

**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 March 31, 2023

OR

**II 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**

(State or other jurisdiction of  
incorporation or organization)

**20-4427682**

(I.R.S. Employer  
Identification No.)

**4020 Stirrup Creek Drive, Suite 110**

**Durham, North Carolina**

(Address of principal executive offices)

**27703**

(Zip Code)

**(919) 485-8080**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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  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  No

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

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

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

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

As of May 5, 2023, there were 28,015,371 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)**

	March 31, 2023	December 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,541	\$ 12,316
Restricted cash, current	646	1,047
Accounts receivable, net	13,836	22,002
Inventory, net	1,116	1,196
Prepaid expenses and other current assets	4,547	5,807
Total current assets	32,686	42,368
Restricted cash, net of current portion	581	583
Property and equipment, net	13,521	13,882
Intangible assets, net	26,998	27,475
Other assets	195	210
Right-of-use lease assets	1,756	1,756
Goodwill	4,056	4,056
Total assets	<u>\$ 79,793</u>	<u>\$ 90,330</u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 14,321	\$ 13,689
Accrued expenses	18,238	18,624
Factoring arrangement payable	7,922	10,302
Deferred revenue, current portion	2,586	2,586
Research and development service obligation liability, current portion	378	555
Contingent consideration liability, current portion	—	451
Operating lease liabilities, current portion	465	191
Total current liabilities	43,910	46,398
Deferred revenue, net of current portion	7,433	8,079
Operating lease liabilities, net of current portion	3,387	3,739
Research and development service obligation liability, net of current portion	—	25
Research and development funding arrangement liability	25,000	25,000
Contingent consideration liability, net of current portion	2,353	2,037
Deferred tax liability	56	—
Other long-term liabilities	482	447
Total liabilities	82,621	85,725
Commitments and contingencies (Note 10)		
Stockholders' (deficit) equity		
Common stock \$0.0001 par value; 200,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 28,016,321 and 24,723,258 shares issued as of March 31, 2023 and December 31, 2022, respectively; 28,015,371 and 24,722,308 shares outstanding as of March 31, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	321,723	315,038
Treasury stock at cost, 950 shares as of March 31, 2023 and December 31, 2022	(155)	(155)
Accumulated deficit	(324,399)	(310,280)
Total stockholders' (deficit) equity	(2,828)	4,605
Total liabilities and stockholders' (deficit) equity	<u>\$ 79,793</u>	<u>\$ 90,330</u>

*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)**

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Net product revenues	\$ 2,411	\$ 718
License and collaboration revenues	585	1,174
Government research contracts and grants revenue	170	36
Total revenue	3,166	1,928
Operating expenses:		
Cost of goods sold	1,285	206
Research and development	4,832	4,833
Selling, general and administrative	10,040	9,994
Amortization of intangible assets	477	121
Change in fair value of contingent consideration	365	—
Total operating expenses	16,999	15,154
Operating loss	(13,833)	(13,226)
Other income (expense), net:		
Interest income	30	3
Interest expense	(277)	(132)
Other income (expense)	17	(25)
Total other income (expense), net	(230)	(154)
Net loss before income taxes	(14,063)	(13,380)
Provision for income tax expense	56	—
Net loss and comprehensive loss	\$ (14,119)	\$ (13,380)
Net loss per share, basic and diluted	\$ (0.54)	\$ (0.71)
Weighted-average common shares outstanding, basic and diluted	26,115,986	18,829,534

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

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

<b>Three Months Ended March 31, 2023</b>							
	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total	
	Shares	Amount					
Balance as of December 31, 2022	24,722,308	\$ 2	\$ 315,038	\$ (155)	\$ (310,280)	\$ 4,605	
Stock-based compensation	—	—	431	—	—	431	
Common stock issued pursuant to equity distribution agreement (at-the-market facility)	543,063	—	865	—	—	865	
Common stock and pre-funded warrants issued pursuant to the March 2023 registered direct offering, net	2,750,000	1	5,389	—	—	5,390	
Net loss	—	—	—	—	(14,119)	(14,119)	
Balance as of March 31, 2023	28,015,371	\$ 3	\$ 321,723	\$ (155)	\$ (324,399)	\$ (2,828)	

<b>Three Months Ended March 31, 2022</b>							
	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	

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flow from operating activities:</b>		
Net loss	\$ (14,119)	\$ (13,380)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization of property and equipment	410	97
Amortization of intangible assets	477	121
Change in fair value of contingent consideration	365	—
Provision for deferred income taxes	56	—
Stock-based compensation	431	381
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	8,166	8,543
Inventory	80	232
Prepaid expenses and other current assets	1,260	565
Accounts payable	606	1,604
Accrued expenses	(1,106)	393
Deferred revenue	(646)	2,591
Research and development service obligation liability	(202)	(297)
Other long-term assets and liabilities	(28)	(84)
Net cash (used in) provided by operating activities	(4,250)	766
<b>Cash flow from investing activities:</b>		
Purchases of property and equipment	(23)	(928)
Payment for EPI Health Acquisition	—	(11,993)
Net cash used in investing activities	(23)	(12,921)
<b>Cash flow from financing activities:</b>		
Proceeds from issuance of common stock and issuance of pre-funded warrants, net of underwriting fees and commissions	5,610	—
Proceeds from factoring arrangement	26,335	—
Repayments under factoring arrangement	(28,715)	—
Proceeds from common stock issued pursuant to equity distribution agreement (at-the-market facility)	865	562
Net cash provided by financing activities	4,095	562
Net decrease in cash, cash equivalents and restricted cash	(178)	(11,593)
Cash, cash equivalents and restricted cash as of beginning of period	13,946	47,668
Cash, cash equivalents and restricted cash as of end of period	\$ 13,768	\$ 36,075
<b>Supplemental disclosure for cash flow information:</b>		
Interest paid	\$ 277	\$ 45
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Contingent consideration from prior acquisitions included in accrued expenses due to milestones being met	\$ 500	\$ —
Deferred offering costs in accounts payable and accrued expenses	\$ 220	\$ —
Purchases of property and equipment with accounts payable and accrued expenses	\$ —	\$ 1,780
Contingent consideration related to EPI Health Acquisition	\$ —	\$ 3,773
Note payable issued for EPI Health Acquisition	\$ —	\$ 16,500
<b>Reconciliation to condensed consolidated balance sheets:</b>		
Cash and cash equivalents	\$ 12,541	\$ 35,492
Restricted cash included in current assets	646	—
Restricted cash included in noncurrent assets	581	583
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	\$ 13,768	\$ 36,075

*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 on 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 and acne.

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 which did not have any operating activity for the quarter ended March 31, 2023.

**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, 2022 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, 2022 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.

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 months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022, and for the three months ended March 31, 2023.

**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 March 31, 2023, the Company had an accumulated deficit of \$324,399.
- As of March 31, 2023, the Company had a total cash and cash equivalents balance of \$12,541.
- 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 March 31, 2023, plus expected receipts associated with product sales from its commercial product portfolio, will provide it with liquidity to fund its planned operating needs into late second quarter 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 potential U.S. regulatory approval of SB206 as a treatment for molluscum, (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 contract manufacturing organizations ("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 through potential NDA approval, including, but not limited to, manufacturing, 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 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 and preparations for potential commercialization activities, furloughing employees or reducing the size of the workforce, 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 other 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.

#### **Significant Accounting Policies**

In the opinion of the Company's management, the Company's significant accounting policies used for the three months ended March 31, 2023, are consistent with those used for the fiscal year ended December 31, 2022, except as noted below. Accordingly, please refer to "Note 1: Organization and Significant Accounting Policies" to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023 (the "Annual Report") for the Company's significant accounting policies.

## **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.

## **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 notes payable issued in conjunction with the acquisition, 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 Annual Report.

## **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. As of March 31, 2023 and December 31, 2022, the Company had recorded a provision for expected losses of \$141.

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.

## **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash, cash equivalents and accounts receivable. The Company places its cash and cash equivalents with financial institutions and these deposits may at times be in excess of insured limits and the Company assesses the creditworthiness of its customers on an on-going basis.

As of March 31, 2023, three of the Company's wholesaler customers accounted for more than 10% of its total accounts receivable balance at 31%, 16% and 11%, respectively. As of December 31, 2022, three of the Company's wholesaler customers accounted for more than 10% of its total accounts receivable balance at 25%, 13% and 12%, respectively.

### **Impairment of Long-Lived Assets**

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for an amount by which the carrying amount of the asset exceeds the fair value of the asset.

### **Revenue Recognition**

The Company accounts for revenue in accordance with Accounting Standards Codification ("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 resulting from transferring control of products to the customer, excluding amounts collected on behalf of third parties. 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 100 days. 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, which involves significant estimates by management. 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 the 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, which involves significant estimates by management.

**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 regulatory approval becomes probable. Future sales-based royalties are not recorded until the subsequent sale occurs.

*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 based on the later of when the third-party sale occurs or 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.

#### **Advertising Costs**

Promotion, marketing and advertising costs are expensed as incurred. Promotion, marketing and advertising costs for the three months ended March 31, 2023, and 2022 were approximately \$835 and \$387, respectively. The costs are included in selling, general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

#### **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 condensed consolidated statement of operations and comprehensive loss. See "Note 16: 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.

### **Fair Value of Financial Instruments**

The carrying values of cash equivalents, accounts receivable, accounts payable and accrued liabilities as of March 31, 2023 and December 31, 2022 approximated their fair values due to the short-term nature of these items.

The Company has categorized its financial instruments, based on the priority of the inputs used to value the investments, into a three-level fair value hierarchy. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). If the inputs used to measure the investments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument. Financial instruments recorded in the accompanying condensed consolidated balance sheets are categorized based on the inputs to valuation techniques as follows:

Level 1 - Observable inputs that reflect unadjusted quoted market prices for identical assets or liabilities in active markets.

Level 2 - Observable inputs other than Level 1 that are observable, either directly or indirectly, in the marketplace for identical or similar assets and liabilities.

Level 3 - Unobservable inputs that are supported by little or no market data, where values are derived from techniques in which one or more significant inputs are unobservable.

See "Note 16: Fair Value" for additional detail regarding the fair value of certain balances reflected within the accompanying condensed consolidated financial statements.

### **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 does not record a federal or state income tax benefit 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.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

The Company's policy for recording interest and penalties is to record them as a component of general and administrative expenses. For the three months ended March 31, 2023 and 2022, the Company accrued no interest and penalties related to uncertain tax positions. For the three months ended March 31, 2023, the Company recorded an insignificant amount of income tax expense related to deferred tax expense as a result of the acquisition of EPI Health in the prior year and the related tax deductible goodwill, which created an indefinite lived deferred tax liability.

Tax years 2019-2021 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2019 are also open to examination to the extent of loss and credit carryforwards from those years.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its net operating loss carryforwards and general business credits, including the research and development credits, created during the tax periods prior to the change in ownership.

### **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 months ended March 31, 2023 and March 31, 2022 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.

	March 31,	
	2023	2022
Warrants to purchase common stock (Note 11)	12,869,671	274,326
Stock options outstanding under the 2008 and 2016 Plans (Note 15)	1,032,120	664,278
Nonvested restricted stock units (Note 15)	423,505	—
Stock appreciation rights outstanding under the 2016 Plan (Note 15)	60,000	60,000
Inducement stock options outstanding (Note 15)	1,250	1,250

#### Related Parties

Members of the Company's board of directors held 27,654 shares of the Company's common stock as of March 31, 2023 and December 31, 2022, respectively.

#### 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 and acne.

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 and (ii) a secured promissory note issued to EPG in the principal amount of \$16,500 (the "Seller Note"). See "Note 9: Notes Payable" for additional detail regarding the Seller Note and its related terms. The Company also paid a total working capital adjustment of \$4,093, including (i) a \$993 payment at closing and (ii) a \$3,100 payment post-closing in July 2022 as the parties agreed to the final net working capital adjustment amount.

The purchase agreement entered into in connection with the EPI Health Acquisition (the "EPI Health Purchase Agreement") included the potential payment of additional contingent consideration totaling up to \$23,000 upon achievement of certain milestones, as follows:

- \$500, 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 (the "Transition Services Agreement Milestone");
- \$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 (the "First Sales Based Milestone");
- 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 Wyzora Cream ("Wyzora") exceeding certain quarterly thresholds or an annual threshold of \$12,500 during the period from April 1, 2022 through March 31, 2023 (the "Wyzora Milestone");
- \$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 (the "Second Sales Based Milestone"); and
- 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.

From the EPI Health Acquisition date through March 31, 2022, \$1,246 of total net revenue and a net loss of \$726 associated with EPI Health's operations are included in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2022.

During the three months ended March 31, 2023, two potential milestone payments of contingent consideration expired without being triggered: (i) the First Sales Based Milestone; and (ii) the Wyzora Milestone. In addition, one milestone payment, the Transition Services Agreement Milestone, was triggered and has been reclassified to accrued expenses within the condensed consolidated balance sheet as of March 31, 2023. See "Note 8: Accrued Expenses" and "Note 16: Fair Value" for additional detail.

#### *Purchase Consideration*

The following table presents the estimated fair value of purchase consideration. The estimated fair value of purchase consideration was 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 *Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired*.

	<b>As of December 31, 2022</b>
Initial cash consideration to Seller	\$ 11,000
Secured promissory note issued to Seller	13,305
Closing date fair value of contingent consideration liability	3,648
Remaining working capital adjustment paid	3,100
Working capital adjustment paid at close	993
Total estimated purchase consideration	<u>\$ 32,046</u>

#### *Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired*

ASC 805, *Business Combinations* ("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 allocated to the estimated fair values of the assets acquired and liabilities assumed as of March 11, 2022 as follows:

	<u>As of December 31, 2022</u>	
Assets acquired and liabilities assumed:		
Accounts receivable, net of \$282 allowance	\$	19,804
Inventory		1,179
Prepaid expenses and other current assets		3,692
Property and equipment		100
Intangible assets		29,000
Other assets		27
Right-of-use lease assets		400
Total assets	\$	54,202
Accounts payable	\$	947
Accrued expenses		24,425
Operating lease liabilities, current portion		208
Operating lease liabilities, net of current portion		342
Other long-term liabilities		290
Total liabilities	\$	26,212
Total identifiable net assets acquired	\$	27,990
Goodwill		4,056
Total estimated purchase consideration	\$	32,046

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 fair values of the assets and liabilities identified at the time of the EPI Health Acquisition. 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 and has therefore been allocated to the Research and Development Operations reporting unit.

### Note 3: Inventory, net

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

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Finished goods available for sale	\$ 1,957	\$ 2,037
Reserve for obsolescence	(841)	(841)
Inventory, net	\$ 1,116	\$ 1,196

**Note 4: Prepaid Expenses and Other Current Assets**

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

	March 31, 2023	December 31, 2022
Inventory and raw material deposits	\$ 1,280	\$ 1,280
Prepaid service contracts	163	121
Prepaid insurance	936	1,341
Prepaid Prescription Drug User Fee Act (PDUFA) fees	788	1,182
Product samples	937	1,362
Prepaid expenses and other current assets	443	521
<b>Total prepaid expenses and other current assets</b>	<b>\$ 4,547</b>	<b>\$ 5,807</b>

**Note 5: Property and Equipment, net**

Property and equipment consisted of the following:

	March 31, 2023	December 31, 2022
Computer equipment	\$ 58	\$ 58
Furniture and fixtures	43	43
Laboratory equipment	6,206	6,195
Office equipment	177	177
Leasehold improvements	10,144	10,117
Property and equipment, gross	16,628	16,590
Less: Accumulated depreciation and amortization	(3,107)	(2,708)
<b>Total property and equipment, net</b>	<b>\$ 13,521</b>	<b>\$ 13,882</b>

Depreciation and amortization expense was \$410 and \$97 for the three months ended March 31, 2023 and 2022, respectively.

*Corporate and Manufacturing Facility*

As of March 31, 2023 and December 31, 2022, the Company had construction in progress amounts related to leasehold improvements of \$239 and \$210, 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 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 Leases in 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 was \$20 for months 1-12, inclusive of taxes and operating expenses such as maintenance and insurance.

In February 2023, EPI Health entered into a new lease agreement in Charleston, South Carolina for 800 rentable square feet of office space. This office lease is less than twelve months in duration, from March 1, 2023 through February 28, 2024.

#### *TBC Lease and South Carolina Leases*

Rent expense, including both short-term and variable lease components was \$143 for the three months ended March 31, 2023 and \$137 for the three months ended March 31, 2022.

The remaining lease term for the TBC Lease was 8.92 years as of March 31, 2023. The weighted average discount rate for the TBC lease was 8.35%.

Future net minimum lease payments, net of amounts expected to be received related to the tenant improvement allowance, as of March 31, 2023 were as follows:

<b>Maturity of Lease Liabilities</b>	<b>Operating Lease</b>
2023	\$ 457
2024	208
2025	645
2026	665
2027	685
2028 and beyond	3,016
Total future undiscounted lease payments	\$ 5,676
Less: imputed interest	(1,824)
Total reported lease liability	\$ 3,852

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 cash outflows related to the 2024 fiscal year presented above includes the expected timing of the remaining balance of the total tenant improvement allowance of \$419 being funded by the TBC Landlord, which the Company reasonably expects to receive within that year.

Components of lease assets and liabilities as of March 31, 2023 were as follows:

	<b>March 31, 2023</b>
<b>Assets</b>	
Right-of-use lease assets	\$ 1,756
Total lease assets	\$ 1,756
<b>Liabilities</b>	
Operating lease liabilities, current portion	\$ 465
Operating lease liabilities, net of current portion	3,387
Total lease liabilities	\$ 3,852

**Note 7: Goodwill and Intangible Assets, net**

*Goodwill*

The Company's goodwill balance as of March 31, 2023 and December 31, 2022 was \$4,056. The entire goodwill balance relates to the EPI Health Acquisition. 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 March 31, 2023, comprised primarily of acquired product rights related to the EPI Health Acquisition:

	<b>Initial Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Book Value</b>	<b>Remaining Useful Life (Years)</b>
Rhofade	\$ 15,500	\$ 1,090	\$ 14,410	14.00
Wynzora	2,000	140	1,860	14.00
Minolira	8,500	598	7,902	14.00
Cloderm	1,000	70	930	14.00
Sitavig	2,000	179	1,821	13.69
Website domain	75	—	75	—
Total intangible assets	\$ 29,075	\$ 2,077	\$ 26,998	

The following table presents both definite and indefinite lived intangible assets as of December 31, 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	\$ 835	\$ 14,665	14.25
Wynzora	2,000	108	1,892	14.25
Minolira	8,500	458	8,042	14.25
Cloderm	1,000	54	946	14.25
Sitavig	2,000	145	1,855	13.94
Website domain	75	—	75	—
<b>Total intangible assets</b>	<b>\$ 29,075</b>	<b>\$ 1,600</b>	<b>\$ 27,475</b>	

The Company amortizes the product rights related to its commercial product portfolio over their estimated useful lives.

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

2023	\$ 1,458
2024	1,941
2025	1,935
2026	1,935
2027	1,935
Thereafter	17,719
<b>Total amortization</b>	<b>\$ 26,923</b>

#### Note 8: Accrued Expenses

The following table represents the components of accrued expenses as of March 31, 2023 and December 31, 2022:

	March 31, 2023	December 31, 2022
Accrued rebates, coupons, discounts and chargebacks	\$ 6,964	\$ 8,671
Accrued returns	1,667	3,011
Accrued compensation	2,242	937
Accrued outside research and development services	157	410
Accrued legal and professional fees	1,738	542
Accrued royalties	270	675
Accrued amounts payable to EPG	1,000	—
Accrued milestones	2,250	1,250
Accrued insurance	243	747
Accrued SB206 regulatory activities	—	165
Accrued Wynzora payments due to collaborator	835	532
Accrued MC2 collaboration deposit	—	1,149
Accrued other expenses	872	535
<b>Total accrued expenses</b>	<b>\$ 18,238</b>	<b>\$ 18,624</b>

## **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. 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 months ended March 31, 2022, the Company recorded interest expense of \$132 related to the Seller Note.

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.

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.

## **Note 10: Commitments and Contingencies**

### **Commitments**

#### *Factoring Arrangement*

On December 1, 2022, EPI Health entered into an accounts receivable-backed factoring agreement (the "Factoring Agreement") with CSNK Working Capital Finance Corp. d/b/a Bay View Funding ("Bay View"), a subsidiary of Heritage Bank of Commerce. Pursuant to the Factoring Agreement, EPI Health may sell certain trade accounts receivable to Bay View from time to time, with recourse. The factoring facility provides for EPI Health to have access to the lesser of (i) \$15,000 (the "Maximum Credit") or (ii) the sum of all undisputed receivables purchased by Bay View multiplied by 70% (which percentages may be adjusted by Bay View in its sole discretion), less any reserved funds. Upon receipt of any advance, EPI Health will have sold and assigned all of its rights in such receivables and all proceeds thereof.

In connection with the factoring facility, EPI Health will be charged a finance fee, defined as a floating rate per annum on outstanding advances under the Factoring Agreement, equal to the prime rate plus 2%, due on the first day of each month. EPI Health will also be charged a factoring fee of 0.35% of the gross face value of any trade accounts receivable for each 30 day period after the trade accounts receivable is purchased. Bay View has the right to demand repayment of any purchased receivables that remain unpaid for 90 days after purchase (or 100 days in the case of certain wholesale customers) or with respect to which any account debtor asserts a dispute.

The factoring facility is for an initial term of twelve months and will renew on a year to year basis thereafter, unless terminated in accordance with the Factoring Agreement. EPI Health may terminate the facility at any time upon 60 days' prior written notice and payment to Bay View of an early termination fee equal to 0.25% of the Maximum Credit multiplied by the number of months remaining in the term.

All collections of purchased receivables will go directly to a controlled lockbox and Bay View shall apply these collections to EPI Health's obligations. At the end of each reconciliation period, the collection amount, net of the advanced amount, factoring and financing fees, and other payment obligations, as applicable, will be refunded to EPI Health. Bay View has a full recourse right as stated above. If Bay View cannot collect the factored receivables from debtors, EPI Health must refund the advanced amount for any uncollected receivables from debtors.

The Company has evaluated the Factoring Agreement under the guidance in ASC 860, *Transfers and Servicing* ("ASC 860"). Based upon that evaluation, the Company has concluded that this agreement does not meet the criteria for sales accounting, and therefore is accounting for the Factoring Agreement as a secured borrowing. Accordingly, the Company records the advanced amount outstanding as a short-term liability and amounts in the controlled lockbox, which represent funds in transit to be applied against outstanding borrowings, as current restricted cash on its consolidated balance sheet. As of March 31, 2023 and December 31, 2022, advances of \$7,922 and \$10,302, respectively, were outstanding under the Factoring Agreement.

During the three months ended March 31, 2023, the Company incurred total costs of factoring, including the factoring fees, financing fees and administrative fees of \$491, with \$277 included as interest expense and the remainder included in selling, general and administrative expense in the consolidated statement of operations.

#### **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 such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. See *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 who support its clinical trials, preclinical research studies and other services related to its development activities, including drug substance and drug product manufacturing technical transfer capabilities, production and supportive costs. 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 of notice and receipt of written notice. There have been no material contract terminations as of March 31, 2023.

See "Note 11: Stockholders' Equity" regarding outstanding common stock warrants and pre-funded warrants.

Also, see "Note 14: Research and Development Agreements" regarding the Purchase Agreement with Reedy Creek and the Funding Agreement with Ligand.

#### *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*

There have been no material changes to the obligations and related agreements related to EPI Health as of March 31, 2023. Those obligations have been disclosed and explained in detail within the Annual Report.

#### *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 15: Stock-Based Compensation" regarding stock options, stock appreciation rights and restricted stock units.

#### **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.

*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 March 31, 2023 and December 31, 2022. There were 28,015,371 and 24,722,308 shares of voting common stock outstanding as of March 31, 2023 and December 31, 2022, respectively.

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

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Outstanding warrants to purchase common stock	12,869,671	5,535,637
Outstanding stock options (Note 15)	1,033,370	1,032,570
Outstanding stock appreciation rights (Note 15)	60,000	60,000
Nonvested restricted stock units (Note 15)	423,505	457,406
For possible future issuance under the 2016 Stock Plan (Note 15)	274,902	241,801
	<u>14,661,448</u>	<u>7,327,414</u>

*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 March 31, 2023 and December 31, 2022.

*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 three months ended March 31, 2023, the Company sold 543,063 shares of its common stock at an average price of approximately \$1.64 per share for total net proceeds of \$865 under the Equity Distribution Agreement. During the three months ended March 31, 2022, the Company sold 164,230 shares of its common stock at an average price of \$3.53 per share for total net proceeds of \$562 under the Equity Distribution Agreement.

In relation to the March 2023 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) until September 16, 2023. In addition, the Company agreed not to issue any additional securities under the Equity Distribution Agreement until after May 15, 2023.

Because the Company's public float was less than \$75,000 at the date of the Annual Report, it is currently subject to shelf limitations under its current registration statement on Form S-3, Registration No. 333-262865 (the "Form S-3"). These "baby shelf" limitations, along with restrictions contained within the Equity Distribution Agreement on issuing shares above such limitations, will limit the amount the Company may offer under the Form S-3 and the capital it can raise thereunder until such time as the Company's public float exceeds \$75,000.

*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 March 2023 Registered Direct Offering, the June 2022 Registered Direct Offering, the March 2020 Public Offering, and the March 2020 Registered Direct 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.

	March 31, 2023	December 31, 2022	Current Exercise Price Per Share
Pre-funded Warrants to purchase common stock issued in the March 2023 Registered Direct Offering	2,292,017	—	\$ 0.0001
Warrants to purchase common stock issued in the March 2023 Registered Direct Offering	5,042,017	—	1.20
Warrants to purchase common stock issued in the June 2022 Registered Direct Offering	5,261,311	5,261,311	1.20
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
	<u>12,869,671</u>	<u>5,535,637</u>	

The weighted average exercise price per share for warrants outstanding as of March 31, 2023 and December 31, 2022 was \$1.03 and \$2.86, respectively.

*March 2023 Registered Direct Offering*

On March 13, 2023, the Company entered into a securities purchase agreement with an institutional investor (the "March 2023 Purchaser"), pursuant to which the Company agreed to issue and sell to the March 2023 Purchaser, in a registered direct offering (the "March 2023 Registered Direct Offering") (i) 2,750,000 shares (the "March 2023 Shares") of the Company's common stock, and accompanying common stock warrants (the "March 2023 Common Warrants") to purchase an aggregate of 2,750,000 shares of common stock, for a combined price of \$1.19 per share and accompanying common warrant, and (ii) pre-funded warrants to purchase 2,292,017 shares of the Company's common stock (the "March 2023 Pre-funded Warrants") and accompanying common warrants to purchase 2,292,017 shares of common stock, for a combined price of \$1.1899 per pre-funded warrant and accompanying common warrant. The March 2023 Registered Direct Offering closed on March 16, 2023. Net proceeds from the offering were approximately \$5,390 after deducting fees and commissions and offering expenses of approximately \$610. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

As of March 31, 2023, 2,292,017 March 2023 Pre-funded Warrants and 5,042,017 March 2023 Common Warrants are outstanding.

The exercise price and the number of shares of common stock purchasable upon the exercise of the March 2023 Pre-funded Warrants and March 2023 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.

In their capacity as sole placement agent in connection with the March 2023 Registered Direct Offering, the Company paid H.C. Wainwright & Co., LLC ("H.C. Wainwright") a placement agent fee in cash equal to 6.5% of the gross proceeds from the sale of the March 2023 Shares, the March 2023 Pre-funded Warrants and the March 2023 Common Warrants, and to reimburse certain expenses of H.C. Wainwright in connection with the March 2023 Registered Direct Offering. Each March 2023 Pre-funded Warrant had an exercise price of \$0.0001 per share. The March 2023 Pre-funded Warrants were exercisable immediately upon issuance until all of the March 2023 Pre-funded Warrants are exercised in full. Each March 2023 Common Warrant is exercisable six months after the closing of the March 2023 Registered Direct Offering, has an exercise price of \$1.20 per share and will expire 5.5 years from the date of issuance.

In connection with the March 2023 Registered Direct Offering, the Company and the March 2023 Purchaser agreed to amend the June 2022 Common Warrants, described below, to reduce the exercise price thereof from \$2.851 to \$1.20 per share of common stock, to delay the exercisability of the June 2022 Common Warrant until six months after the closing of the March 2023 Registered Direct Offering, and to extend the exercise period of the June 2022 Common Warrant until December 13, 2027. No other changes to the June 2022 Common Warrants were made.

#### *June 2022 Registered Direct Offering*

On June 9, 2022, the Company entered into a securities purchase agreement with an institutional investor (the "June 2022 Purchaser"), pursuant to which the Company agreed to issue and sell to the June 2022 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 March 31, 2023, no June 2022 Pre-funded Warrants and 5,261,311 June 2022 Common Warrants are outstanding.

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 was immediately exercisable and initially had an exercise price of \$2.851 per share and was to expire five years from the date of issuance. However, as noted above, as part of the March 2023 Registered Direct Offering, these terms were amended.

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.

The Company entered into a placement agent agreement (the "June 2022 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 June 2022 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.

#### *Common Stock Warrants*

The March 2023 Common Warrants and the June 2022 Common Warrants (collectively, the March 2023 and June 2022 Common Warrants") include certain provisions that establish warrant holder settlement rights that take effect upon the occurrence of certain fundamental transactions. The March 2023 and June 2022 Common Warrants define a fundamental transaction to generally include any consolidation, merger or other transaction whereby another entity acquires 50% or more 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 March 2023 and 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 March 2023 and June 2022 Common Warrants, including a defined volatility input equal to the greater of the Company's 100-day historical volatility or 100%.

The March 2023 and 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 March 2023 and 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 March 2023 and June 2022 Common Warrants did not constitute a liability under ASC 480; (ii) the March 2023 and 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 March 2023 and 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 March 2023 and June 2022 Common Warrants are indexed to the Company's common stock; and (vi) the March 2023 and 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 March 2023 and June 2022 Common Warrants are freestanding equity-linked derivative instruments that met the criteria for equity classification. Accordingly, the March 2023 and 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.

The Company also assessed the modification to the June 2022 Common Warrants related to the March 2023 Registered Direct Offering and concluded that the equity classification was appropriate. In addition, the change in the fair value related to the modification of the June 2022 Common Warrants of \$481 was recorded as an offering cost and reflected within additional paid-in capital at the time of modification.

#### *Pre-funded Warrants*

The March 2023 Pre-funded Warrants and the June 2022 Pre-funded Warrants' (collectively, the "March 2023 and June 2022 Pre-funded Warrants") fundamental transaction provision do 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 is only 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. The March 2023 and June 2022 Pre-funded Warrants also include 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 March 2023 and June 2022 Pre-funded Warrants for appropriate equity or liability classification. During this assessment, the Company determined the March 2023 and 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 March 2023 and 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 March 2023 and 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 March 2023 and 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.

#### **Note 12: 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** (clocortolone 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 months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022.

Net product revenues are summarized as follows:

	Three Months Ended		Three Months Ended	
	March 31, 2023		March 31, 2022	
	Total Net Product Revenues	Percentage of Net Product Revenues	Total Net Product Revenues	Percentage of Net Product Revenues
Rhofade	\$ 1,099	45.6 %	\$ 838	116.7 %
Wynzora	532	22.1 %	—	— %
Minolira	345	14.3 %	78	10.9 %
Cloderm	218	9.0 %	42	5.8 %
Other	217	9.0 %	(240)	(34.4) %
Net product revenues	\$ 2,411	100.0 %	\$ 718	100.0 %

For the period March 11, 2022 through March 31, 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.

For the three months ended March 31, 2023, one of the Company's wholesaler customers accounted for more than 10% of its total gross product revenues, at 15%. For the three months ended March 31, 2022, one of the Company's customers accounted for more than 10% of its total gross product revenues, at 13%.

#### *Wynzora Agreement*

As disclosed within the Annual Report, 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. 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.

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 the three months ended March 31, 2023, the Company recognized contra-expenses of \$2,110 under this agreement. The accrued deposit liability related to the receipt of advance payments from MC2 for future incremental costs was zero as of March 31, 2023, which would be presented within accrued expenses in the accompanying condensed consolidated balance sheets.

This agreement is disclosed and explained in detail within the Annual Report.

#### *Other Agreements*

The Company notes that additional licensing and collaboration agreement rights and obligations are disclosed and explained in detail within the Annual Report, and that there were no material changes thereto as of March 31, 2023.

#### **Note 13: License and Collaboration Revenues**

The Company has license and collaboration revenues, summarized as follows:

**Sato Agreement – SB206 and SB204** - the agreement related to SB206, the Company's drug candidate for the treatment of viral skin infections, and SB204, the Company's drug candidate for the treatment of acne vulgaris; both for the Japanese territory.

**Sato Rhofade Agreement** – the agreement for the right and license under certain of EPI Health's intellectual property rights to develop, manufacture and market Rhofade (oxymetazoline hydrochloride cream, 1%) for the treatment of rosacea in Japan.

**Prasco Cloderm AG** – the agreement with Prasco, LLC ("Prasco") for the right and license to purchase, distribute and sell an authorized generic ("AG") version of Cloderm (clocortolone pivalate cream 0.1%) ("Cloderm AG"), indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

These agreement are disclosed and explained in detail within the Annual Report, and there have been no material changes thereto as of March 31, 2023.

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 months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022. License and collaboration revenues are summarized as follows:

	Three Months Ended		Three Months Ended	
	March 31, 2023		March 31, 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	110.4 %	\$ 646	55.0 %
Prasco Agreement - Cloderm AG	(61)	(10.4) %	115	9.8 %
Other	—	— %	413	35.2 %
License and collaboration revenues	\$ 585	100.0 %	\$ 1,174	100.0 %

**Sato Rhofade Agreement**

As disclosed within the Annual Report, in December 2022, the Company entered into a license agreement with Sato Pharmaceutical Co., Ltd. ("Sato") in which they were granted an exclusive, royalty-bearing, non-transferable right and license under certain of EPI Health's intellectual property rights to develop, manufacture and market Rhofade (oxymetazoline hydrochloride cream, 1%) for the treatment of rosacea in Japan (the "Sato Rhofade Agreement"). In addition, per the Sato Rhofade Agreement, during a specified time period, Sato has an exclusive option to negotiate the terms under which its license would be expanded to include certain other countries in the Asia-Pacific region.

For the three months ended March 31, 2023, the Company received in cash the upfront payment of \$5,000 related to this agreement's execution in December 2022. The Company recognized no revenue from the Sato Rhofade Agreement during the three months ended March 31, 2023.

**Sato Agreement – SB206 and SB204**

As disclosed within the Annual Report, on January 12, 2017, the Company entered into a license agreement, and related first amendment, with Sato relating to SB204, its drug candidate for the treatment of acne vulgaris in Japan (the "Sato Agreement"). 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, in addition to the prior agreement related to SB204.

The Company concluded that certain elements of consideration would be included in the transaction price as they were (i) received prior to March 31, 2023, or (ii) payable upon specified fixed dates in the future and not contingent upon clinical or regulatory success in Japan. The Company also concluded that certain elements of consideration would not be included in the transaction price as they are contingent upon clinical or regulatory success in Japan.

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

	<u>Contract Asset</u>	<u>Contract Liability</u>	<u>Net Deferred Revenue</u>
December 31, 2022	\$ —	\$ 10,665	\$ 10,665
March 31, 2023	\$ —	\$ 10,019	\$ 10,019

	<u>Short-term Deferred Revenue</u>	<u>Long-term Deferred Revenue</u>	<u>Net Deferred Revenue</u>
December 31, 2022	\$ 2,586	\$ 8,079	\$ 10,665
March 31, 2023	\$ 2,586	\$ 7,433	\$ 10,019

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.

The change in the net deferred revenue balance during the three months ended March 31, 2023 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 each of the three months ended March 31, 2023 and 2022, the Company recognized \$646 in license and collaboration revenue under the Sato Agreement. The Company has concluded that certain consideration is probable of not resulting in a significant revenue reversal and therefore such consideration is 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 March 31, 2023 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 first quarter of 2027, 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 regulatory approval process in the United States, (iii) the active pharmaceutical ingredient ("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 amount of existing performance obligations associated with the Sato Agreement unsatisfied as of March 31, 2023 was \$10,019. The Company expects to recognize approximately 26% 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.

**Note 14: 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.

During the three months ended March 31, 2023, one regulatory milestone payment due under the Ligand Funding Agreement of \$1,000 was triggered. As of and for the three months ended March 31, 2023, this amount has been recorded within accrued expenses, and research and development expenses within the condensed consolidated balance sheet and condensed consolidated statement of operations, respectively.

For the three months ended March 31, 2023 and 2022, the Company recorded contra-research and development expense related to the SB206 developmental program of \$200 and \$297, respectively, related to amortization of the Ligand Funding Agreement amount.

**Note 15: Stock-Based Compensation***2016 Incentive Award Plan*

During the three months ended March 31, 2023 and 2022, 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.

On March 29, 2023, the Company's board of directors approved an amendment to the 2016 Plan to increase the number of shares reserved for future issuance under the 2016 Plan and also make changes to withhold payment of dividends and dividend equivalents to those that receive grants under the 2016 Plan until such awards vest in full. Such approval is contingent on stockholder approval of the amendment, which the Company will seek at its upcoming annual meeting. See "Note 18: Subsequent Events" for additional detail.

*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.

*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.

*Stock Compensation Expense*

During the three months ended March 31, 2023 and 2022, the Company recorded stock-based compensation expense as follows:

	Three Months Ended March 31,	
	2023	2022
Stock options	\$ 286	\$ 381
Restricted stock units	145	—
Total	\$ 431	\$ 381

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

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 146	\$ 73
Selling, general and administrative	285	308
Total	\$ 431	\$ 381

### 2016 Plan Award Activity

Stock option activity for the three months ended March 31, 2023 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, 2022	1,032,570	\$ 9.34		
Options granted	15,200	1.45		
Options forfeited	(14,400)	3.02		
Options outstanding as of March 31, 2023	1,033,370	\$ 9.31	8.09	\$ —

RSU activity for the three months ended March 31, 2023 is as follows:

	Shares Subject to Outstanding RSUs	Weighted- Average Grant Date Fair Value
Nonvested RSUs outstanding as of December 31, 2022	457,406	\$ 2.86
RSUs granted	12,200	1.50
RSUs forfeited	(46,101)	2.81
RSUs vested	—	—
Nonvested RSUs outstanding as of March 31, 2023	423,505	\$ 2.79

As of March 31, 2023, there were a total of 1,033,370 stock options, 423,505 RSUs and 60,000 SARs outstanding; and there were 274,902 shares available for future issuance under the 2016 Plan.

### Note 16: 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 consolidated balance sheets as both current and long-term liabilities, beginning as of March 11, 2022.

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 Company's contingent consideration liability is measured on a recurring basis using Level 3 inputs.

The following table summarizes the change in fair value, as determined by Level 3 inputs for the contingent consideration liability for the quarter ended March 31, 2023:

Balance at December 31, 2022	\$ 2,488
Change in fair value	365
Reclassification to accrued expenses	(500)
Balance at March 31, 2023	\$ 2,353
Contingent consideration liability, current portion	\$ —
Contingent consideration liability, net of current portion	2,353
Balance at March 31, 2023	\$ 2,353

During the three months ended March 31, 2023, two potential milestone payments of additional contingent consideration expired without being triggered: (i) the First Sales Based Milestone; and (ii) the Wynzora Milestone. In addition, one milestone payment, the Transition Services Agreement Milestone, was triggered and has been reclassified to accrued expenses within the condensed consolidated balance sheet as of March 31, 2023.

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

	<b>Sitavig Milestones (Regulatory)</b>	
Valuation methodology	Probability-Weighted	
Term (in years)		3.0
Payment term (in years)		3.25
Adjusted discount rate		17.59 %

  

	<b>Second Sales Based Milestone</b>	<b>Sitavig Milestones (Commercial)</b>
Valuation methodology	Monte Carlo	Monte Carlo
Risk-adjusted discount rates (minimum)	8.84%	8.52%
Risk-adjusted discount rates (maximum)	9.90%	8.75%
Net sales volatility (per annum)	12.0%	13.0%
Credit spread (continuous)	13.39%	15.02%

For the three months ended March 31, 2023, there was a \$365 increase in fair value of the 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, management forecasts 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 liability as of March 31, 2023:

	<b>Classification</b>	<b>Earnout Period</b>
Second Sales Based Milestone	Non-current portion	1-Apr-2023 to 31-Mar-2026
Sitavig Milestones	Non-current portion	1-Apr-2026 to 1-Oct-2036

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

**Note 17: 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 financial 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 March 31, 2023	Three Months Ended March 31, 2022
<b>Revenue</b>		
Commercial operations	\$ 2,349	\$ 1,246
Research and Development operations	817	682
Total revenue	<u>\$ 3,166</u>	<u>\$ 1,928</u>
<b>Net loss</b>		
Commercial operations	\$ (5,046)	\$ (726)
Research and Development operations	(9,073)	(12,654)
Net loss and comprehensive loss	<u>\$ (14,119)</u>	<u>\$ (13,380)</u>

	As of March 31, 2023
<b>Assets</b>	
Commercial operations	\$ 45,964
Research and Development operations	33,829
Total assets	<u>\$ 79,793</u>

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 or 20% of total revenue, during the three months ended March 31, 2023, which was attributed to the Research and Development Operations segment. During the three months ended March 31, 2022, the Company generated revenue from its licensing partner in Japan of \$646 or 34% of total revenue.

#### Note 18: Subsequent Events

##### 2016 Incentive Award Plan

On April 27, 2023, the Company filed its Definitive Proxy Statement associated with its 2023 Annual Meeting of Stockholders (the "2023 Annual Meeting"). The 2023 Annual Meeting is scheduled for June 6, 2023 and includes a proposal to amend the 2016 Plan that would (i) increase the aggregate number of shares of the Company's common stock that may be issued under the 2016 Plan by 3,980,000 shares, and (ii) provide that dividends and dividend equivalent rights on awards will accrue only to the extent that all of the vesting conditions placed on such award are fully satisfied.

In February 2023, the compensation committee of the board of directors approved the grant of a series of RSUs and stock options to certain of its employees (the "February 2023 Awards") totaling 2,981,000 awards. The February 2023 Awards were granted by the compensation committee on a contingent basis and shall be considered voided in full if the Company fails to obtain stockholder approval of the amendment to the 2016 Plan to authorize sufficient underlying common shares for the February 2023 Awards.

##### Sato Agreement – SB206 and SB204

As discussed in "Note 13: License and Collaboration Revenues", the Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. During the three months ended March 31,

2023, the Company estimated a 10-year performance period, completing in the first quarter of 2027, based upon the most recent Sato-prepared SB206 Japanese development program timeline.

On April 20, 2023, Sato provided an updated Japanese development program timeline related to SB206 and SB204. Based upon that plan, which remains under evaluation by the Company and Sato, the projected performance period may be extended until the third quarter of 2028. Furthermore, Sato has indicated that a SB204 Phase 2/3 study in Japan would be conducted after completion of a Phase 3 study in the U.S. The Company is evaluating the impact of this updated Japanese development program timeline and may adjust its performance period related to this agreement during the second quarter of 2023.

## 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, 2022 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 30, 2023 (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.
- 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 March 31, 2023, we had an accumulated deficit of \$324.4 million and cash and cash equivalents of \$12.5 million. If we are unable to raise capital, we would be forced to delay, reduce, terminate or eliminate our product development programs, or our current and future commercialization efforts and/or delay, defer, or reduce our cash expenditures, or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws. If we are forced to terminate or eliminate our product development programs or pursue other strategic alternatives or corporate transactions, there can be no assurance that such actions would result in any additional stockholder value. If we are forced to wind down our operations, liquidate or seek bankruptcy protection, it is unclear to what extent we will 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 our stockholders, whereby, our stockholders may lose some or all of their investment.
- In March 2022, we acquired EPI Health, LLC, or EPI Health, and such acquisition is referred to as the EPI Health Acquisition. Integrating the EPI Health and legacy Novan businesses is a continuing process that involves risks associated with acquisitions and integrating acquired businesses. Failure to do so effectively may have an adverse effect.
- Raising additional capital 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 setbacks relating to the sale of such commercial products have impaired and may continue to 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, inflation, 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 and have had and may in the future experience delays in manufacturing our products.

- 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, 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.
- 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, 2022 financial statements includes 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.

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 "TM" 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 focused on 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, or molluscum. In the first quarter of 2022, we 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 relations team, 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.

We employ approximately 90 staff, including sales personnel currently covering 42 territories. We promote products for plaque psoriasis, rosacea and acne, 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 17: Segment Information" to the accompanying condensed consolidated financial statements for certain financial information related to our reportable segments.

## **Business Updates**

- In January 2023, we received an upfront payment of \$5.0 million based on entry into an exclusive license agreement with Sato in December 2022 granting Sato the right to develop, manufacture and market Rhofade (oxymetazoline hydrochloride 1% cream) for rosacea in the Japan territory. Under the exclusive license agreement, in addition to this upfront payment, we are entitled to receive a \$2.5 million milestone payment at the time of marketing approval in Japan and royalty payments on net sales of the product in Japan. Sato will be responsible for obtaining regulatory approval in Japan and will have the right to use our U.S. dossier for Rhofade held by EPI Health. Sato will also have a right of first negotiation related to Rhofade in certain other countries in the Asia Pacific region. A portion of the amounts of the upfront and milestone payments are payable by us to a third party under contractual obligations related to Rhofade.
- In March 2023, we announced that the FDA completed its filing review of our NDA submitted in early January seeking marketing approval for berdazimer gel, 10.3% (SB206) for the topical treatment of molluscum contagiosum, or molluscum. The FDA determined our application was sufficiently complete, no filing review issues were identified, the substantive review process had commenced, and we were assigned a Prescription Drug User Fee Act goal date of January 5, 2024.
- In March 2023, we announced the closing of a \$6.0 million registered direct offering with an institutional investor.
- The increase in our net product revenue from the three months ended March 31, 2023 as compared to the three months March 31, 2022 was due to the timing of the EPI Health Acquisition, partially offset by the impacts of a manufacturing delay with one supplier for our Rhofade commercial product. Rhofade was on back order from March 2023 until early April 2023. This temporary "stock out" of Rhofade impacted the overall net product revenue during the first quarter, however, the volume in mid-April of 2023 rebounded when the product was restocked with our customers.
- We are continuing to progress elements of our prelaunch strategy and commercial preparations for SB206. 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, including to support our commercial operations until they are profitable, 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 regulatory approval process and outcome. We are pursuing a broad range of financing options and other potential strategic transactions that could be used to extend our cash runway, including, among other things, to further prepare for commercialization of SB206 following approval.

Further advancement of our molluscum program, including through the NDA process and potential commercialization of SB206, and 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) other sources, such as partnerships, collaborations, licensing, grants or other strategic relationships or transactions. 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 March 31, 2023, we had total cash and cash equivalents of \$12.5 million and a working capital deficit of \$11.2 million. In mid-March 2023, we consummated a registered direct offering with an institutional investor for gross proceeds of approximately \$6.0 million, or the March 2023 Registered Direct Offering. See "Note 11: Stockholders' Equity" to the accompanying condensed consolidated financial statements for more information on the Equity Distribution Agreement and the March 2023 Registered Direct Offering.

We believe that our existing cash and cash equivalents as of March 31, 2023, plus expected receipts associated with product sales from our commercial product portfolio, will provide us with liquidity to fund our planned operating needs into late second

quarter 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.

Because our public float was less than \$75.0 million at the date of our Annual Report, we are currently subject to limitations under our current registration statement on Form S-3, which will limit the amount we may offer under our Form S-3 shelf registration statement. These "baby shelf" limitations, along with restrictions imposed by the Equity Distribution Agreement dated March 11, 2022, or the Equity Distribution Agreement, with Oppenheimer & Co., Inc., or Oppenheimer, on issuing shares above such limitations, will impact our ability to raise capital thereunder until such time as our public float exceeds \$75.0 million.

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 or our preparations for potential commercial launch of SB206 (berdazimer gel, 10.3%), if approved, 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 other 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.

Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

### **Commercial Portfolio**

Our commercial portfolio includes six branded prescription drugs that we acquired in the EPI Health Acquisition. We actively promote three medical dermatological products in the United States and derive 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, and acne. The branded and promoted product portfolio currently includes Wyzora, Rhofade, and Minolira.

The following summarizes our complete commercial product portfolio:

**Wyzora Cream** (calcipotriene and betamethasone dipropionate cream), or Wyzora, 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 Wyzora in the United States, or the MC2 Agreement. Under the MC2 Agreement, MC2 retains full ownership of Wyzora. In particular, we use our commercial infrastructure to promote and sell Wyzora in return for retaining a share of net sales of Wyzora in the United States. The portion of net sales we retain 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 us in commercialization activities according to a budget to be agreed annually between the parties. 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, we are 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 we achieve.

**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, and we are required to pay certain milestones based on future sales of Minolira.

**Cloderm** (clocortolone 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 Clodem, 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. We are party to a license agreement EPI Health entered into with Vectans Pharma, or Vectans, for the rights to commercialize Sitavig in the United States and Canada.

**Nuvail** (poly-urethane 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. We are party to a license agreement EPI Health entered into for the sale of Nuvail and serve 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 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.

### **Priority Development Pipeline**

We are currently focusing our efforts on our Priority Development Pipeline. We presently maintain exclusive, worldwide commercial rights for all product candidates currently in our pipeline, with the exception of the rights we have licensed to Sato to develop, use and sell SB204 and SB206 in Japan.

#### *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.

In early January 2023 we submitted an NDA to the FDA seeking marketing approval for berdazimer gel, 10.3% (SB206), and in March 2023, we announced that the FDA completed its filing review of our NDA. The FDA determined our application was sufficiently complete, no filing review issues were identified, the substantive review process had commenced, and we were assigned a Prescription Drug User Fee Act goal date of January 5, 2024. The Company continues to progress through the NDA review process.

#### *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 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 13: License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

#### **Pipeline Expansion Opportunities**

Our pipeline expansion opportunities are as follows:

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

We previously explored 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 believe there may be an opportunity to expand beyond our preclinical work for the SB019 product candidate. However, the SB019 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

##### *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 Congressionally Directed Medical Research Programs.

These grants have enabled 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.

#### **Trademarks**

Novan® is a registered trademark of our company in the United States, and we own or have a license to use trademarks for our commercial products. In addition, we have pending trademark applications in the United States, including for Nitricil. We previously received notice that the FDA conditionally accepted Kinsolus as the brand name for SB206, if approved. We have determined that we will not be pursuing Kinsolus as the potential brand name for SB206. We are evaluating other potential brand names for SB206, if approved, and we are working with the FDA to determine another conditionally accepted brand name.

#### **Our Customers**

We primarily sell our medical dermatology prescription products direct to pharmacies and to national wholesaler channels. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and others. As of March 31, 2023, three of our wholesaler customers accounted for more than 10% of our total accounts receivable balance at 31%, 16% and 11%, respectively.

#### **Seasonality of Business**

Our business is affected by the standard annual insurance deductible resets, as well as the purchasing patterns and concentration of our customers. In addition, certain dermatological conditions, such as acne, may be impacted by the warmer months and prescriptions may also be impacted based on the activities of those who are prescribed our products, such as school and summer activities; however, our business is not materially impacted by seasonality. There are no assurances that these historical trends will continue in the future.

#### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We consider our primary potential competition to be a broad base of existing providers and drug developers of therapeutics in the field of dermatology. Product competition includes pharmaceutical generics, branded generics, pharmaceutical brands, biologics as well as over-the-counter, or OTC, products.

We expect continued future competition across research and drug development in various different fields of innovation; capital and resource allocation to many of these areas appears to be continuous and of a global nature. In addition, there are certain instances where competition extends into the medical procedure and the medical device spectrums of human health care. Any product candidates that we successfully develop and commercialize will compete with these existing therapies as well as new therapies that may become available in the future. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products and therapies.

#### **Supply Chain**

We continue to assess the impact of global constraints on our supply chain and related vendors 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 and commercial products. 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 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, depend on other third party suppliers for materials and may have other priorities that could affect their ability to perform their supply obligations to us satisfactorily and on a timely basis. Any of these occurrences would be beyond our control. For example, due to a manufacturing delay with one supplier, our Rhofade commercial product was on back order from March 2023 until early April 2023. This temporary "stock out" of Rhofade impacted the overall revenue for Rhofade during the first quarter, however, the volume in mid-April of 2023 rebounded when the product was restocked. 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 of our new facility to support various research and development and cGMP activities, including 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."

### **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 expanded our 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 March 31, 2023, we had an accumulated deficit of \$324.4 million, and there is substantial doubt about our ability to continue as a going concern. We incurred net losses of \$14.1 million and \$13.4 million for the three months ended March 31, 2023 and 2022, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities.

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 and acne, including Rhofade, Wynzora and Minolira.

For additional information regarding our accounting for net product revenues, see "Note 1: Organization and Significant Accounting Policies" and "Note 12: Net Product Revenues" to the accompanying condensed consolidated financial statements.

#### *License and Collaboration Revenues*

License and collaboration revenues consist of (i) the recognition 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, (ii) amounts due under the Sato Rhofade Agreement in the form of upfront and milestone payments, and (iii) a distribution and supply agreement related to an out-license of an authorized generic, or AG, version of Cloderm, or Cloderm AG.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1: Organization and Significant Accounting Policies" and "Note 13: 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.

### **Cost of Goods Sold**

Cost of goods sold includes all costs directly incurred to produce net revenues from our marketed portfolio of medical dermatology products. Cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty and milestone 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) operational testing and validation activities related to the NDA pre-inspection process, and (iii) regulatory and quality documentation compilation related to our CMC information, clinical data, drug manufacturing and related processes.

We also expect to incur substantial costs in 2023 associated with our research and development personnel, and 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 approval updates 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 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 commercial 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 2023 in support of our commercial product portfolio 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 approval updates and potential SB206 commercialization strategies.

We also expect to continue to incur substantial selling, general and administrative expenses in 2023 in support of our operating activities and as necessary to operate in a public company environment. These expenses 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 condensed consolidated statement of operations and comprehensive loss.

For additional information regarding the valuation of contingent consideration, see "Note 16: Fair Value" to the accompanying condensed consolidated financial statements.

***Other Income (Expense), net***

Other income (expense), net consists primarily of (i) interest expense on outstanding notes payable, (ii) interest income earned on cash and cash equivalents, (iii) interest expense on the factoring arrangement and (iv) other miscellaneous income and expenses.

***Provision for Income Tax Expense***

Provision for income tax expense relates our deferred tax expense as a result of the EPI Health Acquisition and the related tax deductible goodwill, which created an indefinite lived deferred tax liability.

**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 currently evaluate certain items at the segment level, including certain selling, general and administrative expenses that result from shared infrastructure, 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.

See "Note 17: 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 March 31, 2023 and 2022

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. The comparative prior year period includes activity relating to EPI Health from March 11, 2022 through March 31, 2022 for our Commercial Operations segment, based on the timing of the EPI Health Acquisition:

	Three Months Ended March 31,		\$ Change	% Change
	2023	2022		
	(in thousands, except percentages)			
Net product revenues	\$ 2,411	\$ 718	\$ 1,693	236 %
License and collaboration revenues	585	1,174	(589)	(50) %
Government research contracts and grants revenue	170	36	134	372 %
Total revenue	3,166	1,928	1,238	64 %
Operating expenses:				
Cost of goods sold	1,285	206	1,079	524 %
Research and development	4,832	4,833	(1)	— %
Selling, general and administrative	10,040	9,994	46	— %
Amortization of intangible assets	477	121	356	294 %
Change in fair value of contingent consideration	365	—	365	*
Total operating expenses	16,999	15,154	1,845	12 %
Operating loss	(13,833)	(13,226)	(607)	5 %
Other income (expense), net:				
Interest income	30	3	27	900 %
Interest expense	(277)	(132)	(145)	110 %
Other income (expense)	17	(25)	42	(168) %
Total other income (expense), net	(230)	(154)	(76)	49 %
Net loss before income taxes	(14,063)	(13,380)	(683)	5 %
Provision for income tax expense	56	—	56	*
Net loss and comprehensive loss	\$ (14,119)	\$ (13,380)	\$ (739)	6 %

\* Not meaningful

#### Net product revenues

The EPI Health Acquisition provided us with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues for the three months ended March 31, 2023 and 2022 were \$2.4 million and \$0.7 million, respectively, 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 and acne, including Rhofade, Wyzora and Minolira. The increase in net product revenue from the prior year comparable period is due to the timing of the EPI Health Acquisition, partially offset by the impacts of a manufacturing delay with one supplier for our Rhofade commercial product. As noted above, Rhofade was on back order from March 2023 until early April 2023. This temporary "stock out" of Rhofade impacted the overall net product revenue during the first quarter, however, the volume in mid-April of 2023 rebounded when the product was restocked with our customers.

For additional information regarding our accounting for net product revenues, see "Note 1: Organization and Significant Accounting Policies" and "Note 12: Net Product Revenues" to the accompanying condensed consolidated financial statements.

#### License and collaboration revenues

License and collaboration revenues were \$0.6 million and \$1.2 million for the three months ended March 31, 2023 and 2022, 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 related to the out-license of Cloderm AG, all recorded in the Commercial Operations segment.

For the three months ended March 31, 2023 and 2022, we recognized \$0.6 million 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 13: License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

*Government research contracts and grants revenue*

Government research contracts and grants revenue totaled \$0.2 million and less than \$0.1 million for three months ended March 31, 2023 and 2022, respectively. These amounts relate to (i) a federal grant from the U.S. Department of Defense's Congressionally Directed Medical Research Programs, and (ii) a federal grant from the NIH for certain nitric oxide based anti-viral therapies and their related development.

*Cost of goods sold*

Cost of goods sold of \$1.3 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively, 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. Cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty and milestone expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products. The increase in cost of goods sold from the prior year comparable period is primarily due to the timing of the EPI Health Acquisition.

For additional information regarding our accounting for cost of goods sold, see "Note 12: Net Product Revenues," and "Note 13: 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 \$4.8 million for each of the three months ended March 31, 2023 and 2022, respectively. Included in the fluctuation from the prior year comparable period was a \$1.0 million net decrease in the SB206 program, offset by a \$1.0 million net increase in other research and development expenses.

The \$1.0 million net decrease in the SB206 program was primarily driven by (i) a \$0.7 million decrease in stability, analytical testing, CMC activities and materials, and (ii) a \$0.4 million decrease in regulatory consulting services, both related to the SB206 NDA submission in January 2023. These decreases were partly offset by a \$0.1 million decrease in contra-research and development expense from the ratable amortization of the development funding and royalties agreement with Ligand Pharmaceuticals, Inc., or Ligand, and such agreement, the Ligand Funding Agreement, liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum.

The \$1.0 million increase in other research and development expenses was primarily driven by a \$1.0 million increase in expense related to a regulatory milestone payment which became due to Ligand during the first quarter of 2023 under the Ligand Funding Agreement.

*Selling, general and administrative expenses*

Selling, general and administrative expenses were approximately \$10.0 million for the three months ended March 31, 2023 and 2022. The table below sets forth our total selling, general and administrative expenses incurred for the three months ended March 31, 2023 and 2022 and the primary drivers of the fluctuations from the prior period:

	<b>Selling, general and administrative expenses</b>	
Three months ended March 31, 2023	\$	10,040
Three months ended March 31, 2022		9,994
<b>Change from prior period</b>	<b>\$</b>	<b>46</b>
		<b>Prior Period Variance Detail</b>
		<b>Increase / (Decrease)</b>
EPI Health Acquisition Transaction-related costs	\$	(4,021)
EPI Health commercial sales operations		3,711
Tax and insurance costs		(330)
Facility and depreciation costs		83
Professional services and other administrative costs		335
Personnel and related benefits		268
<b>Change from prior period</b>	<b>\$</b>	<b>46</b>

The \$4.0 million of transaction-related expenditures incurred in connection with the EPI Health Acquisition in March of 2022 included fees paid to banking advisors, insurance brokers, due diligence costs, and legal, regulatory, intellectual property, information technology, valuation and accounting consultants and specialists.

The increase of \$3.7 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations, partially due to the timing of the EPI Health Acquisition, included (i) an increase of \$2.2 million of salary, incentive compensation and benefits costs, (ii) an increase of \$0.4 million of advertising, promotional and other marketing costs, and (iii) an increase of \$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.

*Amortization of intangible assets*

Amortization of intangible assets of \$0.5 million for the three months ended March 31, 2023 and \$0.1 million for the three months March 31, 2022 is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition. The increase in amortization is due to a partial period of amortization in the prior year comparable period due to the timing 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 March 31, 2023 and 2022, the changes in fair value related to contingent consideration related to the EPI Health Acquisition related primarily to changes in market assumptions, management forecasts and discount rates since the prior measurement date. For additional information regarding contingent consideration valuation, see "Note 16: Fair Value."

*Other income (expense), net*

Total other expense, net was \$0.2 million for the three months ended March 31, 2023. Total other expense, net in the current period is primarily comprised of \$0.2 million of interest related to the accounts receivable-backed factoring agreement with CSNK Working Capital Finance Corp. d/b/a Bay View Funding. For the three months ended March 31, 2022, total other expense, net was primarily comprised of \$0.1 million of interest expense related to the Seller Note issued in March 2022 in connection with the EPI Health Acquisition.

For additional information regarding the factoring facility, see "Note 10: Commitments and Contingencies" to the accompanying condensed consolidated financial statements.

*Provision for income tax expense*

For the three months ended March 31, 2023, we recorded an insignificant amount of income tax expense related to deferred tax expense as a result of the EPI Health Acquisition and the related tax deductible goodwill, which created an indefinite lived deferred tax liability.

**Liquidity and Capital Resources**

As of March 31, 2023, we had an accumulated deficit of \$324.4 million. We incurred net losses of \$14.1 million and \$13.4 million for the quarters ended March 31, 2023 and 2022, respectively, and there is substantial doubt about our ability to continue as a going concern. Despite revenues generated from the sales of commercial products, 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. As is common in the pharmaceutical industry, the revenue we collect is subject to gross-to-net deductions, including rebates, discounts and other items, and our inability to reduce the impact of such deductions or any increase in such deductions has had and may continue to have an adverse effect on our business. 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 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 March 31, 2023, we had total cash and cash equivalents of \$12.5 million and a working capital deficit of \$11.2 million. As discussed below, we used a portion of our cash and cash equivalents in 2022 to pay off and terminate the Seller Note issued in connection with the EPI Health Acquisition, as well as to fund 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 and to further prepare for commercialization of SB206 following approval.

From January 1, 2021 through March 31, 2023, we have raised total equity and debt proceeds of \$74.2 million to fund our operations, including (i) \$19.7 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 and March 2023 Registered Direct Offerings, (ii) \$37.2 million in net proceeds from the sale of common stock in the June 2021 public offering, (iii) \$6.3 million in proceeds from the sale of common stock under our common stock purchase agreements with Aspire Capital, (iv) \$2.5 million from our Equity Distribution Agreement, (v) a net of \$7.9 million from our accounts receivable factoring facility, (vi) an additional \$0.5 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 and (vii) \$0.1 million of proceeds from the exercise of stock options.

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, subject to the limitations 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 March 31, 2023, plus expected receipts associated with product sales from our commercial product portfolio, will provide us with liquidity to fund our planned operating needs into late second quarter 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 (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 through potential NDA approval, including, but not limited to, manufacturing, 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 approval 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 significantly delay, defer or reduce our cash expenditures before late second quarter of 2023. 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 and preparations for potential commercialization activities, furloughing employees or reducing the size of the workforce 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 other 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:

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (4,250)	\$ 766
Investing activities	(23)	(12,921)
Financing activities	4,095	562
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (178)</u>	<u>\$ (11,593)</u>

### Net Cash Used in Operating Activities

During the three months ended March 31, 2023, net cash used in operating activities was \$4.3 million and consisted primarily of a net loss of \$14.1 million, with adjustments for non-cash amounts related primarily to (i) stock-based compensation expense of \$0.4 million, (ii) amortization of definite lived intangible assets acquired in the EPI Health acquisition of \$0.5 million, (iii) \$0.4 million of depreciation and amortization of property and equipment expense, (iv) \$0.4 million change in fair value of contingent consideration, and (vii) a \$8.1 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 \$8.2 million change in accounts receivable related to cash collections on accounts receivable outstanding at December 31, 2022, including \$5.0 million received under the Sato Rhofade Agreement, (ii) a change in accounts payable of \$0.6 million, (iii) a change in prepaid expenses and

other current assets of \$1.3 million, and (iv) a change in inventory of \$0.1 million. The unfavorable impacts to cash related to changes in (i) deferred revenue of \$0.6 million, (ii) research and development service obligation of \$0.2 million, and (iii) accrued expenses of \$1.1 million.

During the three months ended March 31, 2022, net cash provided by operating activities was \$0.8 million and consisted primarily of a net loss of \$13.4 million, with adjustments for non-cash amounts related primarily to (i) stock-based compensation expense of \$0.4 million, (ii) amortization of definite lived intangible assets acquired from EPI Health of \$0.1 million, (iii) \$0.1 million of depreciation and amortization of property and equipment expense, and (iv) a \$13.5 million change in cash related to changes in other operating assets and liabilities. The change in cash related to changes in assets and liabilities was primarily due to (i) \$8.5 million related to accounts receivable, including \$4.2 million received by EPI Health after March 11, 2022 and the receipt of a \$4.3 million time-based developmental milestone payment from Sato, (ii) a change in accounts payable of \$1.6 million, (iii) a change in deferred revenue of \$2.6 million, and (iv) a change in prepaid expenses and other current assets of \$0.6 million. 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.

#### *Net Cash Used in Investing Activities*

During the three months ended March 31, 2023, the \$0.02 million of net cash used in investing activities was primarily related to cash used for purchases of property, and equipment related to our small-scale manufacturing facility in Durham, North Carolina.

During the three months ended March 31, 2022, the \$12.9 million of net cash used in investing activities was primarily related to (i) cash used in connection with the EPI Health Acquisition of \$12.0 million, and (ii) \$0.9 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. See "Note 2: Acquisition of EPI Health" to the accompanying condensed consolidated financial statements for additional detail regarding the purchase of EPI Health.

#### *Net Cash Provided by Financing Activities*

During the three months ended March 31, 2023, net cash provided by financing activities was \$4.1 million and consisted primarily of (i) net proceeds from the March 2023 Registered Direct Offering of \$5.6 million, (ii) proceeds from the sale of our common stock pursuant to the Equity Distribution Agreement entered into in March 2022 of \$0.9 million, offset by net repayments of our factoring arrangement of \$2.4 million.

During the three months ended March 31, 2022, net cash provided by financing activities was \$0.6 million and consisted of proceeds from the sale of our common stock pursuant to the Equity Distribution Agreement entered into in March 2022.

#### *Capital Requirements*

As of March 31, 2023, we had a total cash and cash equivalents balance of \$12.5 million and a working capital deficit of \$11.2 million. While we currently generate revenue from our commercial portfolio of products, 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 from our product candidates. 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 March 31, 2023, we had an accumulated deficit of \$324.4 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 FDA 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, if approved, 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) other 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, we agreed to certain limitations on our ability to raise funds in the short-term through equity financings in connection with the March 2023 Registered Direct Offering. In particular, we agreed not to issue any additional securities for 45 days after closing of the March 2023 Registered Direct Offering and not to make any sales under the Equity Distribution Agreement for 60 days after closing of

the March 2023 Registered Direct Offering. Because our public float was less than \$75.0 million at the date we filed our Annual Report, we are currently subject to limitations in the amount we may offer under our Form S-3 registration statement. These "baby shelf" limitations, along with restrictions contained with the Equity Distribution Agreement on issuing shares above such limitations, could impact our ability to raise capital under this registration statement until such time as our public float exceeds \$75.0 million.

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 and preparations for potential commercialization activities, furloughing employees or reducing the size of the workforce 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 three months ended March 31, 2023 and the year ended December 31, 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 March 31, 2023, we had 28,015,371 shares of common stock outstanding. In addition, as of March 31, 2023, we had reserved 14,661,448 shares of common stock for future issuance related to (i) outstanding pre-funded and common stock 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 March 31, 2023.

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, SB206 and Rhofade 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**

Except for items described in "Note 1: Organization and Significant Accounting Policies," "Note 2: Acquisition of EPI Health," and "Note 10: Commitments and Contingencies" to the accompanying condensed consolidated financial statements, there were no material changes during the three months ended March 31, 2023 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 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.

Our significant accounting policies are more fully described in "Note 1: Organization and Significant Accounting Policies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and in "Note 1: Organization and Significant Accounting Policies" to our audited consolidated financial statements contained in our Annual Report.

During the three months ended March 31, 2023, there were no material changes to our critical accounting policies.

#### **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 our Annual Report. During the three months ended March 31, 2023, there were no material changes to our critical accounting policies.

**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 chief financial officer, 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 officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2023.

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 discussed in "Note 2: Acquisition of EPI Health" to the accompany condensed consolidated financial statements, in March 2022, we completed the EPI Health Acquisition. As permitted by the SEC, management elected to exclude this acquisition from its assessment of the effectiveness of its internal control over financial reporting as of December 31, 2022. In the quarter ended March 31, 2023, we completed the integration of the EPI Health business into our internal control over financial reporting. Otherwise, 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.

**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:

EXHIBIT NO.	DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
			FORM	File No.	Exhibit	Filing Date
4.1	<a href="#">Form of March 2023 Common Warrant.</a>		8-K	001-37880	4.1	March 16, 2023
4.2	<a href="#">Form of March 2023 Pre-funded Warrant.</a>		8-K	001-37880	4.2	March 16, 2023
4.3	<a href="#">Form of June 2022 Common Warrant, as amended.</a>		8-K	001-37880	4.3	March 16, 2023
31.1	<a href="#">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.</a>	X				
31.2	<a href="#">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.</a>	X				
32.1	<a href="#">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.</a>	X				
32.2	<a href="#">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.</a>	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 and Accounting Officer)

Date: May 15, 2023

**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: May 15, 2023

/s/ Paula Brown Stafford

Paula Brown Stafford

*Chief Executive Officer*

(Principal Executive Officer)

**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: May 15, 2023

/s/ John M. Gay

John M. Gay

Chief Financial Officer

(Principal Financial and Accounting Officer)

**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 March 31, 2023 (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: May 15, 2023

/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.

**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 March 31, 2023 (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: May 15, 2023

/s/ John M. Gay

John M. Gay

*Chief Financial Officer*

(Principal Financial and Accounting 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.