	3.00
Underwriter warrants to purchase common stock associated with the March 2020 Public Offering	11,304	11,304	3.75
Placement agent warrants to purchase common stock issued in the March 2020 Registered Direct Offering	10,605	10,605	5.375
	5,535,637	1,274,176	

The weighted average exercise price per share for warrants outstanding as of September 30, 2022 and December 31, 2021 was $2.86 and $37.24, respectively.

June 2022 Registered Direct Offering

On June 9, 2022, the Company entered into a securities purchase agreement with an institutional investor (the "Purchaser"), pursuant to which the Company agreed to issue and sell to the Purchaser, in a registered direct offering priced at-the-market under Nasdaq rules (the "June 2022 Registered Direct Offering") (i) 2,080,696 shares (the "June 2022 Shares") of the Company's common stock, and accompanying common stock warrants (the "June 2022 Common Warrants") to purchase an aggregate of 2,080,696 shares of common stock, for a combined price of $2.851 per share and accompanying common warrant, and (ii) pre-funded warrants to purchase 3,180,615 shares of the Company's common stock (the "June 2022 Pre-funded Warrants") and accompanying common warrants to purchase 3,180,615 shares of common stock, for a combined price of $2.841 per pre-funded warrant and accompanying common warrant. The June 2022 Registered Direct Offering closed on June 13, 2022. Net proceeds from the offering were approximately $14,020 after deducting fees and commissions and offering expenses of approximately $948. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

As of September 30, 2022, no June 2022 Pre-funded Warrants and 5,261,311 June 2022 Common Warrants are outstanding.

The Company entered into a placement agent agreement (the "Placement Agent Agreement") dated as of June 9, 2022, engaging Oppenheimer to act as the sole placement agent in connection with the June 2022 Registered Direct Offering. Pursuant to the Placement Agent Agreement, the Company agreed to pay Oppenheimer a placement agent fee in cash equal to 5.0% of the gross proceeds from the sale of the June 2022 Shares, the June 2022 Pre-funded Warrants and the June 2022 Common Warrants, and to reimburse certain expenses of Oppenheimer in connection with the June 2022 Registered Direct Offering. Each June 2022 Pre-funded Warrant had an exercise price of $0.01 per share. The June 2022 Pre-funded Warrants were exercisable immediately upon issuance until all of the June 2022 Pre-funded Warrants were exercised in full. Each June 2022 Common Warrant is immediately exercisable and has an exercise price of $2.851 per share and will expire five years from the date of issuance.

The exercise price and the number of shares of common stock purchasable upon the exercise of the June 2022 Pre-funded Warrants and June 2022 Common Warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, reclassifications and combinations of the Company's common stock.

Common warrants. The June 2022 Common Warrants include certain provisions that establish warrant holder settlement rights that take effect upon the occurrence of certain fundamental transactions. The June 2022 Common Warrants define a fundamental transaction to generally include any consolidation, merger or other transaction whereby another entity acquires more than 50% of the Company's outstanding common stock or the sale of all or substantially all of the Company's assets. The fundamental transaction provision provides the warrant holders with the option to settle any unexercised warrants for cash in the event of certain fundamental transactions that are within the control of the Company. For any fundamental transaction that is not within the control of the Company, including a fundamental transaction not approved by the Company's board of directors, the warrant holder will only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the stockholders of the Company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. In the event of any fundamental transaction, and regardless of whether it is within the control of the Company, the settlement amount of the June 2022 Common Warrants (whether in cash, stock or a combination thereof) is determined based upon a Black-Scholes value that is calculated using inputs as specified in the June 2022 Common Warrants, including a defined volatility input equal to the greater of the Company's 100-day historical volatility or 100%.

The June 2022 Common Warrants also include a separate provision whereby the exercisability of such warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 4.99% (or an amount up to 9.99% if the holder so elects) of the Company's common stock.

The Company assessed the June 2022 Common Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies." During this assessment, the Company determined (i) the June 2022 Common Warrants did not constitute a liability under ASC 480; (ii) the June 2022 Common Warrants met the definition of a derivative under ASC 815; (iii) the warrant holder's option to receive a net cash settlement payment under the June 2022 Common Warrants only becomes exercisable upon the occurrence of certain specified fundamental transactions that are within the control of the Company; (iv) upon the occurrence of a fundamental transaction that is not within the control of the Company, the warrant holder would receive the same type or form of consideration offered and paid to common stockholders; (v) the June 2022 Common Warrants are indexed to the Company's common stock; and (vi) the June 2022 Common Warrants met all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the June 2022 Common Warrants are freestanding equity-linked derivative instruments that met the criteria for equity classification. Accordingly, the June 2022 Common Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

Pre-funded warrants. The June 2022 Pre-funded Warrants' fundamental transaction provision did not provide the warrant holders with the option to settle any unexercised warrants for cash in the event of any fundamental transactions; rather, in all fundamental transaction scenarios, the warrant holder was only entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that was being offered and paid to the stockholders of the Company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. The June 2022 Pre-funded Warrants also included a separate provision whereby the exercisability of the warrants could be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 4.99% (or an amount up to 9.99% if the holder so elects) of the Company's common stock.

The Company assessed the June 2022 Pre-funded Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies." During this assessment, the Company determined the June 2022 Pre-funded Warrants were freestanding instruments that did not meet the definition of a liability pursuant to ASC 480 and did not meet the definition of a derivative pursuant to ASC 815. The June 2022 Pre-funded Warrants were indexed to the Company's common stock and met all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the June 2022 Pre-funded Warrants were freestanding equity-linked financial instruments that met the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the June 2022 Pre-funded Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

March 2020 Public Offering

On February 27, 2020, the Company entered into an underwriting agreement with H.C. Wainwright, as underwriter, relating to the offering, issuance and sale of common stock, pre-funded warrants, and accompanying common warrants (the "CMPO Common Warrants"), in a public offering (the "March 2020 Public Offering"). The number of CMPO Common Warrants, excluding pre-funded warrants, issued in connection with the March 2020 Public Offering totaled 2,108,333. At closing, the Company also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 59,496 shares of common stock (the "CMPO UW Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in the March 2020 Public Offering.

The CMPO Common Warrants have an exercise price of $3.00 per share and expire five years from the date of issuance. During the three and nine months ended September 30, 2022, there were no exercises of CMPO Common Warrants. During the nine months ended September 30, 2021, warrant holders exercised 10,000 of the CMPO Common Warrants for total proceeds of approximately $30. There were 252,417 of the CMPO Common Warrants outstanding as of September 30, 2022.

The CMPO UW Warrants have an exercise price of $3.75 per share and expire five years from the date of issuance. During the three and nine months ended September 30, 2022, there were no exercises of CMPO UW Warrants. During the nine months ended September 30, 2021, warrant holders exercised 48,192 of the CMPO UW Warrants for total proceeds of approximately $181. There were 11,304 of the CMPO UW Warrants outstanding as of September 30, 2022.

March 2020 Registered Direct Offering

On March 24, 2020, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company agreed to sell and issue shares of the Company's common stock and pre-funded warrants in a registered direct offering priced at the market (the "March 2020 Registered Direct Offering"). The March 2020

Registered Direct Offering closed on March 26, 2020. At closing, the Company issued to designees of H.C. Wainwright, as placement agent, warrants to purchase an aggregate of up to 55,814 shares of common stock (the "RDO PA Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying pre-funded warrants sold in the March 2020 Registered Direct Offering.

The RDO PA Warrants have an exercise price of $5.375 per share and expire five years from the date of issuance. During the three and nine months ended September 30, 2022, there were no exercises of RDO PA Warrants. During the nine months ended September 30, 2021, warrant holders exercised 45,209 of the RDO PA Warrants for total proceeds of approximately $243. There were 10,605 of the RDO PA Warrants outstanding as of September 30, 2022.

January 2018 Offering

There were no exercises of warrants issued in the Company's public offering that closed on January 9, 2018 (the "January 2018 Offering") during the three and nine months ended September 30, 2022. During the nine months ended September 30, 2021, warrant holders exercised 150 of the warrants issued in the January 2018 Offering. On January 9, 2022, the remaining 999,850 outstanding warrants related to the January 2018 Offering expired without being exercised.

July 2020 Aspire Common Stock Purchase Agreement

On July 21, 2020, the Company entered into the Common Stock Purchase Agreement (the "July 2020 CSPA") with Aspire Capital Fund, LLC ("Aspire"), which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire was committed to purchase up to an aggregate of $30,000 of shares of the Company's common stock at the Company's request from time to time during the 30-month term of the July 2020 Aspire CSPA. Upon execution of the July 2020 Aspire CSPA, the Company agreed to sell to Aspire 555,555 shares of its common stock at $9.00 per share for proceeds of $5,000. In consideration for entering into the July 2020 Aspire CSPA, upon satisfaction of certain conditions under the July 2020 Aspire CSPA, the Company issued to Aspire 100,000 shares of the Company's common stock (the "July 2020 Commitment Shares"). The July 2020 Commitment Shares, valued at approximately $847, were recorded in July 2020 as non-cash costs of equity financing and included within general and administrative expenses. The July 2020 Aspire CSPA replaced the June 2020 Aspire Common Stock Purchase Agreement, which was terminated under the terms of the July 2020 Aspire CSPA.

During the nine months ended September 30, 2022, there were no sales of common stock under the July 2020 CSPA. During the nine months ended September 30, 2021, the Company sold 493,163 shares of its common stock at an average price of $1.28 for total proceeds of $6,334.

On March 9, 2022, the Company provided notice to Aspire electing to terminate the July 2020 CSPA effective as of March 10, 2022. By its terms, the July 2020 CSPA could be terminated by the Company at any time, at its discretion, without any penalty or additional cost to the Company.

Note 12: Licensing and Collaboration Arrangements

SB204 and SB206 Agreements

The Company has entered into a license agreement, as subsequently amended, with Sato Pharmaceutical Co., Ltd. ("Sato"), relating to SB204, its drug candidate for the treatment of acne vulgaris, and SB206, its drug candidate for the treatment of viral skin infections (the "Sato Agreement"). Pursuant to the Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of its intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 or SB206 in certain topical dosage forms for the treatment of acne vulgaris or viral skin infections, respectively, and to make the finished form of such products. The Company or its designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the API of SB204 or SB206; rather, the parties agreed to negotiate a commercial supply agreement pursuant to which the Company or its designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. Under the terms of the Sato Agreement, the Company also has exclusive rights to certain intellectual property that may be developed by Sato in the future, which the Company could choose to use for its own development and commercialization of SB204 or SB206 outside of Japan.

The term of the Sato Agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory (adjusted from the tenth anniversary of the first commercial sale in the Sato Agreement). The term of the Sato Agreement may be renewed with respect to a licensed product by mutual written agreement of the parties for additional two-year periods following expiration of the initial term. All other material terms of the Sato Agreement remain unchanged by the Sato Amendment (as defined below).

Sato is responsible for funding the development and commercial costs for the program that are specific to Japan. The Company is obligated to perform certain oversight, review and supporting activities for Sato, including (i) using commercially reasonable efforts to obtain marketing approval of SB204 and SB206 in the United States, (ii) sharing all future scientific information the Company may obtain during the term of the Sato Agreement pertaining to SB204 and SB206, (iii) performing certain additional preclinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of $1,000, and (iv) participating in a joint committee that oversees, reviews and approves Sato's development and commercialization activities under the Sato Agreement. Additionally, the Company has granted Sato the option to use the Company's trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to the Company's approval of such use.

The Sato Agreement may be terminated by (i) Sato without cause upon 120 days' advance written notice to the Company, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) force majeure, (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency, and (v) the Company immediately upon written notice if Sato challenges the validity, patentability, or enforceability of any of the Company's patents or patent applications licensed to Sato under the Sato Agreement. In the event of a termination, no portion of the upfront fees received from Sato are refundable.

Wynzora Agreements

Effective as of January 1, 2022, EPI Health entered into an amended and restated promotion and collaboration agreement with MC2 Therapeutics Limited ("MC2"), relating to the commercialization of Wynzora for treatment of plaque psoriasis in adults in the United States (the "MC2 Agreement"). Pursuant to the MC2 Agreement, which sets forth the collaborative efforts between EPI Health and MC2 to commercialize and promote Wynzora with MC2 in the United States, MC2 granted EPI Health an exclusive right and license under MC2's intellectual property rights to sell, or detail (as defined in the MC2 Agreement), and engage in certain commercialization activities with respect to Wynzora in the United States.

In exchange for the provision of promotional and commercialization activities, under the terms of the MC2 Agreement, EPI Health is entitled to receive:

- Reimbursement for all incremental costs incurred by the Company for the promotion and commercialization of Wynzora, including the incremental portion of the Company's personnel and commercial operating costs. The supply price of Wynzora product inventory is also considered to be an incremental cost that is reimbursed by MC2.
- A commercialization fee equivalent to a percentage of net sales ranging from the mid-teens for net sales less than or equal to $65,000 to the upper single digits for annual net sales greater than $105,000. EPI Health collects this commercialization fee by retaining its portion of the Wynzora product net sales it collects from its customers, with the remainder of the net sales being remitted by EPI Health to MC2 periodically in the form of a royalty payment, pursuant to the MC2 Agreement.
- A contingent incentive fee equal to 5% of the first $30,000 in net sales of Wynzora sold in the United States by EPI Health in each of the 2022 and 2023 calendar years; provided that such incentive fee shall not exceed $1,500 each year and such incentive fee shall not be credited to EPI Health until the royalty payments paid to MC2 surpass the amount of certain commercialization payments made previously by MC2.

The term of the MC2 Agreement runs until the seventh anniversary of the first commercial sale of Wynzora (as defined in the MC2 Agreement) or June 30, 2028, whichever is earlier. Either party may terminate the MC2 Agreement for the other party's material uncured breach or the bankruptcy or insolvency of the other party. MC2 may terminate the MC2 Agreement under certain scenarios, including for convenience with twelve months' advance notice to EPI Health, provided that the termination is not effective unless MC2 pays any unpaid historical liabilities related to commercialization of Wynzora owed by MC2. In the case of such termination, MC2 is also required to make an additional sunset payment to EPI Health, paid in installments over the twenty-four month period following termination. EPI Health may terminate the MC2 Agreement for convenience with twelve months' advance notice to MC2 provided that the termination is not effective unless the Company provides MC2 with a guarantee of the payment of any outstanding royalty payments, to the extent such royalty payments owed by EPI Health exceed any unpaid historical liabilities related to commercialization of Wynzora owed by MC2.

Rhofade Agreements

In connection with the Rhofade Acquisition Agreement that is described in Note 10—"Commitments and Contingencies," EPI Health acquired rights to that certain Assignment and License Agreement, whereby EPI Health licenses certain intellectual property from Aspect Pharmaceuticals, LLC ("Aspect" and such agreement, the "Aspect Agreement"). Under the terms of the Aspect Agreement, EPI Health, as successor-in-interest, has exclusive rights to, and is required to use commercially reasonable efforts to, commercialize the Rhofade product. EPI Health also has a duty to certain other parties to use commercially reasonable efforts to commercialize the Rhofade product based on historical acquisition agreements for Rhofade that were assumed by EPI Health.

The Aspect Agreement expires upon the last-to-expire of patent claims made under the assigned and licensed patents under the Aspect Agreement. Aspect may terminate the agreement upon a material breach by EPI Health after providing an opportunity to cure. Upon such termination by Aspect, EPI Health will cease all development and commercialization of Rhofade and EPI Health will assign and convey to Aspect its entire right, title and interest in and to the assigned intellectual property transferred under the Aspect Agreement.

Additionally, under the Aspect Agreement, the Rhofade Acquisition Agreement and the other historical acquisitions related to Rhofade, EPI Health is also required to pay a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales achieved by EPI Health. EPI Health is also required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

In connection with two abbreviated new drug application ("ANDA") settlement agreements that EPI Health entered into in connection with Rhofade in 2021, EPI Health granted two ANDA filers a license to launch their own generic product for the treatment of erythema in rosacea. The actual timing of the launch of such generic products is uncertain because the launch dates of such products under the settlement agreements are subject to acceleration under certain circumstances. In the absence of any circumstances triggering acceleration, the earliest launch of such a generic product would be in the third quarter of 2026.

Minolira Agreements

In connection with the Minolira acquisition that is described in Note 10—"Commitments and Contingencies," EPI Health assumed the royalty obligation related to an ANDA settlement in connection with Minolira. Accordingly, EPI Health is required to pay a royalty to an ANDA filer in the low double digits of any generic form of Minolira that is the pharmaceutical equivalent of the 105 mg or 135 mg strength Minolira product.

Cloderm Agreements

In connection with the Cloderm acquisition that is described in Note 10—"Commitments and Contingencies," on September 28, 2018, EPI Health entered into a distribution and supply agreement with Prasco, LLC ("Prasco"), whereby EPI Health has agreed to supply and Prasco has the right to purchase, distribute and sell an authorized generic ("AG") version of the Cloderm product in the United States. Prasco is required to pay EPI Health the supply price for the products, along with an amount equal to net sales of the product, minus an amount for certain fees and expenses of Prasco initially equal to the low double digits of net sales of such product, which is retained by Prasco. The agreement will continue, on a product-by-product basis, for an initial five-year term from the first commercial sale of such product, which will automatically renew for an additional one-year term unless either party elects not to renew. The agreement may be terminated for convenience by EPI Health upon nine months' written notice. Prasco may terminate with respect to a specific product based, among other factors, on a failure by EPI Health to deliver launch quantities. Either party may terminate immediately upon the occurrence of certain regulatory matters or based on a force majeure event.

Sitavig Agreements

On February 21, 2020, EPI Health entered into an agreement with Vectans Pharma ("Vectans") in which the parties terminated an existing license agreement dated March 17, 2014 which granted EPI Health the exclusive right to develop and commercialize a prescription Sitavig product in the United States and Canada, and instead provided that EPI Health would purchase outright certain intellectual property (and license other intellectual property) related to the prescription Sitavig Rx product in the United States and Canada (the "Vectans Agreement").

At the time it entered into the Vectans Agreement, EPI Health also entered into an OTC Switch License Agreement (the "OTC License Agreement") with Bayer Healthcare LLC ("Bayer"). Under the OTC License Agreement, EPI Health granted to Bayer an exclusive and sublicensable license to develop and commercialize an OTC product in the United States and Canada.

Under the OTC License Agreement, Bayer has agreed to pay EPI Health various regulatory milestone payments upon the achievement of such regulatory milestones equaling a maximum aggregate amount of $9,500, along with various commercial milestone payments upon the achievement of such commercial milestones equaling a maximum aggregate amount of $20,000. Under the Vectans Agreement, EPI Health is required to pay Vectans various milestone and royalty payments in amounts ranging from 32% - 50% of the amounts paid by Bayer to EPI Health pursuant to the OTC License Agreement, and the Company will also be required to pay a portion of such milestone payments to EPG under the EPI Health Purchase Agreement.

Bayer has also agreed to pay to EPI Health a tiered royalty ranging from a mid-single digit to a low-double digit percentage of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

Bayer is responsible for funding the development and commercial costs for the OTC product in the United States and Canada. The Company is obligated to perform certain oversight, review and supporting activities for Bayer, including (i) maintaining existing EPI Health patents related to the Sitavig product, and (ii) participating in a joint committee that oversees, reviews and approves development and commercialization activities under the OTC License Agreement.

The OTC License Agreement expires on the tenth anniversary of the first commercial sale of an OTC product on a country-by-country basis. The OTC License Agreement may be terminated by (i) Bayer without cause upon nine months' advance written notice to EPI Health, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) either party, upon three months' notice, in the event Bayer provides EPI Health with notice that Bayer has elected to permanently discontinue development of the OTC product in the United States and Canada, and (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency. On the tenth anniversary of the first commercial sale of the OTC product on a country-by-country basis, assuming Bayer is not in breach and the OTC License Agreement has not been terminated, Bayer will have an irrevocable, royalty-free license to commercialize the OTC product without any further obligations to EPI Health.

Nuvail Agreements

On November 7, 2021, a predecessor of EPI Health entered into an exclusive license agreement with Chesson Laboratory Associates, Inc. ("Chesson"), as subsequently amended, for the sale of Nuvail, and pursuant to such agreement, EPI Health serves as an exclusive distributor of this product in the United States. Pursuant to the Nuvail license agreement, EPI Health is required to pay a tiered royalty up to a low double digit percentage of net sales of Nuvail, subject to a minimum annual royalty payment. The initial term of the license agreement expired in 2021 and was automatically extended for an additional five year renewal period. The license agreement may be terminated by either party for material breach. Chesson may terminate the license agreement early for convenience upon 12 months' notice but is required to pay a termination fee based on a multiple of trailing twelve months gross sales. EPI Health is not currently actively promoting this product as part of its commercial portfolio.

UNC Agreements

The Amended, Restated and Consolidated License Agreement dated June 27, 2012, as amended, with the University of North Carolina at Chapel Hill ("UNC," and such agreement, the "UNC License Agreement") provides the Company with an exclusive license to issued patents and pending applications directed to the Company's library of Nitricil compounds, including patents issued in the United States, Japan and Australia, with claims intended to cover NVN1000, the new chemical entity ("NCE") for the Company's current product candidates. The UNC License Agreement requires the Company to pay UNC up to $425 in regulatory and commercial milestones on a licensed product by licensed product basis and a running royalty percentage in the low single digits on net sales of licensed products. Licensed products include any products being developed by the Company or by its sublicensees.

Unless earlier terminated by the Company at its election, or if the Company materially breaches the agreement or becomes bankrupt, the UNC License Agreement remains in effect on a country by country and licensed product by licensed product basis until the expiration of the last to expire issued patent covering such licensed product in the applicable country. The projected date of expiration of the last to expire of the patents issued under the UNC License Agreement is 2036.

Other Research and Development Agreements

The Company has entered into various licensing agreements with universities and other research institutions under which the Company receives the rights, and in some cases substantially all of the rights, of the inventors, assignees or co-assignees to produce and market technology protected by certain patents and patent applications. In addition to the UNC License Agreement, which is the Company's primary license agreement, the counterparties to the Company's various other licensing agreements are the University of Akron Research Foundation, Hospital for Special Surgery, Strakan International S.a.r.l., which is a licensee of the University of Aberdeen, KIPAX AB and KNOW Bio.

The Company is required to make payments based upon achievement of certain milestones and will be required to make royalty payments based on a percentage of future sales of covered products or a percentage of sublicensing revenue. As future royalty payments are directly related to future revenues (either sales or sublicensing), future commitments cannot be determined. No accrual for future payments under these agreements has been recorded, as the Company cannot estimate if, when or in what amount payments may become due.

KNOW Bio Agreements

On December 30, 2015, the Company completed the distribution of 100% of the outstanding membership interests of KNOW Bio, LLC ("KNOW Bio"), a former wholly owned subsidiary of the Company, to Novan's stockholders (the "Distribution"), pursuant to which KNOW Bio became an independent privately held company. In connection with the Distribution, the Company entered into exclusive license agreements and sublicense agreements with KNOW Bio, as described below. The agreements will continue for so long as there is a valid patent claim under the respective agreement, unless earlier terminated, and upon expiration, will continue as perpetual non-exclusive licenses. KNOW Bio has the right to terminate each such agreement, for any reason upon 90 days advance written notice to the Company.

License of existing and potential future intellectual property to KNOW Bio. The Company and KNOW Bio entered into an exclusive license agreement dated December 29, 2015 (the "KNOW Bio License Agreement"). Pursuant to the terms of the KNOW Bio License Agreement, the Company granted to KNOW Bio exclusive licenses, with the right to sublicense, under certain United States and foreign patents and patent applications that were controlled by the Company as of December 29, 2015 or that became controlled by the Company between that date and December 29, 2018, directed towards nitric-oxide releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds and other nitric oxide-based therapeutics.

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the "KNOW Bio Sublicense Agreements" and together with the KNOW Bio License Agreement, the "Original KNOW Bio Agreements"). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the United States and foreign patents and patent applications exclusively licensed to the Company from UNC under the UNC License Agreement, and another third party directed towards nitric oxide-releasing compositions, to develop and commercialize products utilizing the licensed technology. Under the exclusive sublicense to the UNC patents and applications (the "UNC Sublicense Agreement"), KNOW Bio is subject to the terms and conditions under the UNC License Agreement, including milestone and diligence payment obligations. However, pursuant to the terms of the UNC License Agreement, the Company is directly obligated to pay UNC any future milestones or royalties, including those resulting from actions conducted by the Company's sublicensees, including KNOW Bio. Therefore, in the event of KNOW Bio non-performance with respect to its obligations under the UNC Sublicense Agreement, the Company would be obligated to make such payments to UNC. KNOW Bio would then become obligated to repay the Company pursuant to the UNC Sublicense Agreement, otherwise KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. There were no milestone or royalty payments required during the three and nine months ended September 30, 2022 and 2021.

On October 13, 2017, the Company and KNOW Bio entered into certain amendments to the Original KNOW Bio Agreements (the "KNOW Bio Amendments"). Pursuant to the terms of the KNOW Bio Amendments, the Company re-acquired from KNOW Bio exclusive, worldwide rights under certain United States and foreign patents and patent applications controlled by the Company as of December 29, 2015, and that became controlled by the Company between December 29, 2015 and December 29, 2018, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses (the "Oncovirus Field").

KNOW Bio also granted to the Company an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three-year period between December 29, 2015 and December 29, 2018 and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, to develop and commercialize products for use in the Oncovirus Field.

Upon execution of the KNOW Bio Amendments, in exchange for the Oncovirus Field rights, the Company paid KNOW Bio a non-refundable upfront payment of $250. Products the Company develops in the Oncovirus Field based on Nitricil will not be subject to any further milestones, royalties or sublicensing payment obligations to KNOW Bio under the KNOW Bio Amendments. However, if the Company develops products in the Oncovirus Field that incorporate a certain nitric oxide-releasing composition specified in the KNOW Bio Amendments and (i) are covered by KNOW Bio patents or (ii) materially use or incorporate know-how of KNOW Bio or the Company related to such composition that was created between December 29, 2015 and December 29, 2018, the Company would be obligated to make the certain contingent milestone and royalty payments to KNOW Bio under the KNOW Bio Amendments.

The rights granted to the Company in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Original KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and the Company that are set forth in the Original KNOW Bio

Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

The KNOW Bio Amendments also provide a mechanism whereby either party may cause a NCE covered by the Original KNOW Bio Agreements to become exclusive to such party by filing an investigational new drug application ("IND") on the NCE. An NCE that becomes exclusive to a party under this provision may not be commercialized by the other party until the later of expiration of patents covering the NCE or regulatory exclusivity covering the NCE. A party who obtains exclusivity for an NCE must advance development of the NCE pursuant to terms of the KNOW Bio Amendments in order to maintain such exclusivity; otherwise, such exclusivity will expire.

Note 13: Net Product Revenues

The Company has the following commercial products that generate net product revenues:

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Wynzora (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

The post-acquisition operating results of EPI Health are reflected within the Company’s condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2022, specifically from March 11, 2022 through September 30, 2022. Net product revenues are summarized as follows:

	Three Months Ended September 30, 2022		Nine Months Ended September 30, 2022	
	Total Net Product Revenues	Percentage of Net Product Revenues	Total Net Product Revenues	Percentage of Net Product Revenues
Rhofade	$ 3,475	75.5 %	$ 8,566	77.0 %
Wynzora	411	8.9 %	1,061	9.5 %
Minolira	374	8.1 %	764	6.9 %
Cloderm	148	3.2 %	387	3.5 %
Other	197	4.3 %	353	3.2 %
Net product revenues	$ 4,605	100.0 %	$ 11,131	100.0 %

For the period March 11, 2022 through September 30, 2022, the Company recorded adjustments for certain commercial products for accruals that were assumed as of the EPI Health Acquisition date within the Other category in the table above.

As of September 30, 2022, three of the Company’s wholesaler customers accounted for more than 10% of its total accounts receivable balance at 24%, 12% and 15%, respectively.

For the three and nine months ended September 30, 2022, one of the Company’s wholesaler customers accounted for more than 10% of its total gross product revenues, at 11% and 12%, respectively.

Note 14: License and Collaboration Revenues

The Company has the following commercial product that generates license and collaboration revenues:

Cloderm AG (clocortoline pivalate cream 0.1%), or Cloderm AG, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

The post-acquisition operating results of EPI Health are reflected within the Company’s condensed consolidated statement of operations for the three and nine months ended September 30, 2022, specifically from March 11, 2022 through September 30, 2022. License and collaboration revenues are summarized as follows:

	Three Months Ended September 30, 2022		Nine Months Ended September 30, 2022	
	Total License and Collaboration Revenues	Percentage of License and Collaboration Revenues	Total License and Collaboration Revenues	Percentage of License and Collaboration Revenues
Sato Agreement - SB206 and SB204	$ 646	131.3 %	$ 1,939	96.5 %
Prasco Agreement - Cloderm AG	(154)	(31.3) %	71	3.5 %
License and collaboration revenues	$ 492	100.0 %	$ 2,010	100.0 %

Sato Agreement

The Company assessed the Sato Agreement in accordance with ASC 606 and concluded that the contract counterparty, Sato, is a customer within the scope of ASC 606. The Company identified the following promises under the Sato Agreement (i) the grant of the intellectual property license to Sato, (ii) the obligation to participate in a joint committee that oversees, reviews, and approves Sato's research and development activities and provides advisory support during Sato's development process, (iii) the obligation to manufacture and supply Sato with all quantities of licensed product required for development activities in Japan, and (iv) the stand-ready obligation to perform any necessary repeat preclinical studies, up to $1,000 in cost. The Company determined that these promises were not individually distinct because Sato can only benefit from these licensed intellectual property rights and services when bundled together; they do not have individual benefit or utility to Sato. As a result, all promises have been combined into a single performance obligation.

The Sato Agreement also provides that the two parties agree to negotiate in good faith the terms of a commercial supply agreement pursuant to which the Company or a third-party manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. The Company concluded this obligation to negotiate the terms of a commercial supply agreement does not create (i) a legally enforceable obligation under which the Company may have to perform and supply Sato with API for commercial manufacturing, or (ii) a material right because the incremental commercial supply fee consideration framework in the Sato Agreement is representative of a stand-alone selling price for the supply of API and does not represent a discount. Therefore, this contract provision is not considered to be a promise to deliver goods or services and is not a performance obligation or part of the combined single performance obligation described above.

Sato Amendment

On October 5, 2018, the Company and Sato entered into the second amendment to the Sato Agreement (the "Sato Amendment"). The Sato Amendment expanded the Sato Agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections. The Company assessed the Sato Agreement in accordance with ASC 606 and concluded the contract modification should incorporate the additional goods and services provided for in the Sato Amendment into the existing, partially satisfied single bundled performance obligation that will continue to be delivered to Sato over the remaining development period. The Company determined that this contract modification accounting is appropriate as the additional goods and services conveyed under the Sato Amendment were determined to not be distinct from the single performance obligation, and the additional consideration provided did not reflect the standalone selling price of those additional goods and services. As such, the Company recorded a cumulative adjustment as of the amendment execution date to reflect revenue that would have been recognized cumulatively for the partially completed bundled performance obligation.

The Company concluded that the following elements of consideration would be included in the transaction price as they were (i) received prior to September 30, 2022, or (ii) payable upon specified fixed dates and were not contingent upon clinical or regulatory success in Japan:

- The 1.25 billion JPY (approximately $10,813 USD) original upfront payment received on January 19, 2017 following the execution of the Sato Agreement on January 12, 2017.
- A milestone payment of 0.25 billion JPY (approximately $2,162 USD) received during the fourth quarter of 2018 following Sato's initiation of a Phase 1 trial in Japan.
- The Sato Amendment upfront payment of 1.25 billion JPY, payable in installments of 0.25 billion JPY, 0.5 billion JPY and 0.5 billion JPY on October 5, 2018, February 14, 2019 and September 13, 2019, respectively. On October 23, 2018, the Company received the first installment from the Sato Agreement of 0.25 billion JPY (approximately $2,224 USD). On March 14, 2019, the Company received the second installment payment related to the Sato Agreement of 0.5 billion JPY (approximately $4,460 USD). On November 7, 2019, the Company received the third installment payment related to the Sato Agreement of 0.5 billion JPY (approximately $4,554 USD).
- An aggregate of 1.0 billion JPY in non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events. On May 20, 2021,

the Company received one such non-contingent milestone payment in the form of a payment of 0.5 billion JPY (approximately $4,572 USD) related to achievement of a time-based developmental milestone. On February 28, 2022, the Company received the remaining time-based milestone payment of 0.5 billion JPY (approximately $4,323 USD).

The Company concluded that the following elements of consideration would not be included in the transaction price as they are contingent upon clinical or regulatory success in Japan:

- Up to an aggregate of 0.5 billion JPY upon the achievement of various development and regulatory milestones.
- Up to an aggregate of 3.9 billion JPY upon the achievement of various commercial milestones.
- A tiered royalty ranging from a mid-single digit to a low-double digit percentage (adjusted from a mid-single digit percentage in the Sato Agreement) of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

The payment terms contained within the Sato Agreement related to upfront, developmental milestone and sales milestone payments are of a short-term nature and, therefore, do not represent a financing component requiring additional consideration.

The following tables present the Company's contract assets, contract liabilities and deferred revenue balances for the dates indicated.

	Contract Asset	Contract Liability	Net Deferred Revenue
December 31, 2021	$ —	$ 13,251	$ 13,251
September 30, 2022	$ —	$ 11,312	$ 11,312

	Short-term Deferred Revenue	Long-term Deferred Revenue	Net Deferred Revenue
December 31, 2021	$ 2,586	$ 10,665	$ 13,251
September 30, 2022	$ 2,586	$ 8,726	$ 11,312

The Company has recorded the Sato Agreement (both the initial agreement and as amended by the Sato Amendment) transaction price, including the upfront payments received and the unconstrained variable consideration, as deferred revenue (comprised of (i) a contract liability, net of (ii) a contract asset).

The change in the net deferred revenue balance during the three and nine months ended September 30, 2022 was associated with the recognition of license and collaboration revenue associated with the Company's performance during the period (continued amortization of deferred revenue).

During the three and nine months ended September 30, 2022, the Company recognized $646 and $1,939, respectively, in license and collaboration revenue under the Sato Agreement. During the three and nine months ended September 30, 2021, the Company recognized $680 and $2,174, respectively, in license and collaboration revenue under the Sato Agreement. The Company has concluded that the above consideration is probable of not resulting in a significant revenue reversal and therefore included in the transaction price and is allocated to the single performance obligation. No other variable consideration under the Sato Agreement is probable of not resulting in a significant revenue reversal as of September 30, 2022 and therefore, is currently fully constrained and excluded from the transaction price.

The Company evaluated the timing of delivery for its performance obligation and concluded that a time-based input method is most appropriate because Sato is accessing and benefiting from the intellectual property and technology (the predominant items of the combined performance obligation) ratably over the duration of Sato's estimated development period in Japan. Although the Company concluded that the intellectual property is functional rather than symbolic, the services provided under the performance obligation are provided over time. Therefore, the allocated transaction price will be recognized using a time-based input method that results in straight-line recognition over the Company's performance period.

The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. The Company currently estimates a 10-year performance period, completing in the third quarter of 2024, based upon a Sato-prepared SB206 Japanese development program timeline. The SB204 Japanese development plan and program timeline has not been presented by Sato and remains under evaluation by the Company and Sato. Currently, the

Company understands that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato's comprehensive asset developmental program, including SB206.

The estimated timeline remains subject to prospective reassessment and adjustment based upon Sato's interaction with the Japanese regulatory authorities and other developmental and timing considerations. The combined SB204 and SB206 development program timeline in Japan is continuously reevaluated by Sato and the Company, and may potentially be further affected by various factors, including (i) the analyses, assessments and decisions made by the joint development committee and the applicable regulatory authorities, which will influence and establish the combined SB204 and SB206 Japan development program plan, (ii) the remaining timeline and progression of the SB206 NDA submission in the United States, which has been and may be further impacted by the COVID-19 pandemic, (iii) the API and drug product supply chain progression, including the Company's in-house drug manufacturing capabilities, (iv) the Company's manufacturing technology transfer projects with third-party CMOs, and (v) a drug delivery device technology enhancement project with a technology manufacturing vendor.

If the duration of the combined SB204 and SB206 development program timeline is further affected by the establishment of or subsequent adjustments to, as applicable, the mutually agreed upon SB204 and SB206 development plan in the Japan territory, the Company will adjust its estimated performance period for revenue recognition purposes accordingly, as needed.

In future periods, the Company would lift the variable consideration constraint from each contingent payment if there were no longer a probable likelihood of significant revenue reversal. When the constraint is lifted from a milestone payment, the Company will recognize the incremental transaction price using the same time-based input method that is being used to recognize the revenue, which results in straight-line recognition over the performance period. If the Company's performance is not yet completed at the time that the constraint is lifted, a cumulative catch-up adjustment will be recognized in the period. If no other performance is required by the Company at the time the constraint is lifted, the Company expects to recognize all revenue associated with such milestone payments at the time that the constraint is lifted.

Performance Obligations under the Sato Agreement

The net amount of existing performance obligations associated with the Sato Agreement unsatisfied as of September 30, 2022 was $11,312. The Company expects to recognize approximately 23% of the remaining performance obligations as revenue over the next 12 months, and the balance thereafter. The Company applied the practical expedient and does not disclose information about variable consideration related to sales-based or usage-based royalties promised in exchange for a license of intellectual property.

MC2 Agreement

The Company assessed the MC2 Agreement and determined it is a collaboration arrangement within the scope of ASC 808. Per the MC2 agreement, the Company proposes a commercialization plan and incremental cost budget annually, which is developed in consultation with and subject to the approval of MC2. The Company is required to use commercially reasonable efforts to perform its commercialization activities in accordance with the commercialization plan.

The Company and MC2 work collaboratively in promoting and commercializing Wynzora by performing their respective promotional and commercialization responsibilities, as established within the MC2 Agreement. Pursuant to the MC2 Agreement, MC2 is responsible for leading the overall strategy of messaging for the promotional materials for Wynzora and the Company is responsible for generating such promotional materials and executing all field promotional and sales activities via the Company's existing commercial sales force. MC2 is responsible for the manufacturing of Wynzora via a third-party contract manufacturer, and subject to MC2's obligation to supply product under the supply terms, the Company purchases product inventory from MC2 (and its third-party contract manufacturer) by periodically placing firm purchase orders and then taking title, physical possession and control of the product inventory. The Company then fulfills orders and distributes Wynzora to the Company's wholesale, distributor and other pharmacy customers. The parties share regulatory responsibilities, and except for the regulatory responsibilities assigned to the Company under the terms of the MC2 Agreement, MC2 is responsible for maintaining the NDA for Wynzora and all remaining regulatory activities. The MC2 Agreement also establishes a joint steering committee, which monitors and oversees the development, promotion, commercialization, and manufacturing of Wynzora, coordinates the collaborative activities of the parties and resolves disputes.

MC2 pays advance payments to the Company on a quarterly basis, prior to the beginning of each calendar quarter, for incremental costs expected to be incurred by the Company during such calendar quarter for the promotion and commercialization of Wynzora, including (i) promotional campaigns and related services performed by third parties, (ii) a portion of the Company's personnel and commercial operating costs, and (iii) the supply price of Wynzora product inventory. The Company records an accrued deposit liability within accrued expenses on its balance sheets upon receipt of an advance payment for promotional and commercialization services not yet performed or incurred by the Company. As such services are performed and qualifying incremental expenses are incurred, the Company recognizes a contra-expense pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies."

During each of the three and nine months ended September 30, 2022, the Company recognized contra-expenses of $2,918 and $6,081 under this agreement. The accrued deposit liability related to the receipt of advance payments from MC2 for future incremental costs was $2,799 as of September 30, 2022, which is presented within accrued expenses in the accompanying condensed consolidated balance sheets.

The Company also identified the wholesalers, distributors and other pharmacies (collectively referred to as "End Customers") who purchase Wynzora from the Company to be customers pursuant to ASC 606. When more than one party is involved in providing goods or services to the End Customer, ASC 606 requires an entity to determine whether it is a principal or an agent in such transactions by evaluating the nature of its promise to the End Customer. Control of the specified good or service prior to transfer of control to the customer is the determining factor when assessing whether an entity is a principal or an agent. The Company determined it is a principal in this arrangement because it takes title and physical possession of the Wynzora product inventory, at which point it can direct the inventory to any End Customer that submits an enforceable purchase order issued under an active, stand-alone agreement between the Company and the End Customer.

With respect to its performance obligations to the End Customers and associated revenue recognition, the Company recognizes all Wynzora revenues pursuant to its accounting policies for net product revenues as described further in Note 1—"Organization and Significant Accounting Policies" and Note 13—"Net Product Revenues."

Note 15: Research and Development Agreements

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, the Company entered into a royalty and milestone payments purchase agreement (the "Reedy Creek Purchase Agreement") with Reedy Creek Investments LLC ("Reedy Creek"), pursuant to which Reedy Creek provided funding to the Company in an amount of $25,000 for the Company to use primarily to pursue the development, regulatory approval and commercialization activities (including through out-license agreements and other third-party arrangements) for SB206, a topical gel with anti-viral properties being developed as a treatment for molluscum, and advancing programmatically such activities with respect to SB204, a once-daily, topical monotherapy being developed for the treatment of acne vulgaris, and SB414, a topical cream-based product candidate being developed for the treatment of atopic dermatitis. If the Company successfully commercializes any such product following regulatory approval, the Company will be obligated to pay Reedy Creek a low single digit royalty on net sales of such products in the United States, Mexico or Canada.

The Company determined that the Reedy Creek Purchase Agreement is within the scope of ASC 730-20, *Research and Development Arrangements* ("ASC 730-20"), and that there has not been a substantive and genuine transfer of risk related to the Reedy Creek Purchase Agreement. As such, the Company determined that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of $25,000 as cash and cash equivalents, as the Company had the ability to direct the usage of funds, and a long-term liability within its classified balance sheet.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

On May 4, 2019, the Company entered into a development funding and royalties agreement (the "Ligand Funding Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"), pursuant to which Ligand provided funding to the Company of $12,000, for the Company to use to pursue the development and regulatory approval of SB206, a topical gel with anti-viral properties being developed as a treatment for molluscum.

Pursuant to the Ligand Funding Agreement, the Company will pay Ligand up to $20,000 in milestone payments upon the achievement by the Company of certain regulatory and commercial milestones associated with SB206 or any product that incorporates or uses NVN1000, the API for the Company's clinical stage product candidates, as a treatment for molluscum. In addition to the milestone payments, the Company will pay Ligand tiered royalties ranging from 7% to 10% based on annual aggregate net sales of such products in the United States, Mexico or Canada.

The Company determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. As such, the Company concluded that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of $12,000 as a liability and amortize the liability ratably during each reporting period, based on the Ligand funding as a percentage of the total direct costs incurred by the Company during the reporting period related to the estimated total cost to progress the SB206 program to a regulatory approval in the United States. The ratable Ligand funding is presented within the accompanying condensed consolidated statements of operations and comprehensive loss within research and development expenses associated with the SB206 program.

For the three and nine months ended September 30, 2022, the Company recorded contra-research and development expense related to the SB206 developmental program of $223 and $851, respectively, related to amortization of the Ligand Funding Agreement amount. For the three months ended September 30, 2021, the Company recorded contra-research and development expense related to the SB206 developmental program of $117 related to amortization of the Ligand Funding Agreement amount. For the nine months ended September 30, 2021, the Company recorded research and development expense of $93 related to accretion of the Ligand Funding Agreement amount.

Note 16: Stock-Based Compensation

2016 Incentive Award Plan

During the three and nine months ended September 30, 2022 and 2021, the Company continued to administer and grant awards under the 2016 Incentive Award Plan, as amended (the "2016 Plan"), the Company's only active equity incentive plan. Certain of the Company's stock options granted under the Company's 2008 Stock Plan (the "2008 Plan"), which is the predecessor to the 2016 Plan and became inactive upon adoption of the 2016 Plan effective September 20, 2016, remain outstanding and exercisable.

Restricted Stock Units

The Company accounts for restricted stock units ("RSUs") based on their estimated fair values on the date of grant. The fair value of RSUs is estimated based on the closing price of the underlying common stock on the date of grant. Stock-based compensation expense related to the RSUs is recognized on a straight-line basis over the requisite service period, net of estimated forfeitures.

The terms of the RSUs, including the vesting provisions, are determined by the board of directors. Each RSU represents the contingent right to receive one share of common stock of the Company. The RSUs granted typically cliff vest after a one-year period for grants to directors and a two-year period for grants to employees, provided that the grantee remains a director, employee or consultant of the Company as of such vesting date.

For the three and nine months ended September 30, 2022, 50,500 and 476,606 RSUs were granted to directors and employees, respectively. There were no RSU grants for the three and nine months ended September 30, 2021.

Stock Appreciation Rights

The Company has occasionally used stock appreciation rights ("SARs") as a component of executive compensation. As of December 17, 2019, the Company entered into an amended and restated employment agreement with Paula Brown Stafford which provided for a grant of 60,000 SARs with an exercise price of $8.20 per share (the fair market value of the Company's common stock on the grant date) and with a ten year term. These SAR awards were vested in full as of December 31, 2021.

Tangible Stockholder Return Plan

On August 2, 2018, the Company's board of directors approved and established the Tangible Stockholder Return Plan, which was a performance-based long-term incentive plan (the "Performance Plan"). The Performance Plan was effective immediately upon approval and expired on March 1, 2022. The Performance Plan covered all employees, including the Company's executive officers, consultants and other persons deemed eligible by the Company's compensation committee. The core underlying metric of the Performance Plan was the potential achievement of two share price goals for the Company's common stock, which, if achieved, could have represented measurable increases in stockholder value.

The Performance Plan expired on March 1, 2022. As the Company's stock price did not reach the minimum share price targets necessary to trigger a payment, no payments were made under the Performance Plan to any participants during the period the Performance Plan was effective.

Stock Compensation Expense

During the three and nine months ended September 30, 2022 and 2021, the Company recorded stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	$ 283	$ 298	$ 1,029	$ 491
Restricted stock units	226	—	314	—
Stock appreciation rights	—	29	—	87
Tangible Stockholder Return Plan	—	(150)	—	(662)
Total	$ 509	$ 177	$ 1,343	$ (84)

Total stock-based compensation expense included in the accompanying condensed consolidated statements of operations and comprehensive loss is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 127	$ (13)	$ 320	$ (325)
Selling, general and administrative	382	190	1,023	241
Total	$ 509	$ 177	$ 1,343	$ (84)

2016 Plan Award Activity

Stock option activity for the nine months ended September 30, 2022 is as follows:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding as of December 31, 2021	518,553	$ 15.48		
Options granted	543,300	3.25		
Options forfeited	(15,850)	6.50		
Options outstanding as of September 30, 2022	1,046,003	$ 9.26	8.74	$ —

RSU activity for the nine months ended September 30, 2022 is as follows:

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value
Nonvested RSUs outstanding as of December 31, 2021	—	$ —
RSUs granted	476,606	2.88
RSUs forfeited	(12,400)	2.98
RSUs vested	—	—
Nonvested RSUs outstanding as of September 30, 2022	464,206	$ 2.88

As of September 30, 2022, there were a total of 1,046,003 stock options, 464,206 RSUs and 60,000 SARs outstanding; and there were 221,568 shares available for future issuance under the 2016 Plan.

Note 17: Fair Value

The Company has contingent consideration associated with the EPI Health Acquisition that is required to be measured at fair value on a recurring basis, presented within the condensed consolidated balance sheets as both current and long-term liabilities, beginning as of March 11, 2022.

ASC 820-10, *Fair Value Measurement Disclosure*, requires use of a three-tiered hierarchy, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data and therefore, are based primarily upon estimates, are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent uncertainties in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The carrying values of accounts receivable, prepaid expenses and other current assets, accounts payable, and certain accrued expenses as of September 30, 2022 and December 31, 2021 approximate their fair values due to the short-term nature of these items.

The Company's contingent consideration liability is measured on a recurring basis using level 3 inputs. The estimated fair value of the contingent consideration related to the EPI Health Acquisition requires significant management judgment and estimation, is calculated using a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability, and is also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration.

The following table summarizes the change in fair value, as determined by Level 3 inputs for the contingent consideration liabilities for the three and nine months ended September 30, 2022:

Balance at March 31, 2022	$	3,773
Change in fair value		(454)
Balance at June 30, 2022	$	3,319
Change in fair value		186
Measurement period adjustment (see Note 2)		(125)
Balance at September 30, 2022	$	3,380
Contingent consideration liability, current portion	$	438
Contingent consideration liability, net of current portion		2,942
Balance at September 30, 2022	$	3,380

The following tables present the significant inputs and valuation methodologies used for the Company's fair value of the contingent consideration liabilities, in addition to EPI Health's forecasted net sales from the EPI Health legacy products:

	Transition Services Agreement	Sitavig Milestones (Regulatory)
Valuation methodology	Probability-Weighted	Probability-Weighted
Term	0.25	1.34
Payment term	0.5	1.59
Adjusted discount rate	22.30 %	20.66 %

	First Sales Based Legacy Milestone	Wynzora Milestone	Second Sales Based Legacy Milestone	Sitavig Milestones (Commercial)
Valuation methodology	Monte Carlo	Monte Carlo	Monte Carlo	Monte Carlo
Risk-adjusted discount rates (minimum)	7.78%	7.78%	7.78%	8.79%
Risk-adjusted discount rates (maximum)	9.23%	8.61%	9.23%	9.20%
Net sales volatility (per annum)	14.0%	13.0%	14.0%	14.0%
Credit spread (continuous)	18.32%	14.67%	18.32%	17.65%

For the three and nine months ended September 30, 2022, there was a $186 increase and a $268 decrease, respectively, in fair value related to contingent consideration related to the EPI Health Acquisition recorded in the accompanying condensed consolidated statements of operations and comprehensive loss related primarily to changes in market assumptions and discount rates since the transaction date.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of the milestones underlying the contingent consideration would result in a significantly higher or lower fair value of the contingent consideration liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the condensed consolidated statements of operations and comprehensive loss until settlement.

The following table presents information about the classification and potential earnout periods for the Company's contingent consideration liabilities as of September 30, 2022:

	Classification	Earnout Period
Transition Services Agreement	Current portion	11-Mar-2022 to 10-Mar-2023
First Sales Based Legacy Milestone	Current portion	1-Apr-2022 to 31-Mar-2023
Wynzora Milestone	Current portion	1-Apr-2022 to 31-Mar-2023
Second Sales Based Legacy Milestone	Non-current portion	1-Apr-2023 to 31-Mar-2026
Sitavig Milestones	Non-current portion	1-Feb-2024 to 30-Apr-2034

See Note 2—"Acquisition of EPI Health" for additional detail regarding contingent consideration related to the transaction.

Note 18: Segment Information

The Company has determined that it operates in two segments, which represent (i) the promotion of commercial products for the treatment of medical dermatological conditions (the "Commercial Operations" segment), and (ii) research and development activities related to the Company's nitric oxide-based technology to develop product candidates (the "Research and Development Operations" segment).

- The Commercial Operations segment consists of the Company's portfolio of commercial products.
- The Research and Development Operations segment consists of multiple drug product candidates under clinical development.

Costs associated with the development of SB206 are currently included in the Research and Development Operations segment. There are no significant inter-segment sales. The Company evaluates the performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. The Company's chief operating decision-maker ("CODM") is the Company's Chairman, President and Chief Executive Officer.

Segment revenue, net and comprehensive loss and total assets were as follows:

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Revenue		
Commercial operations	$ 4,450	$ 11,202
Research and Development operations	665	1,999
Total revenue	$ 5,115	$ 13,201
Net loss		
Commercial operations	$ (2,269)	$ (3,461)
Research and Development operations	(3,761)	(24,827)
Net loss and comprehensive loss	$ (6,030)	$ (28,288)

	As of September 30, 2022
Assets	
Commercial operations	$ 57,836
Research and Development operations	25,434
Total assets	$ 83,270

The net revenues attributed to the Commercial Operations segment are primarily derived from the sale of the Company's commercial products, and the net revenues attributed to the Research and Development Operations segment are primarily derived from the arrangement with the Company's licensing partner in Japan for SB206 and SB204. Drug development and potential commercialization costs are included in the Research and Development Operations segment. Total assets by reporting segment are not reviewed by the CODM when evaluating the reporting segments' performance, however, the Commercial Operations segment includes the acquired assets associated with the EPI Health Acquisition and changes in such assets, while the Research and Development Operations segment is comprised of the assets associated with the historical business of the Company related to the Company's product candidates that are in development.

Substantially all revenue was derived from product sales or from licensing agreements originating in the United States. All of the Company’s long-lived assets are maintained in the United States.

Although all of the Company’s operations are based in, and all net product revenue is generated from, sales in the United States, the revenue generated from its licensing partner in Japan was $646 and $1,939, or 13% and 15% of total revenue, during the three and nine months ended September 30, 2022, respectively, which was attributed to the Research and Development Operations segment. During the three and nine months ended September 30, 2021, the Company generated revenue from its licensing partner in Japan of $680 and $2,174, or 92% and 94% of total revenue, respectively. Prior to the quarter ended March 31, 2022, the Company operated in only one segment, which was the Research and Development Operations segment.

Note 19: Subsequent Events

Memorandum of Understanding

On November 11, 2022 the Company entered into a nonbinding memorandum of understanding with Sato for a proposed exclusive license to its patents covering Rhofade, which would grant Sato the right to develop, manufacture and market Rhofade for rosacea in Japan. In addition, Sato would have a right of first negotiation related to Rhofade in certain other countries in the Asia Pacific region.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 18, 2022 (referred to herein as our Annual Report).

In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believe," "assume," "contemplate," "continue," "due," "goal," "objective," "plan," "seek," "target," "expect," "believe," "anticipate," "intend," "positioned," "may," "will," "would," "could," "should," "potential," "predict," "project," "estimate," or "continue," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. The forward-looking statements and opinions contained in this Quarterly Report on Form 10-Q are based upon information available to us as of the date hereof and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as may be required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- *We have incurred net losses since our incorporation and anticipate that we will continue to incur net losses for the foreseeable future.*
- *In March 2022, we acquired EPI Health, LLC, or EPI Health, and such acquisition, the EPI Health Acquisition. EPI Health derives revenue from the sale of branded medical dermatology products. Achieving the anticipated benefits of the EPI Health Acquisition will depend in significant part upon us integrating the EPI Health businesses, operations, processes and systems in an efficient and effective manner, including potential synergies and the ability to successfully commercialize the product portfolio acquired.*
- *We will need significant additional funding to continue our commercial operating activities and for the advancement of our product development programs, including potential commercialization efforts for SB206, beyond what is currently included in our operating forecast and related cash projection. As of September 30, 2022, we had an accumulated deficit of $307.3 million. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs, or our current and future commercialization efforts.*
- *Raising additional capital, including through the issuance of shares of our common stock through the March 11, 2022 Equity Distribution Agreement with Oppenheimer & Co. Inc., may reduce the trading price of our common stock. Any future additional issuances of equity, or debt convertible into equity, may result in significant dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, product candidates or commercial products.*
- *The price of our common stock has been and may continue to be volatile and fluctuate significantly, which could result in substantial losses for our existing stockholders.*
- *Our revenue is dependent upon sales of our medical dermatology products, and any setbacks relating to the sale of such commercial products could impair our operating results, including if our competitors develop treatments for our commercial portfolio's target indications or more effectively execute their commercialization strategies, which could limit our commercial opportunity and profitability.*
- *Our products and product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent the regulatory approval for our product candidates, limit the commercial profile of an approved label or result in significant negative consequences.*
- *Our product candidates, if approved, and our commercial products may face significant competition, and our failure to effectively compete may prevent us from achieving significant market penetration or share. We face, and will*

continue to face, competition in the development and marketing of products from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including specialty and other large pharmaceutical companies, and over-the-counter, or OTC, companies and generic manufacturers. The dermatology competitive landscape is highly fragmented, with many mid-size and smaller companies competing in the prescription sector. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care.

- *Our research and development activities relate solely to developing nitric oxide-based therapeutics to treat a range of diseases with significant unmet needs, and if we do not successfully achieve regulatory approval for any of our product candidates or successfully commercialize them, we may not be able to continue as a business.*
- *Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for or regulatory approval of any of our product candidates.*
- *Ongoing or future product development activities may not be successful, including that our preclinical studies may not demonstrate proof-of concept or may show adverse toxicological findings, and our clinical trials may not show the requisite safety and efficacy of our product candidates. The regulatory approval processes of the Food and Drug Administration, or FDA, are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis or at all, our business will be substantially harmed.*
- *Delays or disruptions in the qualification of manufacturing facilities and processes or in the manufacture of our (i) active pharmaceutical ingredients, or APIs, including berdazimer sodium or any other Nitricil new chemical entities, or NCEs, or (ii) clinical trial materials and commercial supplies of any approved products, whether by us or any third-party manufacturer with whom we contract, including any delays in the transfer of technology to third-party manufacturers, could adversely affect our development timelines and result in increased costs of our development programs or in our breaching our obligations to others.*
- *We currently rely on third-party suppliers to provide the raw materials, finished goods and equipment that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, and the equipment used to manufacture our product candidates. Any delay or disruption, especially in light of current global supply chain constraints, or price increases related to such manufacturing could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.*
- *We currently rely on third-party logistics vendors to transport our raw materials, API, drug product and commercial products through our supply chain. Certain materials, including our API for our products in development, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, which could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.*
- *Many factors could cause production or distribution interruptions with the manufacture and distribution of any of our products and product candidates, including human error, natural disasters, pandemics, labor disputes, acts of terrorism or war, equipment malfunctions, or raw material shortages. If our commercial distribution partners are not able to satisfy our requirements within the expected timeframe, or are unable to provide us with accurate or timely information and data, including inventories and sales, serious adverse events, and/or product complaints, our business may be at risk. In addition, if specialty pharmacy services, including our third-party call center services, which provide patient support and financial services, prescription intake and distribution, reimbursement adjudication, and ongoing compliance support, are not effectively managed, the continuance of our sales of our commercial products or our product candidates, if approved, may be delayed or compromised. Finally, our third-party manufacturers may not be able to manufacture the materials required for our products or product candidates at a cost or in quantities necessary to make them commercially viable.*
- *We continue to assess global supply chain constraints, including any further impact of the COVID-19 pandemic and the military conflict between Ukraine and Russia, on our suppliers and vendors. Any delay could impact available inventories of our commercial products and our ability to meet demand.*
- *We rely on third parties to conduct some of our preclinical studies, clinical trials, stability and analytical testing, and regulatory activities. If these third parties do not successfully carry out their contractual duties or meet expected*

deadlines, or are adversely impacted by the COVID-19 pandemic, we may be unable to obtain regulatory approval for or commercialize any of our product candidates as planned or at all.

- *We have entered into and rely on, and may enter into and rely on other, strategic relationships for the further development and commercialization of our products and product candidates. If we are unable to enter into such relationships on favorable terms or at all, or if such relationships are unsuccessful, if disputes arise between us and our strategic partners or if we fail to trigger contingent payments under such strategic relationships, we may be unable to realize the potential economic benefit of our products and product candidates.*
- *Changes to our leadership team or operational resources, including with the EPI Health Acquisition and integration, could prove disruptive to our operations and have adverse consequences for our business and operating results.*
- *If we are unable to obtain and maintain patent protection for our product candidates and commercial products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology, product candidates and commercial products may be impaired.*
- *The ongoing military conflict between Russia and Ukraine has created additional volatile market conditions and uncertainties in the global economy, including increased cybersecurity risks.*
- *The risk that we may not be able to complete the negotiation of a potential exclusive license agreement with Sato Pharmaceutical Co., Ltd, or Sato, discussed herein on terms that are favorable to us or at all, and that, even if an agreement is finalized, we will continue to need significant additional funding to continue our development and operating activities.*
- *As a result of our operating losses and negative cash flows from operations, the report of our independent registered public accounting firm on our December 31, 2021 financial statements included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern.*
- *We may not be able to achieve the objectives or successfully execute our strategy described in the sections entitled "Business Updates," "Commercial Portfolio," "Research and Development Portfolio," "Supply Chain" and "Manufacturing and Supplies" below.*

For a further discussion of risks that could cause or contribute to differences between actual results and those implied by forward-looking statements, see the "Risk Factors" section in our Annual Report and in this Quarterly Report on Form 10-Q.

Novan is a registered trademark of our company in the United States. This Quarterly Report on Form 10-Q also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q generally appear without any "™" or "®" symbol, but the absence of such symbols is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of any applicable licensor, to these trademarks and trade names.

Overview

Novan, Inc. is a medical dermatology company primarily focused on researching, developing, and commercializing innovative therapeutic products for skin diseases. Our goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. We are developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. We recently completed the EPI Health Acquisition. EPI Health equips us with a commercial infrastructure across sales, marketing, and communications, as well as a dedicated market access and pharmacy relation teams, and positions us as a fully integrated dermatology company with a pipeline of development candidates focused primarily on dermatological indications supported by a commercial platform to market and sell therapeutic products for skin diseases.

Following the acquisition, we employ approximately 100 staff, including sales personnel currently covering 42 territories. Through our acquisition of EPI Health, we promote products for plaque psoriasis, rosacea, acne and dermatoses, which we refer to as our Commercial Operations segment. We also have a pipeline of potential product candidates using our proprietary nitric oxide-based technology platform, Nitricil, to generate new treatments for multiple indications, which we refer to as our Research and Development Operations segment. We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See "Note 18—Segment Information" to the accompanying condensed consolidated financial statements for certain financial information related to our reportable segments.

Business Updates

We continue to prepare for a regulatory submission and potential approval of SB206 as a treatment for molluscum. The timing of the targeted NDA submission is dependent upon preparatory activities and data accumulation related to the NDA submission including conducting customary drug substance and drug product stability protocols, regulatory and quality documentation compilation related to our chemistry, manufacturing, and controls, or CMC, data, and our drug manufacturing and related processes.

We are continuing to progress the prelaunch strategy and commercial preparations for SB206, if approved. We believe the addition of the EPI Health commercial infrastructure across the sales, marketing, and communications functions, in addition to the fully dedicated market access and pharmacy relations teams, will benefit the commercial launch of SB206, if approved.

Working Capital and Additional Capital Needs

We will continue to need additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates that are under development, and our funding needs will largely be determined by our commercialization strategy for SB206 (berdazimer gel, 10.3%), subject to the NDA submission timing and the regulatory approval process and outcome. We are pursuing a broad range of financing options that could be used to extend our cash runway beyond the targeted submission of an NDA for our lead product candidate, SB206, including, among other things, to further prepare for commercialization of SB206 following approval.

Further advancement of our molluscum program, including through the potential NDA submission of SB206, or advancement of any other early-stage or late-stage clinical program across our platform, is subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) debt or equity financings, such as through sales of common stock, or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

In addition to the regulatory progression of SB206, including implementing prelaunch strategy and commercial preparation, subject to obtaining additional financing or strategic partnering, we may progress (a) SB204, a topical monotherapy for the treatment of acne, by commencing a pivotal Phase 3 study, or (b) SB019, as a potential intranasal treatment option for respiratory infections.

As of September 30, 2022, we had total cash and cash equivalents of $14.9 million and a working capital deficit of $1.0 million. As of September 30, 2022, we had $48.6 million in remaining availability for sales of our common stock under the Equity Distribution Agreement dated March 11, 2022, or the Equity Distribution Agreement, with Oppenheimer & Co., Inc., or Oppenheimer. Pursuant to the Equity Distribution Agreement, we may from time to time issue and sell our common stock to or through Oppenheimer, acting as our sales agent, in at-the-market transactions. As described below, related to the June 2022 Registered Direct Offering, we agreed not to issue any additional securities in any variable rate transaction, including under the Equity Distribution Agreement, for a period of 6 months following June 13, 2022, unless certain thresholds are met following September 11, 2022. See "Note 11—Stockholders' Equity" to the accompanying condensed consolidated financial statements for more information on the Equity Distribution Agreement.

We will need significant additional funding to continue our operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

COVID-19 Overview

We have continued to closely monitor and rapidly respond to the ongoing impact of the COVID-19 pandemic on our employees, our community and our business operations. We have been able to resume normal operations in most areas of our business but have adopted a series of precautionary measures and plan to continue to adjust as the circumstances warrant.

The timetable for development of our product candidates has been impacted and may face further disruption and our business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of our B-SIMPLE4 Phase 3 trial. In addition, certain factors from the COVID-19 pandemic may delay or otherwise adversely affect our generation of product revenues from our portfolio of therapeutic products for skin diseases, as well as adversely impact our business generally. Therefore, we continue to assess any potential further impact of COVID-19 on our operations.

Commercial Portfolio

On March 11, 2022, we completed the acquisition of EPI Health, a commercial-stage pharmaceutical company founded in 2017 that focuses on the commercialization of medical dermatology pharmaceutical products for the treatment of skin conditions. EPI Health's current portfolio includes six branded prescription drugs. EPI Health actively promotes three medical dermatological products in the United States and derives revenue from the sale of these branded products through pharmaceutical wholesalers as well as direct to pharmacies. These prescription dermatology therapies are targeted to patients with plaque psoriasis, rosacea, acne, and dermatoses. The branded and promoted product portfolio currently includes Wynzora, Rhofade, and Minolira.

The following summarizes the complete EPI Health product portfolio:

Wynzora Cream (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older. EPI Health entered into a collaboration agreement with MC2 Therapeutics, or MC2, in August 2020, as amended effective January 1, 2022, for the commercialization of Wynzora in the United States, or the MC2 Agreement. Under the MC2 Agreement, MC2 retains full ownership of Wynzora. In particular, EPI Health utilizes its commercial infrastructure to promote and sell Wynzora in return for retaining a share of net sales of Wynzora in the United States. The portion of net sales EPI Health retains varies depending on the aggregate annual net sales of the product, and ranges from a percentage in the mid-teens to a mid-single digit percentage as net sales reach certain thresholds. Additionally, MC2 also pays for certain incremental costs incurred by EPI Health in commercialization activities according to a budget to be agreed annually between EPI Health and MC2. The term of the MC2 Agreement expires in June 2028, unless earlier terminated by either party under certain conditions.

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. EPI Health acquired the rights to Rhofade in October 2019. In connection with that acquisition and other historical acquisitions related to Rhofade, EPI Health is required to make certain milestone payments based on future net sales of Rhofade along with paying a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales achieved by EPI Health.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. EPI Health acquired the rights to Minolira in the United States in August 2018. In connection with that acquisition, EPI Health is required to pay certain milestones based on future sales of Minolira.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. EPI Health acquired the rights to Cloderm in September 2018. In connection with that acquisition, EPI Health is required to pay minimum royalty payments on net sales of Cloderm, subject to meeting certain net sales milestones.

Sitavig (acyclovir 50mg buccal tablets), or Sitavig, is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. EPI Health is party to a license agreement with Vectans Pharma, or Vectans, for the rights to commercialize Sitavig in the United States and Canada.

Nuvail (poly-ureaurethane 16% nail solution), or Nuvail, is indicated for managing signs and symptoms of nail dystrophy, i.e. nail splitting or nail fragility, for intact or damaged nails. EPI Health is party to a license agreement for the sale of Nuvail and serves as an exclusive distributor of this product in the United States.

Research and Development Portfolio

Our proprietary technology platform leverages nitric oxide's naturally occurring anti-viral, anti-bacterial, anti-fungal, and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated product candidates. The two key components of our nitric oxide platform are our proprietary Nitricil technology, which drives the creation of macromolecular NCEs and our formulation science, both of which we use to tune our product candidates for specific indications. Our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of diseases.

We have clinical-stage dermatology and anti-infective drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208), and anti-inflammatory (SB414) mechanisms of action. We have also introduced a possible anti-viral product candidate for the treatment of external genital warts (SB207). We have conducted or are currently conducting preclinical work on NCEs, including berdazimer sodium, and formulations for the potential treatment of (i) respiratory infections, including

SARS-CoV-2, the virus that causes COVID-19 (SB019), (ii) antimicrobial indications for the adjacent companion animal health market (NVN4100), (iii) cervical intraepithelial neoplasia caused by high-risk human papilloma virus, or HPV, in the men's and women's health field (WH504 and WH602), and (iv) inflammatory disorders.

Our primary programmatic focus is on our molluscum product candidate, SB206, and we intend to continue to focus our near term development efforts on this program. We are targeting a potential NDA submission of SB206 for molluscum around the end of 2022.

Priority Development Pipeline

SB206, a Topical Anti-viral Treatment for Molluscum Contagiosum (a Viral Skin Infection)

We are developing SB206 (12% berdazimer sodium, 10.3% berdazimer) as a topical gel with anti-viral properties for the treatment of viral skin infections, with a current focus on molluscum contagiosum. Molluscum is a contagious skin infection caused by the molluscipoxvirus that affects up to six million people in the United States annually. The greatest incidence is in children aged one to 14 years. The average time to resolution is 13 months; however, 13% of children experience lesions that may not resolve in 24 months. There is no FDA-approved prescription drug treatment for molluscum. More than half of patients diagnosed with the infection are untreated. The majority of patients in the United States that receive treatment are treated with potentially painful procedures and the remaining are often prescribed products indicated for the treatment of external genital warts.

Following positive results of our phase 3 B-SIMPLE4 trial for SB206, in April 2022, we held a pre-NDA meeting with the FDA, and subsequently received written minutes related to this interaction. Based on the information provided and our consideration thereof, we are currently targeting a potential NDA submission of SB206 for molluscum around the end of 2022 and are preparing for regulatory filing and potential approval of SB206 as a treatment for molluscum.

SB204, for the Treatment of Acne Vulgaris

SB204 is a product candidate designed as a once-daily, topical monotherapy for the treatment of acne vulgaris, a multi-factorial disease with multiple aspects of the disease pathology (immunomodulatory and anti-bacterial). Acne vulgaris is the most common skin condition in the United States. The disease ranges in severity from mild to severe cystic acne and causes both physical and psychological effects, including permanent scarring, anxiety, depression and poor self-esteem. Acne is a multi-factorial disease with several mechanistic contributors to the disease pathology, often requiring multiple treatments that address more than one of the major causes of acne pathogenesis. Localized nitric oxide delivery may provide immunomodulatory (anti-inflammatory) and anti-bacterial mechanisms of action from a single active ingredient. We believe that acne continues to be characterized as an unmet medical need due to the difficulty of balancing efficacy, systemic safety and cutaneous tolerability, as well as the growing concerns with anti-bacterial resistance with existing therapies. In our SB204 clinical development program, topical application of SB204 has been well-tolerated with no significant safety concerns identified. In maximal-use pharmacokinetic trials that we have conducted in adult and pediatric patients with acne vulgaris, we observed no detectable systemic exposure from SB204 following its topical application.

Based on the positive pivotal Phase 3 results in the SB206 molluscum development program, we believe we can optimize the trial design of a pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal trial to support an NDA submission. As such, our intention is to progress SB204 by commencing a pivotal Phase 3 study, subject to obtaining additional financing or strategic partnering.

Sato Agreement

In January 2017, we licensed rights to Sato Pharmaceutical Co., Ltd., or Sato, to develop, use, and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris, and to manufacture the finished form of SB204 for sale in Japan. In 2018, we licensed rights to Sato to develop, use, and sell SB206 in certain topical dosage forms in Japan for the treatment of viral skin infections, and to manufacture the finished form of SB206 for sale in Japan. The significant terms and the related accounting considerations of our licensing arrangement with Sato are further described in "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements. For further information regarding the current status of the Japanese SB206 and SB204 programs see "Note 12—Licensing and Collaboration Arrangements" to the accompanying condensed consolidated financial statements.

SB019, an Intranasal Treatment Option for COVID-19 or Other Respiratory Infections

We continue to explore the use of our proprietary Nitricil technology to progress SB019, a potential intranasal treatment option for COVID-19 or other respiratory infections, targeting the reduction of viral shedding and transmission. Nitric oxide has generally demonstrated the ability to inhibit viral replication of viruses within the *Coronaviridae* family, and we have an extensive body of *in vitro* and *in vivo* data demonstrating the efficacy of our proprietary technology for other anti-viral indications. Based on the scientific literature and data available to-date related to berdazimer sodium and SB206, we believe that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

Based on the positive preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, as well as the public health need to reduce breakthrough infections and transmission of COVID-19 and on our interactions with the FDA, we are expanding our preclinical work for the SB019 product candidate. This includes performing additional preclinical and formulation work, including investigating potential other respiratory infections that could be treated with SB019. As such, our intention is to progress SB019's preclinical development, however, we will not commence potential clinical studies without obtaining additional financing or strategic partnering.

Pipeline Expansion Opportunities

Our pipeline expansion opportunities are as follows:

SB414, for the Treatment of Inflammatory Skin Diseases, including Atopic Dermatitis and Psoriasis

SB414 is a product candidate designed as a topical cream for the treatment of inflammatory skin diseases, with a focus on the treatment of atopic dermatitis and psoriasis. The SB414 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB208, for the Treatment of Athlete's Foot (Tinea Pedis) and Fungal Nail Infections (Onychomycosis)

SB208 is a product candidate designed as a topical broad-spectrum anti-fungal gel for the potential treatment of fungal infections of the skin and nails, including athlete's foot (tinea pedis) and fungal nail infections (onychomycosis). The SB208 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB207, for the Treatment of External Genital Warts

Genital warts are among the world's most common sexually transmitted diseases. We have previously evaluated SB206's anti-viral activity against genital warts caused by HPV. In response to our identification of targeted viral opportunities of high unmet need where we believe our nitric oxide releasing technology could provide clinical benefit to patients, we developed SB207, a new anti-viral product candidate for the treatment of external genital warts. Further advancement of SB207 is subject to further evaluation of clinical plans and developmental timelines, as well as obtaining additional financing or strategic partnering.

Advancement in Men's and Women's Health

We have been awarded federal grants of approximately $1.3 million from the National Institutes of Health, or NIH, and approximately $1.1 million from the U.S. Department of Defense's, or DoD, Congressionally Directed Medical Research Programs, or CDMRP. These grants will enable the conduct of IND-enabling toxicology and pharmacology studies and other preclinical activity of a nitric oxide containing intravaginal gel (WH602) designed to treat high-risk HPV infections that can lead to cervical intraepithelial neoplasias, or CIN, and a non-gel formulation product candidate (WH504). Under the terms of these grants, we are entitled to receive the grant funds in the form of periodic reimbursements of our allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts.

Companion Animal Health

We have initiated exploratory work to evaluate our new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. This program is currently on hold, pending the engagement of potential collaborators or strategic partners to progress this asset, including the conduct of additional studies and formulation work.

Supply Chain

We continue to assess the impact of COVID-19 and related constraints on the global workforce on our supply chain and related vendors and global supply chain constraints across various industries, including interruption of, or delays in receiving, supplies of raw materials, API, drug product or finished goods from third-party manufacturers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems and potential price increases. We are also continuing to evaluate the impacts of COVID-19 and global supply chain constraints on our new facility. We have completed the commissioning of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product. We are in the process of, and proceeding with the related preparatory activities associated with qualifying and validating the manufacturing equipment for use in API production.

We currently rely on third-party suppliers to provide the raw materials that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, that we use to manufacture our product candidates. We also rely on third-party logistics vendors to transport our raw materials, API, and drug products through our supply chain. Certain materials, including our API, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, especially in light of the pandemic and related global supply chain constraints, which could adversely impact the timing or cost of our manufacturing supply chain activities or other associated development activities.

Manufacturing and Supplies

We have adopted a strategy of engaging with, utilizing and relying on third parties through partnerships, collaborations, licensing or other strategic relationships for the performance of activities, processes and services that (i) do not typically result in the generation of significant new intellectual property and (ii) can leverage their existing robust infrastructure, systems and facilities, as well as associated subject matter expertise. A parallel and inter-related strategic objective has been to manage our own internal resources, including our manufacturing capabilities.

Manufacturing and Supply of Commercial Products

We currently rely upon contract manufacturers to produce our commercial product portfolio and expect to continue to rely upon these contract manufacturers for any current and future EPI Health legacy product production. As with any supply agreement with contract manufacturers, obtaining finished goods of appropriate quality cannot be guaranteed. Our third-party manufacturers have other customers and may have other priorities that could affect their ability to perform their supply obligations to us satisfactorily and on a timely basis. Both of these occurrences would be beyond our control. We expect to similarly rely on contract manufacturing relationships for any products that we may acquire in the future.

Preparatory Work for Product Candidates in Development

For our product candidates that are currently in development, which generally use the drug substance berdazimer sodium as the API, we have adopted a dual approach of working with third parties and developing certain focused internal manufacturing capabilities. With third parties, we are conducting manufacturing process feasibility studies with a full-scale API manufacturer that, if successfully completed, could lead to full-scale production of our API, while also establishing a strategic alliance with Orion Corporation, or Orion, a Finnish full-scale pharmaceutical company with broad experience in drug manufacturing, to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with our topical product candidates, and if any of our product candidates are approved, commercial supply of our nitric oxide-based drug products. Importantly, the Orion alliance is being structured to support major global markets in which we and our partners may pursue regulatory approvals for our product candidates. Within these arrangements with third parties, however, there are risks associated with these manufacturers that are similar to the manufacturing arrangements for our commercial products described above. Moreover, given the stage of these relationships, there are risks associated with the complexity, time and expense of technical transfer.

Internally, we have also worked to complete commissioning our new facility to support various research and development and cGMP activities, including the production of cGMP API registration batches necessary to support the SB206 NDA submission as well as other small-scale manufacturing capabilities for API and drug product. While we have more control over our internal manufacturing capabilities as compared to our relationships with third parties, we do face risks associated with operating a manufacturing facility, including supply chain matters, which have impacted and may further impact the validation of our new facility, and the inherent limitations that come from our internal capabilities being limited to small-scale manufacturing capabilities.

As we move forward with these initiatives, we will need significant additional funding to continue our operating activities, including these technical transfer projects, potential utilization and development of internal capabilities and cost structure changes, and to make further advancements in our product development programs, as described in the section entitled "Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Corporate Updates

Working Capital Adjustment Payment

On July 7, 2022, we and Evening Post Group, LLC, or EPG, agreed to the final net working capital adjustment amount as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The total adjustment amount was positive and in the amount of $3.1 million, which was paid to EPG on July 7, 2022.

JAMA Dermatology Publication

On July 13, 2022, we announced the publication of the positive efficacy and favorable safety data from our completed B-SIMPLE 4 pivotal Phase 3 clinical study evaluating berdazimer gel, 10.3% for the treatment of molluscum in the peer-reviewed journal, JAMA Dermatology.

Seller Note Payment and Termination

On July 13, 2022, we reached agreement with EPG regarding payment and termination of the outstanding $16.5 million Seller Note related to the EPI Health Acquisition. We achieved this termination by a payment of $10.0 million, or an approximate 39% discount on the original principal amount of the Seller Note. In addition to saving $6.5 million of principal with this termination, we will also avoid paying interest over the previous term of the Seller Note of approximately $4.6 million.

Pursuant to the terms of the Seller Note, there was no penalty for repaying the Seller Note prior to the end of the term. In connection with the repayment of the Seller Note, the guaranty agreement between EPG and EPI Health, dated March 11, 2022, was terminated as of July 13, 2022. Accordingly, the liens on the membership interests and assets of EPI Health were also terminated such that no obligations with respect to the Seller Note and related securities agreement or the underlying loan remain outstanding.

With the payment and termination of the Seller Note for a reduced amount of principal as described above, we removed that previously existing liability and eliminated the need to make cash payments to service the interest on the Seller Note going forward. This allows us to use our cash for development of our product candidates and to support the commercialization of our products, although we will need to secure additional funding prior to commercializing any of our product candidates currently in development.

See the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" for additional detail.

42nd Fall Clinical Dermatology Conference

On October 14, 2022, we announced that eight abstracts were accepted and posters would be presented at the 42nd Annual Fall Clinical Dermatology Conference held October 20-23, 2022, in Las Vegas, NV. These posters included information on our B-SIMPLE4 study and various posters regarding Wynzora.

Memorandum of Understanding

On November 11, 2022, we entered into a nonbinding memorandum of understanding with Sato for a proposed exclusive license to our patents covering Rhofade, which would grant Sato the right to develop, manufacture and market Rhofade for rosacea in Japan. In addition, Sato would have a right of first negotiation related to Rhofade in certain other countries in the Asia Pacific region.

Financial Overview

Since our incorporation in 2006 through mid-March 2022, we devoted substantially all of our efforts to developing our nitric oxide platform technology and resulting product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. With the acquisition of a commercial entity, EPI Health in March 2022, we have expanded our legacy business into marketing and sales efforts with a portfolio of therapeutic products for skin diseases.

To date, we have focused our funding activities primarily on equity raises and strategic relationships. However, other historical forms of funding have included payments received from licensing and supply arrangements, as well as government research contracts.

We have incurred net losses in each year since inception. As of September 30, 2022, we had an accumulated deficit of $307.3 million, and there is substantial doubt about our ability to continue as a going concern. We incurred net losses of $28.3 million and $21.5 million for the nine months ended September 30, 2022 and 2021, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities, including incurring significant expenses related to product candidate development, commercial product sales, marketing, manufacturing and distribution.

Please refer to the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

Components of our Results of Operations

Revenue

Net Product Revenues

The EPI Health Acquisition has provided our company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, plaque psoriasis, acne and dermatoses, including Rhofade, Wynzora, Minolira and Cloderm.

For additional information regarding our accounting for net product revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 13—Net Product Revenues" to the accompanying condensed consolidated financial statements.

License and Collaboration Revenues

License and collaboration revenues consists of (i) the amortization of certain fixed and variable consideration under the Sato license agreement that was entered into during the first quarter of 2017, as amended in October 2018, or the Sato Agreement, that either has been received to date in the form of upfront and milestone payments or non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates or are contingent milestone payments that become payable upon the achievement of specified milestone events, and (ii) a distribution and supply agreement related to an out-license of Cloderm AG.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Government Research Contracts and Grants Revenue

Government research contracts and grant revenue relates to the research and development of our nitric oxide platform for preclinical advancement of NCEs and formulations related to potential treatments for illnesses in the women's health field. Revenue related to conditional government contracts and grants is recognized when qualifying expenses are incurred.

Product Cost of Goods Sold

Product cost of goods sold includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Product cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

Research and Development Expenses

Research and development activities include conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development expenses, including those paid to third parties for which there is no alternative use, are expensed as they are incurred. Research and development expenses include:

- external research and development expenses incurred under agreements with clinical research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical studies;
- costs to acquire, develop and manufacture supplies for clinical trials and preclinical studies at our facilities;
- costs to establish drug substance and drug product manufacturing capabilities with external contract manufacturing organizations, or CMOs, and to enhance drug delivery device technologies through partnerships with technology manufacturing vendors;
- legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- salaries and related costs, including stock-based compensation, for personnel in our research and development functions; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, utilities, equipment and other supplies.

We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on (i) technical transfer and supportive manufacturing activities by our drug product CMO, (ii) preparatory activities and data accumulation related to the NDA submission including conducting customary drug substance and drug product stability protocols, and (iii) regulatory and quality documentation compilation related to our CMC data, and our drug manufacturing and related processes.

We also expect to incur substantial costs in the last quarter of 2022 associated with our research and development personnel, and certain manufacturing capability costs related to the infrastructure necessary to support small-scale drug substance and drug product manufacturing operations at our corporate headquarters, including capital costs subject to depreciation and various ongoing operating costs. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential SB206 commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

The successful development and potential regulatory approval of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current product candidates or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See the "Risk Factors” section in this Quarterly Report and also within our Annual Report for a discussion of the risks and uncertainties associated with our research and development projects.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation expenses for personnel in our commercial, field sales, marketing, market access, medical affairs, regulatory, finance, corporate development and other functions. Other selling, general and administrative expenses include advertising, promotion, travel, consulting, market research costs, prelaunch strategy costs, medical affairs, and commercial costs, including preparation activities for our lead product candidate, SB206, allocated depreciation and facility-related costs, legal costs of pursuing patent protection of our intellectual property, insurance coverage and professional services fees for auditing, tax, general legal, business development, litigation defense and other corporate and administrative services.

We expect to continue to incur substantial selling, general and administrative expenses in the last quarter of 2022 in support of our commercial product portfolio acquired with the EPI Health Acquisition and the prelaunch strategy and commercial preparation activities for SB206. We may decide to revise our plans or the related timing associated with our commercial product portfolio, and prelaunch strategy and commercial preparation activities for SB206, depending on information we learn through our regulatory submission process and potential SB206 commercialization strategies.

We also expect to continue to incur substantial selling, general and administrative expenses in the last quarter of 2022 in support of our operating activities and as necessary to operate in a public company environment. Significant general and administrative expenses associated with operations in a public company environment include legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors’ and officers’ liability insurance premiums and investor relations activities.

Amortization of Intangible Assets

Amortization of intangible assets is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition.

For additional information regarding the recognition and amortization of our intangible assets, see "Note 7—Goodwill and Intangible Assets, net” to the accompanying condensed consolidated financial statements.

Change in Fair Value of Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to the EPI Health Acquisition. The estimated fair value of contingent consideration was determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health’s forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration. Contingent consideration is remeasured at each reporting date and any changes in the liability are recorded within the consolidated statement of operations and comprehensive loss.

Impairment Loss on Long-lived Assets

During the second quarter of 2021, we assessed the carrying value of a disposal group classified as assets held for sale in the accompanying condensed consolidated balance sheets. The disposal group and related assets consisted of certain manufacturing and laboratory equipment associated with our previous large scale drug manufacturing capability that was being sold over time through a consignment seller. Based on our assessment of the disposal group’s recoverability, during the three months ended

June 30, 2021, we recognized an impairment loss on long-lived assets that represented the full write off of its remaining carrying value.

Other Income (Expense), net

Other income (expense), net consists primarily of (i) foreign currency adjustments related to the contract asset and contract receivables related to the Sato Agreement, (ii) interest expense on outstanding notes payable, (iii) interest income earned on cash and cash equivalents, (iv) gain on extinguishment of debt related to the forgiveness of our PPP loan and extinguishment of our note payable related to the EPI Health Acquisition, and (v) other miscellaneous income and expenses.

Financial Information About Segments

Management evaluates performance of the Company based on operating segments. Segment performance for our two operating segments is based on segment net revenue and net loss. Our reportable segments consist of (i) research and development activities related to our nitric oxide-based technology to develop product candidates, or the Research and Development Operations segment, and (ii) the promotion of commercial products for the treatment of medical dermatological conditions, or the Commercial Operations segment. We do not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select operating expenses including research and development expenses, amortization, and asset sales and impairments, net, as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

See "Note 18—Segment Information" in the accompanying condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

Results of Operations

Comparison of Three Months Ended September 30, 2022 and 2021

The following table sets forth our results of operations for the periods indicated, including information related to our Commercial Operations and Research and Development Operations segments:

	Three Months Ended September 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Net product revenues	$ 4,605	$ —	$ 4,605	*
License and collaboration revenues	492	680	(188)	(28)%
Government research contracts and grants revenue	18	57	(39)	(68)%
Total revenue	5,115	737	4,378	594 %
Operating expenses:				
Product cost of goods sold	1,440	—	1,440	*
Research and development	4,288	4,251	37	1 %
Selling, general and administrative	8,562	2,969	5,593	188 %
Amortization of intangible assets	443	—	443	*
Change in fair value of contingent consideration	186	—	186	*
Total operating expenses	14,919	7,220	7,699	107 %
Operating loss	(9,804)	(6,483)	(3,321)	51 %
Other income (expense), net:				
Interest income	38	4	34	850 %
Interest expense	(635)	—	(635)	*
Gain on debt extinguishment	4,340	—	4,340	*
Other income (expense)	31	(5)	36	(720)%
Total other income (expense), net	3,774	(1)	3,775	*
Net loss	$ (6,030)	$ (6,484)	$ 454	(7)%

** Not meaningful*

Net product revenues

The EPI Health Acquisition has provided the Company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues for the three months ended September 30, 2022 were $4.6 million, which were all generated by our Commercial Operations segment.

Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, plaque psoriasis, acne and dermatoses, including Rhofade, Wynzora, Minolira and Cloderm. There were no such net product revenues in the comparative period in 2021.

For additional information regarding our accounting for net product revenues, see "Note 1—Organization and Significant Accounting Policies” and "Note 13—Net Product Revenues” to the accompanying condensed consolidated financial statements.

License and collaboration revenues

License and collaboration revenues were $0.5 million and $0.7 million for the three months ended September 30, 2022 and 2021, respectively. License and collaboration revenue is comprised of amounts related to (i) the Sato Agreement, related to the Japanese territory out-license of SB206 and SB204, recorded in the Research and Development Operations segment, and (ii) a distribution and supply agreement with Prasco, LLC related to the out-license of Cloderm AG (the "Prasco Agreement”), all recorded in the Commercial Operations segment.

For the three months ended September 30, 2022 and 2021, we recognized $0.6 million and $0.7 million, respectively under the Sato Agreement for our performance during the periods and the related amortization of the non-refundable upfront and expected milestone payments under the Sato Agreement.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1—Organization and Significant Accounting Policies” and "Note 14—License and Collaboration Revenues” to the accompanying condensed consolidated financial statements.

Product cost of goods sold

Product cost of goods sold of $1.4 million for the three months ended September 30, 2022 is recorded by our Commercial Operations segment and includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Product cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

For additional information regarding our accounting for cost of goods sold, see "Note 1—Organization and Significant Accounting Policies," "Note 13—Net Product Revenues," and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Research and development expenses

Our Research and Development Operations segment incurred the substantial majority of our research and development expenses, which were $4.3 million for the three months ended September 30, 2022, which was consistent on a net basis compared to the three months ended September 30, 2021. The nominal net increase of approximately 1%, was primarily related to a $0.3 million net decrease in the SB206 program, offset by a $0.3 million net increase in other research and development expenses.

The $0.3 million net decrease in the SB206 program was primarily driven by (i) a $0.6 million decrease in gross clinical trial costs primarily due to continued B-SIMPLE4 Phase 3 trial execution activities occurring during the prior year comparative period, (ii) a $0.2 million increase in contra-research and development expense from the ratable amortization of the development funding and royalties agreement with Ligand Pharmaceuticals, Inc., or the Ligand Funding Agreement, liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum, partly offset by a (iii) a $0.5 million increase in regulatory consulting services, stability and other analytical testing services, and CMC consulting services and materials in support of our planned SB206 NDA submission.

The $0.3 million increase in other research and development expenses was primarily driven by (i) a $0.5 million net increase in research and development personnel costs and (ii) a $0.3 million net increase in research and development facility operating expenses, partly offset by (iii) a $0.5 million decrease related to SB019 product candidate in vitro and in vivo studies occurring during the prior year comparative period.

The $0.5 million net increase in research and development personnel costs is primarily due to (i) a $0.3 million increase in in recurring salary and benefits costs and (ii) a $0.2 million increase in non-cash compensation expense.

Selling, general and administrative expenses

Selling, general and administrative expenses were $8.6 million for the three months ended September 30, 2022, compared to $3.0 million for the three months ended September 30, 2021.

The table below sets forth our total selling, general and administrative expenses incurred for the three months ended September 30, 2022 and 2021 and the primary drivers of the fluctuations from the prior period:

		Selling, general and administrative expenses
Three months ended September 30, 2022	$	8,562
Three months ended September 30, 2021		2,969
Change from prior period	**$**	**5,593**
		Prior Period Variance Detail Increase / (Decrease)
EPI Health commercial sales operations	$	4,413
SB206 prelaunch and commercial preparation		370
Tax and insurance costs		34
Facility and depreciation costs		122
Professional services and other administrative costs		92
Personnel and related benefits		562
Change from prior period	**$**	**5,593**

The $4.4 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations included (i) $2.0 million of recurring salary, incentive compensation and benefits costs, (ii) $0.7 million of advertising, promotional and other marketing costs, (iii) $1.1 million of administrative costs related to third-party consultants for regulatory services, external third-party data services and other service providers that support the commercial sales and operations teams, and (iv) $0.6 million of travel and expense related costs.

The $0.6 million increase in general and administrative personnel and related costs included (i) a $0.2 million increase in non-cash compensation expense associated with stock based compensation, and (ii) a $0.4 million increase in recurring salary and benefits costs between the two comparative periods, including new corporate positions, such as the Chief Operating Officer and the Chief Commercial Officer.

Amortization of intangible assets

Amortization of intangible assets of $0.4 million for the three months ended September 30, 2022 is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition.

For additional information regarding the recognition and amortization of our intangible assets, see "Note 7—Goodwill and Intangible Assets, net" to the accompanying condensed consolidated financial statements.

Change in fair value of contingent consideration

For the three months ended September 30, 2022, the changes in fair value related to contingent consideration related to the EPI Health Acquisition related primarily to changes in market assumptions and discount rates since the transaction date.

Other income (expense), net

Total other income, net was $3.8 million for the three months ended September 30, 2022. Total other income, net in the current period is primarily comprised of a $4.3 million gain on debt extinguishment recognized in connection with the termination of the Seller Note during the third quarter of 2022 and approximately $0.6 million of interest expense.

For additional information regarding the Seller Note and the accounting for its termination, see "Note 9—Notes Payable" to the accompanying condensed consolidated financial statements.

Comparison of Nine Months Ended September 30, 2022 and 2021

The following table sets forth our results of operations for the periods indicated, including information related to our Commercial Operations and Research and Development Operations segments:

	Nine Months Ended September 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Net product revenues	$ 11,131	$ —	$ 11,131	*
License and collaboration revenues	2,010	2,174	(164)	(8)%
Government research contracts and grants revenue	60	129	(69)	(53)%
Total revenue	13,201	2,303	10,898	473 %
Operating expenses:				
Product cost of goods sold	4,259	—	4,259	*
Research and development	12,265	15,926	(3,661)	(23)%
Selling, general and administrative	27,151	8,086	19,065	236 %
Amortization of intangible assets	1,112	—	1,112	*
Change in fair value of contingent consideration	(268)	—	(268)	*
Impairment loss on long-lived assets	—	114	(114)	(100)%
Total operating expenses	44,519	24,126	20,393	85 %
Operating loss	(31,318)	(21,823)	(9,495)	44 %
Other income (expense), net:				
Interest income	56	10	46	460 %
Interest expense	(1,375)	—	(1,375)	*
Gain on debt extinguishment	4,340	956	3,384	354 %
Other income (expense)	9	(602)	611	(101)%
Total other income (expense), net	3,030	364	2,666	732 %
Net loss	$ (28,288)	$ (21,459)	$ (6,829)	32 %

** Not meaningful*

Net product revenues

The EPI Health Acquisition has provided the Company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. The post-acquisition net product revenues of EPI Health, specifically from March 11, 2022 through September 30, 2022, are reflected within our condensed consolidated statement of operations for the nine months ended September 30, 2022. Net product revenues for the nine months ended September 30, 2022 were $11.1 million, which were all generated by our Commercial Operations segment.

Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, plaque psoriasis, acne and dermatoses, including Rhofade, Wynzora, Minolira and Cloderm. There were no such net product revenues in the comparative period in 2021.

For additional information regarding our accounting for net product revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 13—Net Product Revenues" to the accompanying condensed consolidated financial statements.

License and collaboration revenues

License and collaboration revenues were $2.0 million and $2.2 million for the nine months ended September 30, 2022 and 2021, respectively. License and collaboration revenue is comprised of amounts related to (i) the Sato Agreement, related to the Japanese territory out-license of SB206 and SB204, recorded in the Research and Development Operations segment, and (ii) the Prasco Agreement, related to out-license of Cloderm AG, all recorded in the Commercial Operations segment.

For the nine months ended September 30, 2022 and 2021, we recognized $1.9 million and $2.2 million, respectively under the Sato Agreement for our performance during the periods and the related amortization of the non-refundable upfront and expected milestone payments under the Sato Agreement. During the nine months ended September 30, 2022, we recognized revenues of $0.1 million associated with the Prasco Agreement.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Product cost of goods sold

Product cost of goods sold of $4.3 million for the nine months ended September 30, 2022 is recorded by our Commercial Operations segment and includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Product cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

For additional information regarding our accounting for cost of goods sold, see "Note 1—Organization and Significant Accounting Policies," "Note 13—Net Product Revenues," and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Research and development expenses

Our Research and Development Operations segment incurred the substantial majority of our research and development expenses, which were $12.3 million for the nine months ended September 30, 2022, compared to $15.9 million for the nine months ended September 30, 2021. The net decrease of $3.7 million, or 23%, was primarily related to a $4.8 million net decrease in the SB206 program, partially offset by a $1.1 million increase in other research and development expenses.

In the SB206 program, we experienced (i) a $6.2 million decrease in gross clinical trial costs primarily due to the B-SIMPLE4 Phase 3 trial execution activities that occurred during the prior year comparative period, and (ii) a $1.0 million increase in contra-research and development expense from the ratable amortization (or accretion, as was recognized during the prior year comparative period) of the Ligand Funding Agreement liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum, partly offset by (iii) a $2.4 million increase in regulatory consulting services, stability and other analytical testing services, and CMC consulting services and materials in support of our planned SB206 NDA submission.

The $1.1 million increase in other research and development expenses was primarily driven by (i) a $1.4 million net increase in research and development personnel costs, including costs related to manufacturing and analytical testing activities and (ii) a $0.2 million net increase in research and development facility operating expenses, partly offset by (iii) a $0.5 million net decrease in preclinical development activity costs and research and development facility operating expenses.

The $1.4 million net increase in research and development personnel costs is primarily due to (i) a $0.7 million increase in non-cash compensation expense, including stock based compensation, and (ii) a $0.7 million increase in recurring salary and benefits costs.

Selling, general and administrative expenses

Selling, general and administrative expenses were $27.2 million for the nine months ended September 30, 2022, compared to $8.1 million for the nine months ended September 30, 2021.

The table below sets forth our total selling, general and administrative expenses incurred for the nine months ended September 30, 2022 and 2021 and the primary drivers of the fluctuations from the prior period:

		Selling, general and administrative expenses
Nine months ended September 30, 2022	$	27,151
Nine months ended September 30, 2021		8,086
Change from prior period	**$**	**19,065**

		Prior Period Variance Detail Increase / (Decrease)
EPI Health Acquisition Transaction-related costs	$	4,811
EPI Health commercial sales operations		9,323
SB206 prelaunch and commercial preparation		2,319
Tax and insurance costs		412
Facility and depreciation costs		225
Professional services and other administrative costs		317
Personnel and related benefits		1,658
Change from prior period	**$**	**19,065**

The $4.8 million of transaction- and integration-related expenditures incurred in connection with the EPI Health Acquisition included transaction-related fees paid to banking advisors, insurance brokers, due diligence costs, and legal, regulatory, intellectual property, information technology, valuation and accounting consultants and specialists, and integration-related expenditures associated with transition services, information technology systems, integration project management and continued valuation and accounting consultants and specialists.

The $9.3 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations included (i) $4.8 million of recurring salary, incentive compensation and benefits costs, (ii) $1.3 million of advertising and promotion costs, (iii) $2.1 million of administrative costs related to third-party consultants for regulatory services, external third-party data services and other service providers that support the commercial sales and operations teams, and (iv) $1.1 million of travel and expense related costs.

The $1.7 million increase in general and administrative personnel and related costs includes (i) a $0.8 million increase in non-cash compensation expense associated with stock based compensation, and (ii) a $0.9 million increase in recurring salary and benefits costs between the two comparative periods, including new corporate positions, such as the Chief Operating Officer and the Chief Commercial Officer.

Amortization of intangible assets

Amortization of intangible assets of $1.1 million for the nine months ended September 30, 2022 is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition.

For additional information regarding the recognition and amortization of our intangible assets, see "Note 7—Goodwill and Intangible Assets, net" to the accompanying condensed consolidated financial statements.

Change in fair value of contingent consideration

For the nine months ended September 30, 2022, the changes in fair value related to contingent consideration related to the EPI Health Acquisition related primarily to changes in market assumptions and discount rates since the transaction date.

Impairment loss on long-lived assets

During the second quarter of 2021, we assessed the carrying value of a disposal group classified as assets held for sale in our condensed consolidated balance sheets. The disposal group and related assets consisted of certain manufacturing and laboratory equipment associated with our previous large scale drug manufacturing capability that was being sold over time through a consignment seller. Based on our assessment of the disposal group's recoverability, during the nine months ended September 30, 2021, we recognized a $0.1 million non-cash impairment loss on long-lived assets that represented the full write off of its remaining carrying value.

Other income (expense), net

Total other income, net was $3.0 million for the nine months ended September 30, 2022, compared to $0.4 million other income, net for the nine months ended September 30, 2021. Total other income, net in the current period is primarily comprised of (i) a $4.3 million gain on debt extinguishment recognized in connection with the termination of the Seller Note during the third quarter of 2022, (ii) approximately $0.1 million of interest and other income, partially offset by (iii) $1.4 million of interest expense related to the Seller Note issued in March 2022 in connection with the EPI Health Acquisition.

Total other income, net in the comparative 2021 period is primarily comprised of a $1.0 million gain on extinguishment of debt related to the forgiveness of our PPP loan in 2021, partially offset by $0.6 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to the Sato Agreement.

For additional information regarding the Seller Note and the accounting for its termination, see "Note 9—Notes Payable" to the accompanying condensed consolidated financial statements.

Liquidity and Capital Resources

As of September 30, 2022, we had an accumulated deficit of $307.3 million. We incurred net losses of $28.3 million and $21.5 million for the nine months ended September 30, 2022 and 2021, respectively, and there is substantial doubt about our ability to continue as a going concern. Despite revenues generated from the sales of commercial products acquired during the EPI Health Acquisition, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we further commercialize our existing commercial products and continue the development of, and seek regulatory approvals for, our product candidates and potentially begin commercialization activities for our product candidates that are currently under development. We are subject to all of the risks inherent in the commercialization of drug products, such as risks related to competition, supply issues or issues that may impact use of our commercial drug products, and in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The sales of our commercial products will decrease over time if and when they face generic competition or if other risks materialize, and we do not expect to generate revenue from product sales for our clinical-stage product candidates unless and until we obtain regulatory approval from the FDA for such product candidates. We will continue to incur significant expenses related to the commercialization of our commercial products, and if we obtain regulatory approval for any of our product candidates, we and/or our commercial partners and commercial solutions providers would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

As of September 30, 2022, we had total cash and cash equivalents of $14.9 million and a working capital deficit of $1.0 million. As discussed in "Corporate Updates," we used a portion of our cash and cash equivalents to pay off and terminate the Seller Note issued in connection with the EPI Health Acquisition, as well as satisfy our obligations under the post-closing purchase price adjustment required in connection with the EPI Health Acquisition. With the payment and termination of the Seller Note for a reduced amount of principal, we have removed certain previously existing liabilities and eliminated the need to make cash payments to service the interest on the Seller Note going forward. This allows us to use our cash for development of our product candidates and to support the commercialization of our products. The payment and termination of the Seller Note removed encumbrances from the assets of EPI Health and allows us to pursue a broader range of financing options that could be used to extend our cash runway beyond the targeted submission of our NDA for our lead product candidate, SB206, and be used to further prepare for commercialization of SB206 following approval.

From January 1, 2020 through September 30, 2022, we have raised total equity and debt proceeds of $112.2 million to fund our operations, including (i) $14.0 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the June 2022 registered direct offering, (ii) $37.2 million in net proceeds from the sale of common stock in the June 2021 public offering, (iii) $5.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the March 2020 public offering, (iv) $7.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) in the March 2020 registered direct offering, (v) an additional $6.0 million of proceeds associated with exercises of common stock warrants issued as part of the March 2020 public offering and March 2020 registered direct offering, (vi) $40.3 million in proceeds from the sale of common stock under our common stock purchase agreements with Aspire Capital, (vii) $1.3 million from our Equity Distribution Agreement, and (viii) less than $0.1 million of proceeds from the exercise of stock options. We also obtained a loan under the Paycheck Protection Program, or PPP, of approximately $1.0 million in April 2020 to support certain qualified expenses, including payroll and rental expense. The PPP loan was forgiven in June 2021.

To date, we have focused our funding activities primarily on equity financings, while generating additional liquidity and capital through other sources, including (i) governmental research contracts and grants totaling $12.9 million, (ii) our licensing and supply arrangements with Sato, totaling $33.1 million, and (iii) $25.0 million and $12.0 million in proceeds from two funding transactions during the second quarter of 2019 with Reedy Creek Investments LLC, or Reedy Creek, and Ligand, respectively.

Going forward, we plan to finance our needs principally from the following:

- equity and/or debt financing, including but not limited to sales under the Equity Distribution Agreement, with certain limitations as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Capital Requirements";

- revenues from product sales;
- payments under existing out-license and distribution arrangements for our product candidates and commercial products; and
- payments under current or future collaboration and licensing agreements with strategic partners.

We believe that our existing cash and cash equivalents as of September 30, 2022, plus expected receipts associated with product sales from our commercial product portfolio, will provide us with adequate liquidity to fund our planned operating needs into the beginning of 2023. Variability in our operating forecast, driven primarily by (i) commercial product sales, (ii) timing of operating expenditures, and (iii) unanticipated changes in net working capital, will impact our cash runway. This operating forecast and related cash projection includes (i) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum, including NDA-enabling drug stability studies for SB206, (ii) costs associated with the readiness and operation of our new manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party CMOs, (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution, and supportive activities, related to our portfolio of therapeutic products for skin diseases acquired with the EPI Health Acquisition, and (v) initial efforts to support potential commercialization of SB206, but excludes additional operating costs that could occur between a potential NDA submission for SB206 through NDA approval, including, but not limited to, marketing and commercialization efforts to achieve potential launch of SB206. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

We will need significant additional funding to continue our operating activities, make further advancements in our product development programs and potentially commercialize any of our product candidates beyond those activities currently included in our operating forecast and related cash projection. Therefore, we will need to secure additional capital or financing and/or delay, defer or reduce our cash expenditures before the end of the fourth quarter of 2022. There can be no assurance that we will be able to obtain additional capital or financing on terms acceptable to us, on a timely basis or at all.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. We may pursue additional capital through equity or debt financings, including potential sales under the Equity Distribution Agreement, or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. Alternatively, we may seek to engage in one or more potential transactions, which could include the sale of our company, or the sale, licensing or divestiture of some of our assets, such as a sale of our dermatology platform assets, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or at all on terms that are favorable to us.

If we are unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, we may instead determine to dissolve and liquidate our assets or seek protection under applicable bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under applicable bankruptcy laws, it is unclear to what extent we would be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Our cash and cash equivalents are held in a variety of interest-bearing instruments, including money market accounts. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (19,774)	$ (16,036)
Investing activities	(17,794)	(3,500)
Financing activities	5,386	44,089
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (32,182)	$ 24,553

Net Cash Used in Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was $19.8 million and consisted primarily of a net loss of $28.3 million, with adjustments for non-cash amounts related primarily to (i) stock-based compensation expense of $1.3 million, (ii) amortization of definite lived intangible assets acquired in the EPI Health acquisition of $1.1 million, (iii) $0.8 million of depreciation and amortization of property and equipment expense, (iv) $0.3 million change in fair value of contingent consideration, (v) $4.3 million related to a gain on the extinguishment of the Seller Note, (vi) $0.6 million accretion of debt discount, and (vii) a $9.2 million change in cash related to changes in other operating assets and liabilities. The favorable impacts to cash related to changes in assets and liabilities was primarily due to (i) a $9.7 million change in accounts receivable, (ii) a change in accounts payable of $1.0 million, (iii) a change in prepaid expenses and other current assets of $2.6 million, and (iv) a change in inventory of $0.1 million. The unfavorable impacts to cash related to changes in (i) deferred revenue of $1.9 million, (ii) research and development service obligation of $0.9 million, (iii) accrued expenses of $1.1 million, and (iv) a change in other long-term assets and liabilities of $0.3 million. The change in operating assets and liabilities and related changes from the prior period partially relate to the continued operations of the Research and Development Operations segment as it incurs expenditures to progress SB206, but primarily relate to the recently acquired EPI Health business, which comprises the Commercial Operations segment. See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements for additional detail regarding the purchase of EPI Health and the related impacts of the opening balances related to the EPI Health Acquisition.

During the nine months ended September 30, 2021, net cash used in operating activities was $16.0 million and consisted primarily of a net loss of $21.5 million, with adjustments for non-cash amounts related primarily to (i) depreciation expense of $0.2 million, (ii) impairment of long-lived assets of $0.1 million, (iii) a net favorable adjustment to stock-based compensation of $0.1 million, caused by fair market value adjustments to the Tangible Stockholder Return Plan, (iv) a foreign currency transaction loss of $0.7 million related to fair value adjustments for payments received and to be received under the Amended Sato Agreement, (v) a $1.0 million gain on debt extinguishment related to forgiveness of the PPP loan, and (vi) a $5.4 million favorable change in cash related to changes in other operating assets and liabilities. The favorable change in cash related to changes in assets and liabilities was primarily due to (i) a $4.4 million decrease in contracts and grants receivable primarily related to receipt of a $4.6 million time-based developmental milestone payment, (ii) a $2.1 million decrease in prepaid insurance, prepaid expenses and other current assets primarily related to the amortization of prepaid service contracts and directors and officers insurance premiums, (iii) a $0.8 million increase in accrued expenses, (iv) a $0.1 million increase in research and development service obligation liabilities related to the accretion of the liability associated with Ligand, and (v) a $0.2 million increase in other long-term assets and liabilities. These increases in cash were partially offset by a $2.2 million decrease in deferred revenue associated with our performance under, and revenue recognition of, the Amended Sato Agreement during the nine months ended September 30, 2021.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2022, the $17.8 million of net cash used in investing activities was primarily related to (i) cash used in connection with the EPI Health Acquisition of $15.1 million, and (ii) $3.2 million in cash used for purchases of property, equipment and services associated with the build-out of our corporate headquarters and small-scale manufacturing facility in Durham, North Carolina, offset by $0.5 million of payments received related to the landlord funded tenant improvement allowance. See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements for additional detail regarding the purchase of EPI Health.

During the nine months ended September 30, 2021, the $3.5 million of net cash used in investing activities was primarily related to purchases of property, equipment and services associated with the planning, design and build-out of our new corporate headquarters and small-scale manufacturing facility in Durham, North Carolina; offset by payments received related to the landlord funded tenant improvement allowance. As of September 30, 2021, we also had goods and services associated with the planning, design and build-out of our new facility of $3.9 million included in accounts payable or other accrued expenses in the accompanying balance sheets.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $5.4 million and consisted primarily of (i) net proceeds from the June 2022 Registered Direct Offering of $14.0 million, and (ii) proceeds from the sale of our common stock pursuant to the Equity Distribution Agreement entered into in March 2022 of $1.3 million, offset by the repayment and termination of the Seller Note for $10.0 million.

During the nine months ended September 30, 2021, net cash provided by financing activities was $44.1 million and consisted primarily of (i) $37.6 million of proceeds from the sale of our common stock pursuant to the June 2021 Public Offering, (ii) $6.3 million of proceeds from the sale of our common stock pursuant to the July 2020 Aspire CSPA, (iii) $0.5 million of proceeds from the exercise of common warrants associated with the March 2020 Public Offering and March 2020 Registered Direct Offering, and (iv) $0.1 million of proceeds from the exercise of stock options; partially offset by $0.4 million of payments of costs related to the June 2021 Public Offering.

Capital Requirements

As of September 30, 2022, we had a total cash and cash equivalents balance of $14.9 million and a working capital deficit of $1.0 million. While we currently generate revenue from our commercial portfolio of products acquired in the EPI Health Acquisition, we do not believe that such revenues will be sufficient to fund the operating expenses of our business. To date, we have not generated any revenue from product sales of our product candidates, and we do not know when, or if, we will generate any such revenue. We do not expect to generate revenue from product sales of our product candidates unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization of such product candidate. As of September 30, 2022, we had an accumulated deficit of $307.3 million.

We will need significant additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates, and our funding needs will largely be determined by our commercialization strategy for SB206, subject to the NDA submission timing and the regulatory approval process and outcome.

Our ability to continue to operate our business, including our ability to advance development programs unrelated to SB206, as well as our ability to progress SB206 for molluscum subsequent to an NDA submission, is dependent upon future sales of our commercial products along with our ability to access additional sources of capital, including, but not limited to (i) equity or debt financings, including but not limited to potential sales using the remaining availability under the Equity Distribution Agreement, or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. There can be no assurance that we will be able to obtain new funding on terms acceptable to us, on a timely basis, or at all. In addition, there are certain limitations on the usage of the Equity Distribution Agreement related to the Registered Direct Offering closed in June 2022. In relation to the June 2022 Registered Direct Offering, we agreed not to issue any additional securities in any variable rate transaction (as defined in the related securities purchase agreement), including under the Equity Distribution Agreement, until December 13, 2022, unless, on or after September 11, 2022, the VWAP (as defined in the related securities purchase agreement) for the trading day prior to the date of the transaction is greater than 50% above the exercise price for the June 2022 Common Warrants.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development or commercialization-related timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. We are also exploring the potential for alternative transactions, such as strategic acquisitions or in-licenses, sales, out-licenses or divestitures of some of our assets, or other potential strategic transactions, which could include a sale of the company. If we were to pursue such a transaction, we may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to us.

Our equity issuances during the year ended December 31, 2021 and the nine months ended September 30, 2022 have resulted in significant dilution to our existing stockholders. Any future additional issuances of equity, or debt that could be convertible into equity, would result in further significant dilution to our existing stockholders.

As of September 30, 2022, we had 24,462,228 shares of common stock outstanding. In addition, as of September 30, 2022, we had reserved 7,327,414 shares of common stock for future issuance related to (i) outstanding warrants to purchase common stock, (ii) outstanding stock options and stock appreciation rights, (iii) nonvested restricted stock units, and (iv) future issuances under the 2016 Incentive Award Plan. Our common stock consists of 200,000,000 authorized shares as of September 30, 2022.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount or timing of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- market acceptance of approved products and successful commercialization of such products by either us or our partners;
- our decision to expand our internal commercialization capabilities;
- the initiation, progress, timing, costs, results, and evaluation of results of trials for our clinical-stage product candidates, including trials conducted by us or potential future partners;
- the progress, timing, costs and results of development and preclinical study activities relating to other potential applications of our nitric oxide platform;
- the number and characteristics of product candidates that we pursue;
- the achievement of milestones that would require payment and whether such milestone payments are paid in cash or shares of our common stock, including those set forth in "Note 10—Commitments and Contingencies" to the accompanying condensed consolidated financial statements;
- our ability to enter into strategic relationships to support the continued development of certain product candidates and the success of those arrangements;
- our success in optimizing the size and capability of our new manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204 and SB206 in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies;
- subject to receipt of marketing approval, revenue received from commercial sales or out licensing of our product candidates; and
- revenue received from commercial sales of our existing medical dermatology products.

Contractual Obligations and Contingent Liabilities

During the three and nine months ended September 30, 2022, there were no material changes to our commitments under contractual obligations, other than those related to the EPI Health Acquisition. The EPI Health Acquisition is described in "Note 2—Acquisition of EPI Health" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Our significant accounting policies are more fully described in "Note 1—Organization and Significant Accounting Policies" to the accompanying condensed consolidated financial statements, including those related to the EPI Health Acquisition, and as described within the condensed consolidated financial statement footnotes within this Quarterly Report on Form 10-Q.

Except for items described in "Note 1—Organization and Significant Accounting Policies," "Note 2—Acquisition of EPI Health," "Note 9—Notes Payable," "Note 10—Commitments and Contingencies" and "Note 12—Licensing and Collaboration Arrangements" to the accompanying condensed consolidated financial statements, there were no material changes during the three and nine months ended September 30, 2022 in our commitments under contractual obligations, as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Significant estimates made by us include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of contingent consideration, classification of warrants and contingencies. Actual results may differ materially and adversely from these estimates.

Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. To the extent there are material differences between the estimates and actual results, our future results of operations will be affected.

While our significant accounting policies are more fully described in the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our condensed consolidated financial statements and understanding and evaluating our reported financial results.

Business Acquisitions

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification, or ASC, 805, *Business Combinations,* or ASC 805. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, *Fair Value Measurements*, as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires us to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion, in addition to "Note 17—Fair Value," related to the EPI Health Acquisition.

Revenue Recognition

We account for revenue in accordance with ASC 606, *Revenue from Contracts with Customers,* or ASC 606. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we (i) identify the contract with a customer, (ii) identify the performance obligations within the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations within the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Net Product Revenues

Net product revenues encompass sales recognized resulting from transferring control of products to customers, excluding amounts collected on behalf of other third parties and sales taxes. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when a product is delivered and legal transfer of title has occurred. We record a reduction of the transaction price for estimated chargebacks, rebates, coupons, discounts and returns. A liability is recognized for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present based on the fact that typical payment terms are less than one year. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. We recognize provisions at the time of sale and adjust them if the actual amounts differ from the estimated provisions.

There can be a significant lag between our establishment of an estimate and the timing of the invoicing or claim. We believe we have made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we had estimated.

See "Note 1—Organization and Significant Accounting Policies ” and "Note 13—Net Product Revenues” to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion.

License and Collaboration Revenues

We have entered into various types of agreements that either license our intellectual property to a third party, acquire license rights to intellectual property of a third party, or both.

Agreements where we license our intellectual property to a third party for development and commercialization in a licensed territory. If the applicable license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. We re-evaluate the estimated performance period and measure of progress each reporting period and, if necessary, adjust related revenue recognition accordingly. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, we do not recognize any contingent payments until after regulatory approval has been achieved.

Agreements where we acquire license rights to, or otherwise access, a third party's intellectual property for commercialization of the third party's product in a licensed territory. We also enter into various types of arrangements to commercialize products. Our services provided to the third party under such arrangements, in exchange for compensation that may take the form of cost reimbursements, may include promoting, marketing, selling and distributing the third party's developed drugs, and may also involve certain license rights granted to the parties for use of the other party's intellectual property while providing defined services under the arrangements. We assess the nature of each such arrangement and the various rights granted and services performed thereunder.

Royalty revenue from licenses provided to our collaboration partners, which is based on sales to third parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied.

When we perform and incur marketing and promotional services expense under an arrangement that is determined to be within the scope of ASC 808, and where such services are on behalf of a collaboration partner that is not considered a customer under ASC 606, we recognize a contra-expense that reflects the value of the cost reimbursement to which we are expected to be entitled in exchange for those services. Such contractually required reimbursements are reported as a liability or an asset within the accompanying condensed consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

See "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion.

Classification of Warrants and Pre-Funded Warrants Issued in Connection with Offerings of Common Stock Warrants. In our June 2022 Registered Direct Offering, March 2020 Public Offering, March 2020 Registered Direct Offering, and January 2018 Offering we issued warrants to purchase shares of our common stock. We assessed the warrants for appropriate equity or liability classification pursuant to our accounting policies described in "Note 1—Organization and Significant Accounting Policies" to the accompanying condensed consolidated financial statements. The warrants provide each warrant holder with the right to require net cash settlement of the warrants upon the occurrence of certain fundamental transactions, provided that such transactions are within our control. For any fundamental transaction that is not within our control, including a fundamental transaction not approved by our board of directors, the warrant holder will only be entitled to receive from us or any successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to our common stockholders in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. In the event of any fundamental transaction, and regardless of whether it is within our control, the settlement amount of the warrants (whether in cash, stock or a combination thereof) is determined based upon a Black-Scholes value that is calculated using inputs as specified in the warrants, including a defined volatility input equal to the greater of our 100-day historical volatility or 100%.

Pre-Funded Warrants. In the June 2022 Registered Direct Offering, March 2020 Public Offering and March 2020 Registered Direct Offering, we also issued pre-funded warrants to purchase shares of our common stock. We assessed the pre-funded warrants for appropriate equity or liability classification pursuant to our accounting policy described in "Note 1—Organization and Significant Accounting Policies" to the accompanying condensed consolidated financial statements. The pre-funded warrants did not provide each warrant holder with the option to settle any unexercised warrants for cash in the event of any fundamental transactions. In all fundamental transaction scenarios, the warrant holder was only entitled to receive from us or any successor entity the same type or form of consideration (and in the same proportion) that was being offered and paid to our stockholders in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. The pre-funded warrants also included a separate provision whereby the exercisability of the warrants was limited if, upon exercise, the warrant holder or any of its affiliates would have beneficially owned more than 4.99% (or an amount up to 9.99% if the holder so elects) of our common stock.

See "Note 11—Stockholders' Equity" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding the terms of the pre-funded warrants and the applicable accounting treatment.

Accounts Receivable

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables. An account receivable is considered to be past due if any portion of the receivable balance is outstanding beyond the agreed-upon due date.

As needed, we record an allowance for credit losses, which includes a provision for expected losses based on historical write-offs, adjusted for current conditions as deemed necessary, reasonable and supportable forecasts about future conditions that affect the expected collectability of the reported amount of the financial asset, and a specific reserve for accounts deemed at risk. The allowance is our estimate for accounts receivable as of the balance sheet date that ultimately will not be collected. Any changes in the allowance are reflected in the results of operations in the period in which the change occurs. We write off accounts receivable and the related allowance recorded previously when it becomes probable, based upon customer facts and circumstances, that such amounts will not be collected.

Account balances are written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Recoveries of receivables previously written off are recorded when received. We do not charge interest on accounts receivable.

Inventory

We maintain inventory consisting of for-sale pharmaceuticals related to our marketed product portfolio. We measure inventory using the first-in, first out-method and value inventory at the lower of cost or net realizable value. Net realizable value represents the estimated selling price for inventories less all estimated costs to sell.

We perform an analysis and record a provision for potentially obsolete inventory. The reserve for obsolescence is generally an estimate of the amount of inventory held at period end that is expected to expire in the future based on projected sales volume and expected product expiration or sell-by dates. These assumptions require us to analyze the aging of and forecasted demand for our inventory and make estimates regarding future product sales.

Intangible Assets and Goodwill

Intangible assets represent identifiable intangible assets including pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term of the agreement or the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, we compare the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being evaluated for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis at September 30 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test. A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in our stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Key assumptions used in the annual goodwill impairment test are highly judgmental. Any change in these indicators or key assumptions could have a significant negative impact on our financial condition, impact the goodwill impairment analysis or cause us to perform a goodwill impairment analysis more frequently than once per year.

See "Note 7—Goodwill and Intangible Asset, net" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding intangible assets and goodwill related to the EPI Health Acquisition.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable vendor personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

See "Note 8—Accrued Expenses" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional detail.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. The estimated fair value of contingent consideration is determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products is simulated over the measurement period to calculate the contingent consideration.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability.

The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the condensed consolidated statements of operations and comprehensive loss until settlement.

See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding purchase consideration, including contingent consideration related to the EPI Health Acquisition.

Reedy Creek Purchase Agreement

We have previously determined that the Royalty and Milestone Payments Purchase Agreement with Reedy Creek, or the Reedy Creek Purchase Agreement, is within the scope of ASC 730-20, *Research and Development Arrangements,* or ASC 730-20. We concluded that there has not been a substantive and genuine transfer of risk related to the Reedy Creek Purchase Agreement as (i) Reedy Creek has the opportunity to recover its investment regardless of the outcome of the research and development programs within the scope of the agreement (prior to commercialization of any in scope assets through potential out-licensing agreements and related potential future milestone payments), and (ii) there is a presumption that we are obligated to pay Reedy Creek amounts equal to its investment based on the related party relationship at the time the parties entered into the Reedy Creek Purchase Agreement. The Reedy Creek Purchase Agreement is a broad funding arrangement, due to (i) the multi-asset, or portfolio approach including three developmental assets that are within the scope of the arrangement, and (ii) Reedy Creek's approximate 5% ownership of our outstanding shares of common stock at the time of entry into the Reedy Creek Purchase Agreement.

As such, we have determined that the appropriate accounting treatment under ASC 730-20 was to record the initial proceeds of $25.0 million as cash and cash equivalents, as we had the ability to direct the usage of funds, and a long-term liability within our classified balance sheet. The long-term liability will remain until we receive future milestones from other potential third parties, as defined within the Reedy Creek Purchase Agreement, of which 25% will be contractually owed to Reedy Creek. If potential future milestones are received by us, and become partly due to Reedy Creek, the corresponding partial repayment to Reedy Creek will result in a ratable reduction of the total long-term obligation to repay the initial purchase price.

See "Note 15—Research and Development Agreements" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding the applicable accounting treatment of the Reedy Creek Purchase Agreement.

Ligand Funding Agreement

We have previously determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. In addition, the Ligand Funding Agreement also states that if all development of SB206 is ceased prior to the first regulatory approval, we must pay to Ligand an amount equal to the purchase price less the amount spent in accordance with the development budget on development activities conducted prior to such cessation. As such, we concluded that the appropriate accounting treatment under ASC 730-20 was to record the initial proceeds of $12.0 million, as a liability and as restricted cash on our consolidated balance sheet, as the funds could only be used for the progression of SB206.

We amortize the liability ratably during each reporting period, based on the Ligand funding as a percentage of the total direct costs we incur during the reporting period related to the estimated total cost to progress the SB206 program to a regulatory approval in the United States. The ratable Ligand funding has been presented within our accompanying consolidated statements of operations and comprehensive loss as an offset to research and development expenses associated with the SB206 program.

However, because the aggregate amount spent in accordance with the SB206 development budget on SB206 development activities had exceeded the $12.0 million purchase price, we reported no restricted cash balance related to the Ligand Funding Agreement, as of December 31, 2021 in our consolidated balance sheet.

See "Note 15—Research and Development Agreements" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding the applicable accounting treatment of the Ligand Funding Agreement.

Determination of the Fair Value of Stock-based Compensation Grants

We record the fair value of stock options, restricted stock units and other stock-based compensation issued to employees and non-employees as of the grant date as stock-based compensation expense. We typically recognize compensation expense over the requisite service period, which is typically the vesting period.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option-pricing model, which requires the input of assumptions, some of which are highly subjective, including (i) the fair value of our common stock on the date of grant, (ii) the expected volatility of our stock, (iii) the expected term of the award, (iv) the risk-free interest rate and (v) expected dividends. In applying these assumptions, we considered the following factors:

- We have based our estimate of expected volatility, in part, on the historical volatility of a group of similar companies that are publicly traded, in addition to our own historical volatility. We are transitioning to using our historical volatility as a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We considered characteristics such as industry, stage of life cycle, financial leverage, enterprise value, risk profiles and position within the industry, along with historical share price information sufficient to meet the expected life of the stock-based awards in selecting the similar companies. We compute the historical volatility data using the daily closing prices during the equivalent period of the calculated expected term of our stock-based awards.
- We have estimated the expected term of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option.
- The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of granted stock-based awards.
- We have never declared or paid any cash dividends to common stockholders and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero.

We estimate the fair value of restricted stock units awarded to employees and non-employees based on their estimated fair values on the date of grant. The fair value of restricted stock units is estimated based on the closing price of the underlying common stock on the date of grant.

We estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We use historical data to estimate pre-vesting option and restricted stock unit forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

See "Note 16—Stock-Based Compensation" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding stock based compensation awards.

Recent Accounting Pronouncements

Recently issued accounting pronouncements that we have adopted or are currently evaluating are described in detail within "Note 1—Organization and Significant Accounting Policies" to the accompanying condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (the "Exchange Act") reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and financial officers, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rules 13a-15(e) and 15d-15(e) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and financial officers, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive and financial officers concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

We closed the EPI Health Acquisition on March 11, 2022, and EPI Health's total assets and revenues constituted 69.5% and 84.9%, respectively, of our consolidated total assets (including goodwill and intangible assets, net) and revenues as shown on our condensed consolidated financial statements as of and for the nine months ended September 30, 2022. As the EPI Health Acquisition occurred in the first quarter of fiscal 2022, we excluded the internal control over financial reporting of EPI Health from the scope of our assessment of the effectiveness of our disclosure controls and procedures as of September 30, 2022. This exclusion is in accordance with the general guidance issued by the Staff of the Securities and Exchange Commission that an assessment of a recently-acquired business may be omitted from our scope in the year of acquisition, if specified conditions are satisfied.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all errors and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Controls Over Financial Reporting

As noted above, on March 11, 2022, we completed the EPI Health Acquisition. We are in the process of integrating the operations of EPI Health into our overall internal control over financial reporting process. This process may result in additions or changes to our internal control over financial reporting.

There has been no other change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings and are not aware of any claims or actions pending against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial statements. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in our Annual Report, except as follows:

Risks related to the EPI Health Acquisition

Integrating the EPI Health and legacy Novan businesses requires that management balance the interests of integration and managing the day-to-day business of the combined company, and failure to do so effectively may have an adverse effect.

Achieving the anticipated benefits of the EPI Health Acquisition depends in significant part upon our ability to integrate the EPI Health businesses, operations, processes, and systems in an efficient and effective manner. The integration of operations following the EPI Health Acquisition requires the dedication of significant management and external resources, which requires that management attend to and balance both integration efforts and the day-to-day business of the combined company and has required significant expenditures that are reflected in the accompanying condensed consolidated financial statements. Any inability of management to successfully and timely integrate the companies could have a material adverse effect on the business and results of operations of the combined company.

EPI Health may have liabilities that are not known to us.

EPI Health may have liabilities that we failed, or were unable, to discover in the course of performing our due diligence investigations in connection with the EPI Health Acquisition. We may learn additional information about EPI Health that materially and adversely affects us and EPI Health, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Moreover, EPI Health may be subject to audits, reviews, inquiries, investigations, and claims of non-compliance and litigation by federal and state regulatory agencies which could result in liabilities or other sanctions. Any such liabilities or sanctions, individually or in the aggregate, could have an adverse effect on our business, financial condition, and results of operations.

We have made certain assumptions relating to the EPI Health Acquisition that may prove to be materially inaccurate.

We have made certain assumptions relating to the EPI Health Acquisition that may prove to be inaccurate, including as the result of the potential failure to realize the expected benefits of the EPI Health Acquisition, failure to realize expected revenue growth rates, higher than expected operating and transaction costs, as well as general economic and business conditions that could adversely affect the combined company.

The EPI Health Acquisition involves substantial costs.

We have incurred, and expect to continue to incur, a number of non-recurring costs associated with the EPI Health Acquisition. The substantial majority of the non-recurring expenses have consisted of transaction costs related to the EPI Health Acquisition. We have and will also continue to incur transaction fees and costs related to formulating and implementing integration plans, including system consolidation costs and employment-related costs. We continue to assess the magnitude of these costs, and additional unanticipated costs may be incurred relating to the EPI Health Acquisition and integration. Although we anticipate that the elimination of duplicative costs and the realization of other efficiencies and synergies related to the integration should allow us to offset integration-related costs over time, this net benefit may not be achieved in the near term, or at all.

Risks Relating to our Common Stock

The market price and trading volume of our common stock has fluctuated substantially. The market price and trading volume of our common stock may fluctuate widely in the future and the value of an investment in our common stock may decline.

Our stock price has experienced extreme volatility and could vary significantly as a result of many factors. Between January 1, 2021 and November 2, 2022, the last reported sales price of our common stock fluctuated between a high of $25.50 and a low of $1.03. The market price and trading volume of our common stock may continue to fluctuate from time to time as a result of factors outside of our control. For example, the trading price of our common shares increased significantly in June 2021, which we believe was attributable to general market conditions and recognition of our announcement of top-line results of our B-SIMPLE4 study of SB206 as a potential treatment for molluscum contagiosum, and has since declined. There is a potential for rapid and substantial decreases in the price of our common stock, including decreases unrelated to our operating performance or prospects, which could result in substantial losses for our existing stockholders.

In addition, the stock market in general and smaller reporting companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These broad market and industry fluctuations, including but not limited to those connected with the ongoing military conflict between Russia and Ukraine and trade and monetary sanctions in response to such developments, may negatively impact the price or liquidity of our common stock, regardless of our operating performance. Any actual or perceived negative operational developments or market or industry fluctuations may compound each other's negative impacts on the price of liquidity of our common stock.

Risks Relating to Technology

We may be subject to confidential information theft or misuse, which could harm our business and results of operations. Our internal computer systems, or those of any of our existing or potential future collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, expose the Company to liability, affect our reputation and otherwise harm our business.

We face attempts by others to gain unauthorized access to our information technology systems on which we maintain proprietary and other confidential information. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs, CMOs, and other contractors, consultants and collaborators are vulnerable to damage from cyberattacks, "phishing" attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, including in the context of global conflicts, such as the war in Ukraine. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our increased reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, the FDA and comparable foreign regulatory authorities regulate, among other things, the record keeping and storage of data pertaining to approved and potential pharmaceutical products, and we currently store most of our preclinical research data, our clinical data and our manufacturing data at our facilities. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to applicable data privacy and security law and regulations. We would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be subject to material legal claims and incur liability or other negative consequences, including increased cybersecurity protection costs, damage to our reputation, disruption of our internal operations and delays in the further development of and potential commercialization of our product candidates.

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

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following exhibits are being filed herewith or are being incorporated by reference and are numbered in accordance with Item 601 of Regulation S-K:

			INCORPORATED BY REFERENCE			
EXHIBIT NO.	DESCRIPTION	Filed Herewith	FORM	File No.	Exhibit	Filing Date
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL Instance document included in Exhibit 101.					

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Novan, Inc.

By: /s/ Paula Brown Stafford
Paula Brown Stafford
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

/s/ John M. Gay
John M. Gay
Chief Financial Officer
(Principal Financial Officer)

/s/ Andrew J. Novak
Andrew J. Novak
Vice President, Accounting and Business Operations
(Principal Accounting Officer)

Date: November 14, 2022

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paula Brown Stafford, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novan, Inc. (the "registrant");

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 14, 2022

/s/ Paula Brown Stafford

Paula Brown Stafford
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John M. Gay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novan, Inc. (the "registrant");

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 14, 2022

/s/ John M. Gay

John M. Gay
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

I, Paula Brown Stafford, Chief Executive Officer of Novan, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2022 (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 for the periods presented therein.

Date: November 14, 2022

/s/ Paula Brown Stafford
Paula Brown Stafford
Chief Executive Officer
(Principal Executive Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

I, John M. Gay, Chief Financial Officer of Novan, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2022 (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 for the periods presented therein.

Date: November 14, 2022

/s/ John M. Gay
John M. Gay
Chief Financial Officer
(Principal Financial Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.