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, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37880

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

Delaware	**20-4427682**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4105 Hopson Road **Morrisville, North Carolina**	**27560**
(Address of principal executive offices)	(Zip Code)

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.0001 par value	NOVN	Nasdaq Global Market

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

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

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

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

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. x

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

As of May 14, 2020, there were 75,471,388 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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,785	$ 13,711
Contracts and grants receivable	189	419
Deferred offering costs	58	49
Prepaid expenses and other current assets	1,420	1,545
Total current assets	23,452	15,724
Restricted cash	539	540
Intangible assets	75	75
Other assets	387	419
Property and equipment, net	10,231	10,506
Right-of-use lease assets	1,826	1,833
Total assets	$ 36,510	$ 29,097
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 997	$ 1,602
Accrued compensation	1,107	437
Accrued outside research and development services	1,928	1,013
Accrued legal and professional fees	173	616
Other accrued expenses	428	553
Deferred revenue, current portion	4,401	4,428
Research and development service obligation liability, current portion	1,566	3,088
Lease liabilities, current portion	1,167	1,162
Total current liabilities	11,767	12,899
Deferred revenue, net of current portion	5,960	7,076
Lease liabilities, net of current portion	4,947	5,100
Research and development service obligation liability, net of current portion	736	727
Research and development funding arrangement liability, related party	25,000	25,000
Other long-term liabilities	460	578
Total liabilities	48,870	51,380
Commitments and contingencies (Note 8)		
Stockholders' deficit		
Common stock $0.0001 par value; 200,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 72,028,562 and 26,744,300 shares issued as of March 31, 2020 and December 31, 2019, respectively; 72,019,062 and 26,734,800 shares outstanding as of March 31, 2020 and December 31, 2019, respectively	7	3
Additional paid-in capital	213,939	197,853
Treasury stock at cost, 9,500 shares as of March 31, 2020 and December 31, 2019	(155)	(155)
Accumulated deficit	(226,151)	(219,984)
Total stockholders' deficit	(12,360)	(22,283)
Total liabilities and stockholders' deficit	$ 36,510	$ 29,097

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

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

	Three Months Ended March 31,	
	2020	2019
License and collaboration revenue	$ 1,024	$ 1,100
Government research contracts and grants revenue	189	—
Total revenue	1,213	1,100
Operating expenses:		
Research and development	4,916	4,827
General and administrative	2,507	2,994
Total operating expenses	7,423	7,821
Operating loss	(6,210)	(6,721)
Other income, net:		
Interest income	35	28
Other income, net	8	56
Total other income, net	43	84
Net loss and comprehensive loss	$ (6,167)	$ (6,637)
Net loss per share, basic and diluted	$ (0.17)	$ (0.25)
Weighted-average common shares outstanding, basic and diluted	37,043,876	26,066,064

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

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

	Three Months Ended March 31, 2020					
	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2019	26,734,800	$ 3	$ 197,853	$ (155)	$ (219,984)	$ (22,283)
Share-based compensation	—	—	385	—	—	385
Common stock and pre-funded warrants issued pursuant to public offering, net	15,498,602	2	5,156	—	—	5,158
Exercise of pre-funded warrants related to public offering	4,333,334	—	—	—	—	—
Common stock and pre-funded warrants issued pursuant to registered direct offering, net	10,550,000	1	7,224	—	—	7,225
Exercise of pre-funded warrants related to registered direct offering	4,602,326	—	—	—	—	—
Exercise of common stock warrants	9,600,000	1	2,879	—	—	2,880
Common stock issued pursuant to common stock purchase agreement	700,000	—	442	—	—	442
Net loss	—	—	—	—	(6,167)	(6,167)
Balance as of March 31, 2020	72,019,062	$ 7	$ 213,939	$ (155)	$ (226,151)	$ (12,360)

	Three Months Ended March 31, 2019					
	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2018	26,056,735	$ 3	$ 195,483	$ (155)	$ (188,893)	$ 6,438
Share-based compensation	—	—	168	—	—	168
Exercise of stock options	12,999	—	10	—	—	10
Net loss	—	—	—	—	(6,637)	(6,637)
Adoption of new accounting standards	—	—	—	—	(714)	(714)
Balance as of March 31, 2019	26,069,734	$ 3	$ 195,661	$ (155)	$ (196,244)	$ (735)

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

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flow from operating activities:		
Net loss	$ (6,167)	$ (6,637)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	495	503
Share-based compensation	272	214
Loss on disposal and write-offs of property and equipment	44	—
Changes in operating assets and liabilities:		
Contracts and grants receivable	230	—
Prepaid expenses and other current assets	125	45
Accounts payable	(692)	242
Accrued compensation	670	615
Accrued outside research and development services	915	254
Accrued legal and professional fees	(508)	(199)
Other accrued expenses	(52)	(406)
Deferred revenue	(1,143)	3,360
Research and development service obligation liabilities	(1,513)	—
Other long-term assets and liabilities	(114)	(101)
Net cash used in operating activities	(7,438)	(2,110)
Cash flow from investing activities:		
Purchases of property and equipment	(352)	(17)
Proceeds from the sale of property and equipment	15	—
Net cash used in investing activities	(337)	(17)
Cash flow from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net of underwriting fees and commissions	12,577	—
Proceeds from exercise of common stock warrants	2,880	—
Proceeds from issuance of common stock under common stock purchase agreement	442	—
Payments related to public offering costs	(26)	—
Payments of offering costs related to new registration statement	(25)	—
Proceeds from exercise of stock options	—	10
Net cash provided by financing activities	15,848	10
Net increase (decrease) in cash, cash equivalents and restricted cash	8,073	(2,117)
Cash, cash equivalents and restricted cash as of beginning of period	14,251	8,733
Cash, cash equivalents and restricted cash as of end of period	$ 22,324	$ 6,616
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment with accounts payable and accrued expenses	$ 6	$ 69
Deferred offering costs in accounts payable and accrued expenses	$ 152	$ —
Deferred offering costs reclassified to additional paid-in capital	$ 16	$ —
Reconciliation to condensed consolidated balance sheets:		
Cash and cash equivalents	$ 21,785	$ 6,077
Restricted cash included in noncurrent assets	539	539
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 22,324	$ 6,616

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 and Basis of Presentation

Novan, Inc. ("Novan" and together with its subsidiaries, the "Company"), is a North Carolina-based clinical development-stage biotechnology company focused on leveraging 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. Novan was incorporated in January 2006 under the state laws of Delaware. Its wholly-owned subsidiary, Novan Therapeutics, LLC was organized in 2015 under the state laws of North Carolina. On March 14, 2019, the Company completed registration of a wholly-owned Ireland-based subsidiary, Novan Therapeutics, Limited.

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The December 31, 2019 year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. Additionally, the Company's independent registered public accounting firm report for the December 31, 2019 financial statements included an explanatory paragraph indicating that there is 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.

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 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, 2020, the Company had an accumulated deficit of $226,151.

- As described below, in March 2020 the Company completed a public offering of its common stock (or pre-funded warrants to purchase common stock in lieu thereof) and common warrants to purchase common stock pursuant to the Company's then effective shelf registration statement (the "March 2020 Public Offering"). Net proceeds from the offering were approximately $5,158 after deducting underwriting discounts and commissions and offering expenses of approximately $791. The Company has also received proceeds from the exercises of common warrants issued in the March 2020 Public Offering of approximately $2,880 through March 31, 2020.

- Also described below, in March 2020 the Company completed a registered direct offering of its common stock (or pre-funded warrants to purchase common stock in lieu thereof) pursuant to the Company's then effective shelf registration statement (the "March 2020 Registered Direct Offering"). Net proceeds from the offering were approximately $7,225 after deducting fees and commissions and offering expenses of approximately $774.

- As of March 31, 2020, the Company had a total cash and cash equivalents balance of $21,785.

- The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company raise substantial doubt about its ability to continue as a going concern.

The Company believes that its existing cash and cash equivalents balance, including (i) the net proceeds of approximately $15,263 related to the March 2020 offerings and related warrant exercises, and (ii) expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its operating needs into the second half of 2021, excluding costs associated with the execution of the Company's late-stage clinical development programs, which will require additional funding or strategic partnering in order to complete. Specifically, this operating forecast and related cash projection excludes the potential costs associated with an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum beyond the initial start-up phase, along with any other new clinical stage development programs. Further advancement of the additional confirmatory Phase 3 trial for molluscum beyond the trial start-up phase and into the enrollment initiation phase, or advancement of any other late-stage clinical development program across our platform, is subject to additional funding or strategic partnering, and has been and may be further impacted by the COVID-19 pandemic.

If the Company is unable to secure the additional capital necessary to advance its late-stage clinical development programs, including funding necessary to complete an additional confirmatory Phase 3 trial for SB206, the Company expects that it would align its operations accordingly to support conduct of its early stage research and development programs, while also continuing to evaluate strategic alternatives.

The failure of the Company to obtain additional funding on acceptable terms could have a material adverse effect on the Company's business and cause the Company to alter or reduce its planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve its cash and cash equivalents. The Company needs and intends to secure additional capital from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships, or through equity or debt financings. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders. Alternatively, the Company may seek to engage in one or more potential transactions, such as the sale of the Company, or sale or divestiture of some of its assets, such as a sale of its dermatology platform assets, but there can be no assurance that the Company will be able to enter into such a transaction or transactions on a timely basis or at all on terms that are favorable to the Company. Under these circumstances, the Company may 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 will be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

March 2020 Public Offering

On February 27, 2020, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC ("H.C. Wainwright"), as underwriter, relating to the offering, issuance and sale of 14,000,000 shares of common stock, pre-funded warrants to purchase 4,333,334 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 18,333,334 shares of common stock. The Company also granted H.C. Wainwright, as underwriter, a 30-day option to purchase up to 2,750,000 additional shares of common stock and/or common warrants to purchase up to an aggregate of 2,750,000 shares of common stock, which H.C. Wainwright partially exercised on March 2, 2020 to purchase 1,498,602 shares of common stock and common warrants to purchase 2,750,000 shares of common stock. The March 2020 Public Offering closed on March 3, 2020. At closing, the Company also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 594,958 shares of common stock representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in this offering.

The shares issued as part of the March 2020 Public Offering, and upon exercises of common warrants and pre-funded warrants issued as part of the March 2020 Public Offering, increased the number of shares outstanding, which impacts the comparability of the Company's reported net loss per share calculations between 2020 and 2019 periods.

See Note 9—Stockholders' Equity (Deficit) for further information regarding the March 2020 Public Offering.

March 2020 Registered Direct Offering

On March 24, 2020, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering priced at the market, an aggregate of 10,550,000 shares of the Company's common stock and pre-funded warrants to purchase 8,054,652 shares of common stock. The March 2020 Registered Direct Offering closed on March 26, 2020. At closing, the Company also issued to designees of H.C. Wainwright, as placement agent, warrants to purchase an aggregate of up to 558,140 shares of common stock

representing 3.0% of the aggregate number of shares of common stock and shares of common stock underlying the pre-funded warrants sold in this offering.

The shares issued as part of the March 2020 Registered Direct Offering, and upon exercises of pre-funded warrants issued as part of the March 2020 Registered Direct Offering, increased the number of shares outstanding, which impacts the comparability of the Company's reported net loss per share calculations between 2020 and 2019 periods.

See Note 9—Stockholders' Equity (Deficit) for further information regarding the March 2020 Registered Direct Offering.

COVID-19

In December 2019, the novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), which causes novel coronavirus disease 2019 ("COVID-19") was reported in China, and in March 2020, the World Health Organization declared it a pandemic. The extent to which COVID-19 and global efforts to contain its spread 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 at this time, and include the duration, severity and scope of the pandemic and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19. The timetable for development of the Company's product candidates has been impacted and may face further disruption and the Company's business could be further adversely affected by the outbreak of COVID-19. At this time, the extent to which COVID-19 may impact the Company's financial condition or results of operations is uncertain. In particular, COVID-19 has impacted the trial execution plans of the Company's B-SIMPLE4 Phase 3 trial for SB206, and the Company is assessing any further impact of COVID-19 on the B-SIMPLE4 Phase 3 trial for SB206, which is also subject to additional funding, including delay, postponement or other impacts to the trial.

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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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, 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 and as of each subsequent quarterly period end date while the warrants are outstanding.

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 liability-classified warrants are recognized as a non-cash gain or loss on the consolidated statements of operations and comprehensive loss.

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. Actual results could differ from these estimates.

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 (consisting of adjustments of a normal, recurring nature and the impact of the Company's restatement of its consolidated financial statements for the Affected Periods (as defined below)) 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 financial

statements and notes for the year ended December 31, 2019 set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, as amended, filed with the SEC as discussed below.

Restatement of Previously Issued Financial Statements

On May 14, 2020, the Company revised its prior position on accounting for warrants and concluded that its previously issued consolidated financial statements for the year ended December 31, 2018, and all quarterly periods of 2019 and 2018 (the "Affected Periods") should not be relied upon because of a misapplication in the guidance on warrant accounting. On May 20, 2020, the Company restated its consolidated financial statements for all Affected Periods in its Annual Report on Form 10-K/A (Amendment No. 1) for the fiscal year ended December 31, 2019. As such, the comparative information provided for the three months ended March 31, 2019 contained in the preceding condensed consolidated financial statements and the accompanying footnotes reflect these previously restated amounts.

Restricted Cash

Restricted cash as of March 31, 2020 and December 31, 2019 includes funds maintained in a separate deposit account to secure a letter of credit for the benefit of the lessor of facility space leased by the Company.

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.

During the three months ended March 31, 2020 and 2019, respectively, the Company concluded there were no such events or changes in circumstances requiring review of the carrying amount of the Company's long-lived assets.

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, 2020 and 2019 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,	
	2020	**2019**
Warrants to purchase common stock associated with January 2018 public offering (Note 9)	10,000,000	10,000,000
Warrants to purchase common stock associated with March 2020 public offering (Note 9)	12,078,292	—
Warrants to purchase common stock associated with March 2020 registered direct offering (Note 9)	558,140	—
Stock options outstanding under the 2008 and 2016 Plans (Note 10)	2,010,603	1,544,857
Stock appreciation rights outstanding under the 2016 Plan (Note 10)	600,000	—
Inducement options outstanding (Note 10)	96,167	100,500

Segment and Geographic Information

The Company has determined that it operates in one segment. The Company uses its nitric oxide-based technology to develop product candidates. The Chief Executive Officer, who is the Company's chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company has only had limited revenue since its inception, but substantially all revenue was derived from licensing agreements originating in the United States. All of the Company's long-lived assets are maintained in the United States.

Although all operations are based in the United States, the Company generated revenue from its licensing partner in Japan of $1,024, or approximately 84% of total revenue, and $1,100 or 100% of total revenue, during the three months ended March 31, 2020 and 2019, respectively.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-13 *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* This guidance is intended to improve the effectiveness of disclosure requirements on fair value measurements in Topic 820. The new standard modifies certain disclosure requirements and is effective for annual reporting periods beginning after December 15, 2019. This ASU was effective for the Company as of January 1, 2020. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements.

In October 2018, the FASB issued ASU No. 2018-17 *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities.* This guidance is intended to improve the accounting for variable interest entities and whether the entity should be consolidated. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within those annual reporting periods, with early adoption permitted. This ASU was effective for the Company as of January 1, 2020. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18 *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This guidance is intended to reduce diversity in practice and clarify the interaction between Topic 808, *Collaborative Arrangements*, and Topic 606, *Revenue from Contracts with Customers*. This ASU provided guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within those annual reporting periods, with early adoption permitted. This ASU was effective for the Company as of January 1, 2020. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements.

Accounting Pronouncements Being Evaluated

In December 2019, the FASB issued ASU No. 2019-12 *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* This guidance is intended to improve consistent application and simplify the accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. This standard is effective for annual reporting periods beginning after December 15, 2020, including interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact of adoption of this ASU and does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

Note 2: KNOW Bio, LLC

On December 30, 2015, the Company completed the distribution of 100% of the outstanding member interests of KNOW Bio, LLC ("KNOW Bio"), a former wholly owned subsidiary of the Company, to Novan's stockholders (the "Distribution"), pursuant to which KNOW Bio became an independent privately held company.

KNOW Bio is an independent, privately held company with a portfolio of operating subsidiaries that are advancing nitric oxide-based therapies using technology that is proprietary and/or in fields where they have exclusive intellectual property rights. The Company does not own any equity interest in KNOW Bio, has no common management or board representation at KNOW Bio, and the contractual arrangements between the two entities do not provide the Company with decision-making authority or power to influence KNOW Bio's drug and medical device development activities.

The Company conducted an initial assessment of KNOW Bio under the variable interest consolidation model pursuant to FASB ASC 810, *Consolidation*, at the time of the Distribution in 2015 and has monitored KNOW Bio during each subsequent reporting period, including two required ASC 810 reassessments performed during 2017. The Company has consistently determined that KNOW Bio should not be consolidated in its consolidated financial statements. In the fourth quarter of 2018, KNOW Bio and its operating subsidiaries received significant additional equity investments that enable progression of their technology. These events required the Company to conduct another reassessment of variable interest entity characteristics, pursuant to FASB ASC 810-10, *Consolidation*, in which it determined that KNOW Bio should not be consolidated in its consolidated financial statements.

KNOW Bio Technology Agreements

In connection with the Distribution, the Company entered into exclusive license agreements and sublicense agreements with KNOW Bio, as described below. The agreements will continue for so long as there is a valid patent claim under the respective agreement, unless earlier terminated, and upon expiration, will continue as perpetual non-exclusive licenses. KNOW Bio has the right to terminate each such agreement, for any reason upon 90 days advance written notice to the Company.

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

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the "KNOW Bio Sublicense Agreements" and together with the KNOW Bio License Agreement, the "Original KNOW Bio Agreements"). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the U.S. and foreign patents and patent applications exclusively licensed to the Company from the University of North Carolina at Chapel Hill ("UNC") under the Amended, Restated and Consolidated License Agreement dated June 27, 2012, as amended (the "UNC License Agreement"), and another third party directed towards nitric oxide-releasing compositions, to develop and commercialize products utilizing the licensed technology. Under the exclusive sublicense to the UNC patents and applications (the "UNC Sublicense Agreement"), KNOW Bio is subject to the terms and conditions under the UNC License Agreement, including milestone and diligence payment obligations. However, pursuant to the terms of the UNC License Agreement, the Company is directly obligated to pay UNC any future milestones or royalties, including those resulting from actions conducted by the Company's sublicensees, including KNOW Bio. Therefore, in the event of KNOW Bio non-performance with respect to its obligations under the UNC Sublicense Agreement, the Company would be obligated to make such payments to UNC. KNOW Bio would then become obligated to repay the Company pursuant to the UNC Sublicense Agreement, otherwise KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. There were no milestone or royalty payments required during the three months ended March 31, 2020 and 2019.

Amendments to License and Sublicense Agreements with KNOW Bio

On October 13, 2017, the Company and KNOW Bio entered into certain amendments to the Original KNOW Bio Agreements (the "KNOW Bio Amendments"). Pursuant to the terms of the KNOW Bio Amendments, the Company re-acquired from KNOW Bio exclusive, worldwide rights under certain U.S. and foreign patents and patent applications controlled by the Company as of December 29, 2015, and that became controlled by the Company between December 29, 2015 and December 29, 2018, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses (the "Oncovirus Field"). The Company also obtained a three-year exclusive option, subject to payment of separate option exercise fees, to include up to four additional specified oncoviruses in the Oncovirus Field.

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

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

The rights granted to the Company in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Original KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and the Company that are set forth in the Original KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field if: (i) the Company does not file a first investigational new drug ("IND") application with the FDA for a product in the Oncovirus Field by October 2020; or (ii) the Company does not file a first new drug application ("NDA") with the FDA by October 2025 for a product in the Oncovirus Field and does not otherwise have any active clinical programs related to the Oncovirus Field at such time.

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

The terms of the KNOW Bio Amendments were negotiated at arms-length and do not provide the Company with an ability to significantly influence KNOW Bio or its operations.

Note 3: Research and Development Licenses

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

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

UNC License Agreement

The UNC License Agreement provides the Company with an exclusive license to issued patents and pending applications directed to the Company's library of Nitricil compounds, including patents issued in the U.S., Japan and Australia, with claims intended to cover NVN1000, the NCE for the Company's current product candidates. The UNC License Agreement requires the Company to pay UNC up to $425 in regulatory and commercial milestones on a licensed product by licensed product basis and a running royalty percentage in the low single digits on net sales of licensed products. Licensed products include any products being developed by the Company or by its sublicensees.

Unless earlier terminated by the Company at its election, or if the Company materially breaches the agreement or becomes bankrupt, the UNC License Agreement remains in effect on a country by country and licensed product by licensed product basis until the expiration of the last to expire issued patent covering such licensed product in the applicable country. The projected date of expiration of the last to expire of the patents issued under the UNC License Agreement is 2033.

Note 4: Licensing Arrangements

Sato License Agreement

Significant Terms

On January 12, 2017, the Company entered into a license agreement, and related first amendment, with Sato Pharmaceutical Co., Ltd. ("Sato"), relating to SB204, its drug candidate for the treatment of acne vulgaris in Japan (the "Sato Agreement"). Pursuant to the Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable right and license under certain of the Company's intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 in certain topical dosage forms for the treatment of acne vulgaris, and to make the finished form of such products.

On October 5, 2018, the Company and Sato entered into the second amendment (the "Sato Amendment") to the Sato Agreement (collectively, the "Amended Sato Agreement"). The Sato Amendment expanded the Sato Agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections. Pursuant to the Amended Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of its intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 or SB206 in certain topical dosage forms for the treatment of acne vulgaris or viral skin infections, respectively, and to make the finished form of such products. The Company or its designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the active pharmaceutical ingredient ("API") of SB204 or SB206; rather, the parties agreed to negotiate a commercial supply agreement pursuant to which the Company or its designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. Under the terms of the Amended Sato Agreement, the Company also has exclusive rights to certain intellectual property that may be developed by Sato in the future, which the Company could choose to use for its own development and commercialization of SB204 or SB206 outside of Japan.

Under the Amended Sato Agreement, in exchange for the SB204 and SB206 license rights granted to Sato, Sato agreed to pay the Company the following:

- An upfront payment of 1.25 billion Japanese Yen ("JPY") payable in installments of 0.25 billion JPY, 0.5 billion JPY and 0.5 billion JPY on October 5, 2018, February 14, 2019 and September 13, 2019, respectively. This is in addition to the 1.25 billion JPY (approximately $10,813 USD) paid on January 19, 2017 following the execution of the Sato Agreement on January 12, 2017. On October 23, 2018, the Company received the first installment from the Amended Sato Agreement of 0.25 billion JPY (approximately $2,224 USD). On March 14, 2019, the Company received the second installment payment related to the Amended Sato Agreement of 0.5 billion JPY (approximately $4,460 USD). On November 7, 2019, the Company received the third installment payment related to the Amended Sato Agreement of 0.5 billion JPY (approximately $4,554 USD).
- Up to an aggregate of 1.75 billion JPY (adjusted from 2.75 billion JPY in the Sato Agreement) upon the achievement of various development and regulatory milestones, including (i) a 0.25 billion JPY (approximately $2,162 USD) milestone payment received during the fourth quarter of 2018 following Sato's initiation of a Phase 1 trial in Japan; and (ii) an aggregate of 1.0 billion JPY that becomes payable upon the earlier occurrence of specified fixed future dates or the achievement of milestone events.
- Up to an aggregate of 3.9 billion JPY (adjusted from 0.9 billion JPY in the Sato Agreement) upon the achievement of various commercial milestones.
- A tiered royalty ranging from a mid-single digit to a low-double digit percentage (adjusted from a mid-single digit percentage in the Sato Agreement) of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

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

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

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

Note 5: Revenue Recognition

Sato Agreement

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

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

Amended Sato Agreement

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

The Company concluded that the following consideration would be included in the transaction price as they were (i) received prior to March 31, 2020; or (ii) payable upon specified fixed dates in the future and are not contingent upon clinical or regulatory success in Japan:

- The 1.25 billion JPY (approximately $10,813 USD) original upfront payment received on January 19, 2017 following the execution of the Sato Agreement on January 12, 2017.

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

The following table presents the Company's contract assets and contract liabilities balances for the periods indicated.

	Contract Asset	Contract Liability	Net Deferred Revenue
December 31, 2019	$ 8,974	$ 20,478	$ 11,504
March 31, 2020	$ 8,895	$ 19,256	$ 10,361

	Short-term Deferred Revenue	Long-term Deferred Revenue	Net Deferred Revenue
December 31, 2019	$ 4,428	$ 7,076	$ 11,504
March 31, 2020	$ 4,401	$ 5,960	$ 10,361

The Company has recorded the Sato Agreement and Amended Sato Agreement transaction price, including the upfront payments received and the unconstrained variable consideration, as deferred revenue (comprised of (i) a contract liability; net of (ii) a contract asset). The change in the net deferred revenue balance during the three months ended March 31, 2020 was associated with the recognition of license and collaboration revenue associated with the Company's performance during the period (continued amortization of deferred revenue). During the three months ended March 31, 2020 and 2019, the Company recognized $1,024 and $1,100, respectively, in license and collaboration revenue under this agreement.

The Company has concluded that the above consideration is probable of not resulting in a significant revenue reversal and therefore included in the transaction price and is allocated to the single performance obligation. No other variable consideration under the Amended Sato Agreement is probable of not resulting in a significant revenue reversal as of March 31, 2020 and therefore, is currently fully constrained and excluded from the transaction price.

The Company evaluated the timing of delivery for each of the obligations 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.

Prior to the Sato Amendment, the Company estimated the Sato Agreement development timeline for the SB204 product candidate to be approximately 5 years, starting in February 2017 and completing in the first quarter of 2022. With the Amended Sato Agreement, the Company and Sato are now developing both the SB204 and SB206 product candidates for the Japan territory. The parties continue to work collaboratively to reach agreement, but have not yet reached agreement, with respect to the combined SB204 and SB206 development plan for the Japan territory, including a corresponding timeline and estimated duration for the combined development program. The Company's current estimated timeline is 7.5 years, starting in February 2017 and completing in the third quarter of 2024. The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. The Company expects to reassess the estimated performance period during the second quarter of 2020, as the Company considers how the combined SB204 and SB206 development program timeline in Japan may potentially be affected by various factors, including (i) the results from the Company's SB206 Phase 3 trials in the U.S., including but not limited to top-line efficacy results announced in January 2020, (ii) the Company's

plans and timelines for potential further clinical development of SB206 in the U.S., which have been informed by feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and have been and may be further impacted by the COVID-19 pandemic, and (iii) the Company's in-house drug manufacturing capabilities and the progression of the Company's manufacturing technology transfer projects with third-party contract manufacturing organizations. Therefore, if the duration of the combined SB204 and SB206 development program timeline is affected by the establishment or subsequent adjustments to a 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 will lift the variable consideration constraint from each contingent payment when there is 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.

Contract Costs—Sato Agreement

The Company has incurred certain fees and costs in the process of obtaining the Amended Sato Agreement that were payable upon contract execution and, therefore, have been recognized as other assets and amortized as general and administrative expense on a straight-line basis over the same estimated performance period being used to recognize the associated revenue. These fees are associated with the following two arrangements and are described as follows:

- The Company entered into an agreement with a third party to assist the Company in exploring the licensing opportunity which led to the execution of the Sato Agreement. The Company is obligated to pay the third party a low-single-digit percentage of all upfront and milestone payments the Company receives from Sato under the Amended Sato Agreement.

- The intellectual property rights granted to Sato under the Sato Agreement include certain intellectual property rights which the Company has licensed from UNC. Under the UNC License Agreement described in Note 3—Research and Development Licenses, the Company is obligated to pay UNC a running royalty percentage in the low single digits on net sales of licensed products, including net sales that may be generated by Sato. Additionally, the Company is obligated to make payments to UNC that represent the portion of the Sato upfront and milestone payments that were estimated to be directly attributable to the UNC intellectual property rights included in the license to Sato.

Performance Obligations under the Sato Agreement

The net amount of existing performance obligations under long-term contracts unsatisfied as of March 31, 2020 was $10,361. The Company expects to recognize approximately 23% of the remaining performance obligations as revenue over the next 12 months, and the balance thereafter. The Company applied the practical expedient and does not disclose information about variable consideration related to sales-based or usage-based royalties promised in exchange for a license of intellectual property. This expedient specifically applied to the sales-based milestone payments that are present in the Amended Sato Agreement (3.9 billion JPY), as well as percentage-based royalty payments in the Amended Sato Agreement that are contingent upon future sales.

Government Contracts and Grant Revenue

The Company assessed the following Federal grants in accordance with Topic 958 and concluded that both represent conditional non-exchange transactions.

In August 2019, the Company received a Phase 1 Federal grant of approximately $223 (the "NIH Phase 1 Grant") from the National Institutes of Health (the "NIH"). The funds are to be used to advance formulation development of a nitric oxide-containing intravaginal gel (WH602) designed to treat high-risk human papilloma virus ("HPV") infections that can lead to cervical intraepithelial neoplasia ("CIN"). The specific focus is to ensure the nitric oxide delivery from the gel replicates doses of nitric oxide previously demonstrated to be effective against HPV in the Company's clinical and in vitro studies. Revenue recognized under the NIH Phase 1 Grant was $24 during the three months ended March 31, 2020.

In February 2020, following the successful progression of the NIH Phase 1 Grant, the Company was awarded a Phase 2 Federal grant of approximately $997 from the NIH (the "NIH Phase 2 Grant") that will enable the conduct of IND-enabling toxicology and pharmacology studies and other preclinical activity with respect to WH602. The NIH Phase 2 Grant funds will be received by the Company in the form of periodic cost reimbursements as the underlying research and development activities are performed. The Company may be eligible to receive additional funding as part of the NIH Phase 2 Grant, subject to availability of NIH funds and satisfactory progress of the project during the initial 12-month term. No revenue was recognized under the NIH Phase 2 Grant during the three months ended March 31, 2020.

In September 2019, the Company received a grant from the U.S. Department of Defense's Congressionally Directed Medical Research Programs of approximately $1,113 as part of its Peer Reviewed Cancer Research Program. The grant will support the development of a non-gel formulation product candidate (WH504) designed to treat high-risk HPV infections that can lead to CIN, with well-characterized physical chemical properties suitable for intravaginal administration. In addition, the grant will support the evaluation of the effect of varying concentrations and treatment durations of berdazimer sodium (NVN1000) against HPV-18 in human raft cell culture in vitro studies. Revenue recognized under this grant was $165 during the three months ended March 31, 2020.

Note 6: Research and Development Arrangements

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 "Purchase Agreement") with Reedy Creek Investments LLC ("Reedy Creek"), pursuant to which Reedy Creek provided funding to the Company in an initial amount of $25,000, for the Company to use primarily to pursue the development, regulatory approval and commercialization (including through out-license agreements and other third-party arrangements) activities for SB206, a topical anti-viral gel being developed for the treatment of molluscum contagiosum, 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. Reedy Creek was to provide additional funding to the Company of $10,000 contingent upon the achievement by the Company of SB206 clinical trial success, defined as (i) the achievement, no later than March 31, 2020, of statistically significant rates of complete clearance of lesions for molluscum contagiosum in humans at week 12 in each of the two Phase 3 clinical trials or any other primary endpoint required or accepted by the FDA for the SB206 product; or (ii) equivalent achievement (as agreed upon by the parties).

On January 2, 2020, the Company announced top-line results from two pivotal Phase 3 clinical trials of SB206 for the treatment of molluscum contagiosum. SB206 did not achieve statistically significant results in the primary endpoint in both trials, which was the complete clearance of all molluscum lesions at Week 12. Based on such results, the Company understands that Reedy Creek will not be paying the Company the contingent $10,000 of additional funding.

Pursuant to the Purchase Agreement, the Company will pay Reedy Creek ongoing quarterly payments, calculated based on an applicable percentage per product of any upfront fees, milestone payments, royalty payments or equivalent payments received by the Company pursuant to any out-license agreement for SB204, SB206 or SB414 in the United States, Mexico or Canada, net of any upfront fees, milestone payments, royalty payments or equivalent payments paid by the Company to third parties pursuant to any agreements under which the Company has in-licensed intellectual property with respect to such products in the United States, Mexico or Canada. The applicable percentage used for determining the ongoing quarterly payments, applied to amounts received directly by the Company pursuant to any out-license agreement for each product, ranges from 10% for SB206 to 20% for SB204 and SB414. However, the agreement provides that the applicable percentage for each product will be 25% for fees or milestone payments received by the Company (but not royalty payments received by the Company) until Reedy Creek has received payments under the Purchase Agreement equal to the total funding amount provided by Reedy Creek under the Purchase Agreement. If the Company decides to commercialize any product on its own following regulatory approval, as opposed to commercializing through an out-license agreement or other third-party arrangement, the Company will be obligated to pay Reedy Creek a low single digits royalty on net sales of such products.

The Company determined that the Reedy Creek Purchase Agreement is within the scope of ASC 730-20, *Research and Development Arrangements*. The Company concluded that there has not been a substantive and genuine transfer of risk related to the Purchase Agreement as (i) Reedy Creek has the opportunity to recover its investment regardless of the outcome of the research and development programs within the scope of the agreement (prior to commercialization of any in scope assets through potential out-licensing agreements and related potential future milestone payments); and (ii) there is a presumption that the Company is obligated to pay Reedy Creek amounts equal to its investment based on the related party relationship at the time the parties entered into the Purchase Agreement. The Purchase Agreement is a broad funding arrangement, due to (i) the multi-

asset, or portfolio approach including three developmental assets that are within the scope of the arrangement; and (ii) Reedy Creek's approximate 5% ownership of the outstanding shares of common stock of the Company.

As such, the Company determined that the appropriate accounting treatment under ASC 730-20 was to record the initial 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. The long-term liability will remain until the Company receives future milestones from other potential third parties, as defined within the Purchase Agreement, of which 25% will be contractually owed to Reedy Creek. If potential future milestones are received by the Company, and become partly due to Reedy Creek, the corresponding partial repayment to Reedy Creek will result in a ratable reduction of the total long-term obligation to repay the initial purchase price.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

On May 4, 2019, the Company entered into a development funding and royalties agreement (the "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 anti-viral gel being developed for the treatment of molluscum contagiosum.

Pursuant to the 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 active pharmaceutical ingredient for the Company's clinical stage product candidates, for the treatment of molluscum contagiosum. 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. In addition, the Funding Agreement also states that if all development of SB206 is ceased prior to the first regulatory approval, the Company must pay to Ligand an amount equal to the purchase price less the amount spent in accordance with the development budget on development activities conducted prior to such cessation.

As such, the Company concluded that the appropriate accounting treatment under ASC 730-20 was to record the initial proceeds of $12,000, as a liability and as restricted cash on its consolidated balance sheet, as the funds could only be used for the progression of SB206.

The Company amortizes 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 U.S. The ratable Ligand funding is presented within the consolidated statement of operations as an offset to research and development expenses associated with the SB206 program. As of March 31, 2020, the Company is reassessing the estimated total cost to progress the SB206 program to a potential U.S. regulatory approval, including consideration of how such estimated costs may potentially be affected by various factors, including (i) the results from the Company's SB206 Phase 3 trials in the U.S., including but not limited to top-line efficacy results announced in January 2020, (ii) the Company's plans and timelines for potential further clinical development of SB206 in the U.S., which have been informed by feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and have been and may be further impacted by the COVID-19 pandemic, and (iii) the Company's in-house drug manufacturing capabilities and the progression of the Company's manufacturing technology transfer projects with third-party contract manufacturing organizations. This reassessment is expected to continue as the Company evaluates pathways to secure additional funding or a strategic transaction that may enable the conduct of further clinical development activities.

The initial restricted cash balance was also reduced ratably during interim reporting periods in 2019 in a manner consistent with the amortization method for the Ligand funding liability balance. As of December 31, 2019, the aggregate amount spent in accordance with the SB206 development budget on SB206 development activities had exceeded the $12,000 purchase price, causing the aforementioned repayment provision provided for in the Funding Agreement to no longer be enforceable. Therefore, the Company reported no restricted cash balance related to the Funding Agreement, as of December 31, 2019 or March 31, 2020 in its condensed consolidated balance sheet.

For the three months ended March 31, 2020, the Company recorded $1,513 as contra-research and development expense related to the SB206 developmental program, funded by Ligand.

Note 7: Property and Equipment, Net

Property and equipment consisted of the following:

	March 31, 2020	December 31, 2019
Computer equipment	$ 575	$ 575
Furniture and fixtures	305	305
Laboratory equipment	8,077	7,898
Office equipment	339	339
Leasehold improvements	7,053	7,068
Property and equipment, gross	16,349	16,185
Less: Accumulated depreciation and amortization	(6,118)	(5,679)
Total property and equipment, net	$ 10,231	$ 10,506

Depreciation and amortization expense was $495 and $503 for the three months ended March 31, 2020 and 2019, respectively.

Note 8: Commitments and Contingencies

Lease Obligations

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

Pursuant to the Company's accounting policy and applicable guidance in ASC 842, *Leases*, the Company assesses all arrangements that convey the right to control the use of property, plant and equipment, at inception, to determine if each such arrangement is, or contains, a lease based on the unique facts and circumstances present in that arrangement. For those leases identified, the Company determines the lease classification, recognition, and measurement at the lease commencement date. For arrangements that contain a lease the Company: (i) identifies lease and non-lease components; (ii) determines the consideration in the contract; (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease Right of Use ("ROU") assets and corresponding lease liabilities. Lease liabilities are recorded based on the present value of lease payments over the expected lease term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents; (ii) remaining unamortized initial direct costs and lease incentives; and (iii) any impairments of the ROU asset.

The Company separates lease components (fixed rent payments) from non-lease components (common-area maintenance costs) on its real estate assets. Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are expensed as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within the Company's condensed consolidated statements of operations. The Company does not recognize an ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

The interest rate implicit in the Company's lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. The weighted average discount rate utilized on the Company's operating lease liabilities as of March 31, 2020 was 9.85%. The weighted average remaining lease term for the Company's operating leases as of March 31, 2020 was 6.25 years.

Primary Facility Lease

In August 2015, the Company entered into a lease agreement for approximately 51,000 rentable square feet of facility space in Morrisville, North Carolina, commencing in April 2016 (the "Primary Facility Lease"). The initial term of the Primary Facility Lease extends through June 30, 2026. The Company has an option to extend the Primary Facility Lease by five years upon completion of the initial lease term; however, the renewal period was not included in the calculation of the lease obligation. Current contractual base rent payments are $95 per month, subject to a three percent increase annually over the term of the Primary Facility Lease.

Rent expense, including both short-term and variable lease components associated with the primary facility lease, was $224 and $157 for the three months ended March 31, 2020 and 2019, respectively.

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. 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, 2020.

See Note 3—Research and Development Licenses regarding the Company's research and development license agreements.

See Note 6—Research and Development Arrangements regarding the Purchase Agreement with Reedy Creek and the Funding Agreement with Ligand.

See Note 9—Stockholders' Equity (Deficit) regarding outstanding warrants relating to the January 2018 Public Offering, the March 2020 Public Offering and the March 2020 Registered Direct Offering.

Legal Proceedings

The Company is not currently a party to any material legal proceedings and is not aware of any claims or actions pending or threatened 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

In conjunction with the departures of two former Company officers in 2019, the Company entered into separation and general release agreements that included separation benefits consistent with the Company's obligations under their previously existing employment agreements for "separation from service" for "good reason." The Company recognized related severance expense of $0 and $878, during the three months ended March 31, 2020 and 2019, respectively. The accrued severance obligation in respect of the two former officers was $33 as of December 31, 2019 and was fully paid as of March 31, 2020.

As part of a strategic objective to reduce the Company's costs related to internal resources, facilities, and infrastructure capabilities, the Company took actions in February 2020 to reduce the Company's internal resources. Employee severance costs associated with this action were $59, which were expensed during the first quarter of 2020. As of March 31, 2020, severance costs of $50 were accrued in the accompanying condensed consolidated balance sheet.

See Note 10—Share-Based Compensation regarding the Stock Appreciation Rights granted in January 2020.

See Note 11—Tangible Stockholder Return Plan regarding the Tangible Stockholder Return Plan adopted in August 2018.

Note 9: Stockholders' Equity (Deficit)

Capital Structure

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

March 2020 Public Offering

On February 27, 2020, the Company entered into an underwriting agreement with H.C. Wainwright, as underwriter, relating to the offering, issuance and sale of 14,000,000 shares of common stock, pre-funded warrants to purchase 4,333,334 shares of common stock (the "CMPO Pre-Funded Warrants"), and accompanying common warrants to purchase up to an aggregate of 18,333,334 shares of common stock (the "firm warrants"). The Company also granted H.C. Wainwright, as underwriter, a 30-day option to purchase up to 2,750,000 additional shares of common stock and/or common warrants to purchase up to an aggregate of 2,750,000 shares of common stock, which H.C. Wainwright partially exercised on March 2, 2020 to purchase 1,498,602 shares of common stock and common warrants to purchase 2,750,000 shares of common stock (the "option warrants," and together with the firm warrants, the "CMPO Common Warrants"). The combined price to the public in this offering for each share of common stock and accompanying common warrants was $0.30, and the combined price to the public in this offering for each pre-funded warrant and accompanying common warrant was $0.2999. The March 2020 Public Offering closed on March 3, 2020. At closing, the Company also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 594,958 shares of common stock (the "CMPO UW Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in the March 2020 Public Offering.

The CMPO Pre-Funded Warrants have an exercise price of $0.0001 per share and continue in effect until such warrants are exercised in full. The CMPO Common Warrants have an exercise price of $0.30 per share and expire five years from the date of issuance. The CMPO UW Warrants have an exercise price of $0.375 per share and expire five years from the date of issuance.

Through March 31, 2020, warrant holders exercised a total of 4,333,334 CMPO Pre-Funded Warrants and 9,600,000 CMPO Common Warrants. As of March 31, 2020, there were 11,483,334 CMPO Common Warrants and 594,958 CMPO UW Warrants outstanding. As of March 31, 2020, all of the CMPO Pre-Funded Warrants had been exercised in full, such that there were no more CMPO Pre-Funded Warrants outstanding as of such date. Net proceeds from the offering were approximately $5,158 after deducting underwriting discounts and commissions and offering expenses of approximately $791. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital. In addition, proceeds from the exercises of CMPO Common Warrants were approximately $2,880 through March 31, 2020.

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

The CMPO Common Warrants and CMPO UW 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 has assessed the CMPO Common Warrants and the CMPO UW 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 CMPO Common Warrants and the CMPO UW Warrants do not constitute a liability under ASC 480; (ii) the CMPO Common Warrants and the CMPO UW Warrants meet the definition of a derivative under ASC 815; (iii) the warrant holder's option to receive a net cash settlement payment under the CMPO Common Warrants and the CMPO UW 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 CMPO Common Warrants and the CMPO UW Warrants are indexed to the Company's

common stock; and (vi) the CMPO Common Warrants and the CMPO UW Warrants meet all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the CMPO Common Warrants and the CMPO UW Warrants are freestanding equity-linked derivative instruments that meet the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, the CMPO Common Warrants and the CMPO UW Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance.

Pre-funded warrants. The CMPO Pre-Funded Warrants' fundamental transaction provision does 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 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. The CMPO Pre-Funded Warrants also include a separate provision whereby the exercisability of the 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 has assessed the CMPO Pre-Funded Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—Organization and Significant Accounting Policies. During this assessment, the Company determined the CMPO Pre-Funded Warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815. The CMPO Pre-Funded Warrants are indexed to the Company's common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the CMPO Pre-Funded Warrants are freestanding equity-linked financial instruments that meet the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the CMPO Pre-Funded Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance.

March 2020 Registered Direct Offering

On March 24, 2020, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering priced at the market, an aggregate of 10,550,000 shares of the Company's common stock and pre-funded warrants to purchase 8,054,652 shares of common stock (the "RDO Pre-Funded Warrants"). The purchase price for each share of common stock was $0.43, and the price for each pre-funded warrant was $0.4299. The March 2020 Registered Direct Offering closed on March 26, 2020. At closing, the Company also issued to designees of H.C. Wainwright, as placement agent, warrants to purchase an aggregate of up to 558,140 shares of common stock (the "RDO PA Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in the March 2020 Registered Direct Offering. Net proceeds from the offering were approximately $7,225 after deducting fees and commissions and offering expenses of approximately $774. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

The RDO Pre-Funded Warrants have an exercise price of $0.0001 per share and continue in effect until such warrants are exercised in full. The RDO PA Warrants have an exercise price of $0.5375 per share and expire five years from the date of issuance.

Through March 31, 2020, warrant holders exercised a total of 4,602,326 RDO Pre-Funded Warrants. As of March 31, 2020, there were 3,452,326 RDO Pre-Funded Warrants and 558,140 RDO PA Warrants outstanding.

Placement agent warrants. The RDO PA Warrants contain substantially similar terms as the CMPO UW Warrants, including fundamental transaction settlement provisions. The Company conducted an assessment of the RDO PA Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—Organization and Significant Accounting Policies. The Company reached the same determinations as described above for the CMPO UW Warrants, and the Company concluded that the RDO PA Warrants are freestanding equity-linked derivative instruments that meet the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, the RDO PA Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance.

Pre-funded warrants. The RDO Pre-Funded Warrants contain substantially similar terms as the CMPO Pre-Funded Warrants, including fundamental transaction settlement provisions that 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 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. The Company conducted an assessment of the RDO Pre-Funded Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—Organization and Significant Accounting Policies. The Company reached the same determinations as described above for the CMPO Pre-Funded Warrants, and the Company concluded that the RDO Pre-Funded Warrants are freestanding equity-linked financial instruments that meet the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the RDO Pre-Funded Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance.

January 2018 Offering

On January 9, 2018, the Company completed a public offering of its common stock and warrants pursuant to the Company's effective shelf registration statement (the "January 2018 Offering"). The Company sold an aggregate of 10,000,000 shares of common stock and warrants to purchase up to 10,000,000 shares of the Company's common stock at a public offering price of $3.80 per share of common stock and accompanying warrant. The warrant exercise price is $4.66 per share and will expire four years from the date of issuance. Net proceeds from the offering were approximately $35,194 after deducting underwriting discounts and commissions and offering expenses of approximately $2,806. The warrants issued in connection with the January 2018 Offering are freestanding equity-linked derivative instruments that meet the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, such warrants have been classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

Aspire Common Stock Purchase Agreement

On August 30, 2019, the Company entered into the Aspire Common Stock Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25,000 of shares of the Company's common stock at the Company's request from time to time during the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), registering the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Aspire Common Stock Purchase Agreement. On September 16, 2019, the Company filed with the SEC, a prospectus to the effective Registration Statement on Form S-1 (File No. 333-233632) registering 7,032,630 shares of common stock that have been and may be offered to Aspire Capital from time to time under the Aspire Common Stock Purchase Agreement.

Under the Aspire Common Stock Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 100,000 shares of the Company's common stock per business day, up to $25,000 of the Company's common stock in the aggregate at a per share price (the "Purchase Price") equal to the lesser of (i) the lowest sale price of the Company's common stock on the purchase date, or (ii) the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date. The aggregate purchase price payable by Aspire Capital on any one purchase date may not exceed $500.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Aspire Common Stock Purchase Agreement, so long as the most recent purchase has been completed.

The Aspire Common Stock Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Aspire Common Stock Purchase Agreement on any purchase date where the closing sale price of the Company's common stock is less than $0.25. There are no trading volume requirements or restrictions under the Aspire Common Stock Purchase

Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the Aspire Common Stock Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financing transactions, rights of first refusal, participation rights, penalties or liquidated damages in the Aspire Common Stock Purchase Agreement. The Aspire Common Stock Purchase Agreement may be terminated by the Company at any time, at its discretion, without any penalty or additional cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the Aspire Common Stock Purchase Agreement. Any proceeds the Company receives under the Aspire Common Stock Purchase Agreement are expected to be used for working capital and general corporate purposes.

The Aspire Common Stock Purchase Agreement provides that the number of shares that may be sold pursuant to the Aspire Common Stock Purchase Agreement will be limited to 5,211,339 shares (the "Exchange Cap"), which represents 19.99% of the Company's outstanding shares of common stock on August 30, 2019, unless stockholder approval or an exception pursuant to the rules of the Nasdaq Global Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Aspire Common Stock Purchase Agreement is equal to or greater than $2.17, which was the closing sale price of the Company's common stock immediately preceding the execution of the Aspire Common Stock Purchase Agreement. The Company is not required or permitted to issue any shares of common stock under the Aspire Common Stock Purchase Agreement if such issuance would breach its obligations under the rules or regulations of the Nasdaq Global Market. The Company may, in its sole discretion, determine whether to obtain stockholder approval to issue more than 19.99% of its outstanding shares of Common Stock hereunder if such issuance would require stockholder approval under the rules or regulations of the Nasdaq Global Market.

In consideration for entering into the Aspire Common Stock Purchase Agreement, concurrently with the execution of the Aspire Common Stock Purchase Agreement, the Company issued to Aspire Capital 345,622 shares of the Company's common stock (the "Commitment Shares"). These Commitment Shares valued at $750 were recorded in August 2019 as non-cash costs of equity financing and charged against additional paid-in capital.

As of March 31, 2020, the Company has sold 1,000,000 shares of common stock at an average price of $1.19 per share under the Aspire Common Stock Purchase Agreement.

In addition to the limitations noted above, pursuant to the securities purchase agreement relating to the March 26, 2020 Registered Direct Offering, the Company is prohibited from issuing additional securities in any variable rate transaction (as defined in the securities purchase agreement), including under the Aspire Common Stock Purchase Agreement for a period of one year, unless, following the 60th day of the date of the securities purchase agreement, the VWAP (as defined in the securities purchase agreement) is greater than the per share purchase price of the March 2020 Registered Direct Offering for five consecutive trading days.

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, 2020 and December 31, 2019. There were 72,019,062 and 26,734,800 shares of voting common stock outstanding as of March 31, 2020 and December 31, 2019, respectively.

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

	March 31, 2020	December 31, 2019
Outstanding stock options (Note 10)	2,106,770	1,789,303
Warrants to purchase common stock issued in January 2018 Offering (Note 9)	10,000,000	10,000,000
Warrants to purchase common stock issued in March 2020 Public Offering (Note 9)	12,078,292	—
Warrants to purchase common stock issued in March 2020 Registered Direct Offering (Note 9)	558,140	—
Pre-funded warrants to purchase common stock issued in March 2020 Registered Direct Offering (Note 9)	3,452,326	—
Outstanding stock appreciation rights (Note 10)	600,000	1,000,000
For possible future issuance under 2016 Stock Plan (Note 10)	441,663	388,463
	29,237,191	13,177,766

Preferred Stock

The Company's amended and 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, 2020 and December 31, 2019.

Note 10: Share-Based Compensation

2016 Stock Plan

During the three months ended March 31, 2020, the Company continued to administer and grant awards under the 2016 Incentive Award Plan (the "2016 Plan"), the Company's only active equity incentive plan. Certain of the Company's outstanding and exercisable stock options remain subject to the terms of 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.

On July 31, 2019, the Company's stockholders approved an amendment to the 2016 Plan ("the 2016 Plan Amendment"), to increase the number of shares reserved under the 2016 Plan by 1,000,000 and to increase the award limit on the maximum aggregate number of shares of the Company's common stock that may be granted to any one person during any calendar year from 250,000 to 1,000,000 shares of the Company's common stock. All other material terms of the 2016 Plan otherwise remain unchanged.

Stock Appreciation Rights

On August 8, 2018, the Company entered into an employment agreement with G. Kelly Martin (the "Martin Employment Agreement"). The Employment Agreement provided for 1,000,000 stock appreciation rights ("SARs") (the "Martin SAR Award") granted on a contingent basis that would have been irrevocably forfeited and voided in full if the Company had failed to obtain stockholder approval for the 2016 Plan Amendment. If such approval had not been obtained, the Company would have been required to pay Mr. Martin the cash equivalent of the value of the Martin SAR Award. Following stockholder approval of the 2016 Plan Amendment, the Martin SAR Award was no longer considered to be granted on a contingent basis.

The Martin SAR Award entitled Mr. Martin to a payment (in cash, shares of common stock or a combination of both) equal to the fair market value of one share of the Company's common stock on the date of exercise less the exercise price of $3.80 per share. The SARs were to be deemed automatically exercised and settled as of February 1, 2020, provided Mr. Martin remained continuously employed with the Company through such date unless vesting was otherwise expressly accelerated pursuant to the Martin SAR Award. The Martin SAR Award vested in full on February 1, 2020. On February 1, 2020, the fair market value of the Company's common stock was $0.52 per share, and as such, the Martin SAR Award expired unexercised and 1,000,000 shares became available to be granted under the 2016 Plan.

Effective December 17, 2019, the Company entered into an amended and restated employment agreement with Paula Brown Stafford (the "Amended and Restated Stafford Employment Agreement"). On January 6, 2020, following the release of top-line results of the Company's Phase 3 molluscum clinical program as provided in the Amended and Restated Stafford Employment Agreement, 600,000 SARs were granted to Ms. Stafford with an exercise price of $0.82 per share (the fair market value of the Company's common stock on the grant date) and with a ten year term (the "Stafford SAR Award"). The Stafford SAR Award was granted on a contingent basis and would have been considered irrevocably forfeited and voided in full if sufficient shares of the Company's common stock were not available under the 2016 Plan or if the Company failed to obtain stockholder approval for amendments to the 2016 Plan at the next annual stockholders' meeting to provide sufficient shares for the Stafford SAR Award. Such shares became available under the 2016 Plan on February 1, 2020, and the Stafford SAR Award was no longer considered granted on a contingent basis.

During the three months ended March 31, 2020 and 2019, the Company recorded employee share-based compensation expense related to both SAR awards, of $62 and $7, respectively.

Inducement Grants

During the years ended 2019 and 2018, the Company awarded nonstatutory stock options to purchase shares of common stock to newly-hired employees, as inducements material to the individuals' entering into employment with the Company within the meaning of Nasdaq Listing Rule 5635(c)(4) (the "Inducement Grants"). On May 31, 2018, the Company awarded 100,500 Inducement Grants with an exercise price of $3.15 per share, and on September 6, 2019, the Company awarded 25,000

Inducement Grants with an exercise price of $2.62 per share. The Inducement Grants were awarded outside of the Company's 2016 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), but have terms and conditions generally consistent with the Company's 2016 Plan and vest over three years, subject to the employee's continued service as an employee or consultant through the vesting period.

During the three months ended March 31, 2020, the 25,000 Inducement Grants related to the September 6, 2019 award were forfeited in their entirety.

Stock Compensation Expense

During the three months ended March 31, 2020 and 2019, the Company recorded employee share-based compensation expense of $272 and $214, respectively. Total share-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss is as follows:

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 208	$ 61
General and administrative	64	153
	$ 272	$ 214

Stock option activity for the three months ended March 31, 2020 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, 2019	1,789,303	$ 3.89		
Options granted	383,000	0.47		
Options forfeited	(65,533)	2.71		
Options exercised	—	—		
Options outstanding as of March 31, 2020	2,106,770	$ 3.30	7.86	$ 4

On February 13, 2020, the Company issued 383,000 stock options from the 2016 Plan, (the "Retention Grants"). These Retention Grants were issued to certain employees, vest quarterly and will be fully vested on December 31, 2020, provided that the grantee remains an employee or consultant to the Company as of each vesting date.

As of March 31, 2020, there were a total of 2,106,770 stock options outstanding, including 96,167 inducement grants. In addition, there were 441,663 shares available for future issuance under the 2016 Plan as of March 31, 2020.

Note 11: Tangible Stockholder Return Plan

Performance Plan

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

The Performance Plan is tiered, with two separate tranches, each of which has a distinct share price target (measured as the average publicly traded share price of the Company's common stock on the Nasdaq stock exchange for a 30 consecutive trading day period) that will, if achieved, trigger a distinct fixed bonus pool. The share price target for the first tranche and related bonus pool are $11.17 per share and $25,000, respectively. The share price target for the second tranche and related bonus pool are $25.45 per share and $50,000, respectively. The compensation committee has discretion to distribute the bonus pool related to each tranche among eligible participants by establishing individual minimum bonus amounts before, as well as by distributing the remainder of the applicable pool after, the achievement of each tranche specific share price target. Otherwise, if the Company does not achieve one or both related share price targets, as defined, no portion of the bonus pools will be paid.

The Performance Plan provides for the distinct fixed bonus pools to be paid in the form of cash. However, the compensation committee has discretion to pay any bonus due under the Performance Plan in the form of cash, shares of the Company's common stock or a combination thereof, provided that the Company's stockholders have approved the reservation of shares of the Company's common stock for such payment.

The Performance Plan permits the compensation committee to make bonus awards subject to varying payment terms, including awards that vest and are payable immediately upon achieving an applicable share price target as well as awards that pay over an extended period (either with or without ongoing employment requirements). The Performance Plan contemplates that no bonus award payments will be delayed beyond 24 months for named executive officers or more than 12 months for all other participants.

For purposes of determining whether a share price target has been met, the share price targets will be adjusted in the event of any stock splits, cash dividends, stock dividends, combinations, reorganizations, reclassifications or similar events. In the event of a change in control, as defined in the Performance Plan, during the term of the Performance Plan, a performance bonus pool will become due and payable to participants on a pro-rata basis, as calculated and determined by the compensation committee based on the Company's progress toward the share price target as of the date of the change in control and subject to adjustment by the compensation committee as permitted under the Performance Plan.

The Company has concluded that the Performance Plan is within the scope of ASC 718, *Compensation—Stock Compensation* as the underlying plan obligations are based on the potential attainment of certain market share price targets of the Company's common stock. Any awards under the Performance Plan would be payable, at the discretion of the Company's compensation committee following the achievement of the applicable share price target, in cash, shares of the Company's common stock, or a combination thereof, provided that, prior to any payment in common stock, the Company's stockholders have approved the reservation of shares of the Company's common stock for such payment.

ASC 718 requires that a liability-based award should be classified as a liability on the Company's condensed consolidated balance sheets and the amount of compensation cost recognized should be based on the fair value of the liability. When a liability-based award includes both a service and market condition, the market condition is taken into account when determining the appropriate method to estimate fair value and the compensation cost is amortized over the estimated service period. Therefore, the liability associated with the Performance Plan obligation is recorded within other long-term liabilities on the Company's condensed consolidated balance sheets at the estimated fair value on the date of issuance and is re-valued each subsequent reporting period end. The Company recognizes share-based compensation expense within operating expenses in the condensed consolidated statements of operations, including adjustments to the fair value of the liability-based award, on a straight-line basis over the requisite service period.

The fair value of obligations under the Performance Plan are estimated using a Monte Carlo simulation approach. The Company's common stock price is simulated under the Geometric Brownian Motion framework under each simulation path. The other assumptions for the Monte Carlo simulation include the risk-free interest rate, estimated volatility and the expected term. Expected stock price volatility is based on the Company's actual historical volatility over a historical period equal to the expected remaining life of the plan. The fair value of the underlying common stock is the published closing market price on the Nasdaq Global Market as of each reporting date, as adjusted for significant results, as necessary (if applicable). The risk-free interest rate is based on the U.S. Treasury yield curve in effect on the date of valuation equal to the remaining expected life of the plan. The dividend yield percentage is zero because the Company does not currently pay dividends, nor does it intend to do so during the expected term of the plan. The expected life of bonus awards under the Performance Plan is assumed to be equivalent to the remaining contractual term based on the estimated service period including the service inception date of the plan participants and the contractual end of the Performance Plan.

During the three months ended March 31, 2020 and 2019, the Company recorded adjustments to the fair value of the Performance Plan obligation in share-based compensation expense of a reduction of $113 and an increase of $39, respectively.

Note 12: Related Party Transactions

Members of the Company's board of directors held 1,104,776 and 1,002,776 shares of the Company's common stock as of March 31, 2020 and December 31, 2019, respectively.

Health Decisions

On October 25, 2018, the Company announced the formation of a dedicated women's health business unit as well as a foundational collaboration with Health Decisions, Inc. ("Health Decisions"). Health Decisions is a full-service contract research organization specializing in clinical studies of therapeutics for women's health indications. The Company's women's health business unit is led by Paula Brown Stafford, who also is a shareholder and serves on the board of directors of Health Decisions.

Reedy Creek

Reedy Creek beneficially owns approximately 5% of the Company's outstanding common stock and approximately 3.9 million warrants, all of which was acquired during the Company's January 2018 Offering. Accordingly, Reedy Creek is a related party of the Company. The purchase agreement with Reedy Creek, described in Note 6—Research and Development Arrangements, was evaluated and approved pursuant to the Company's existing related party transactions policy.

2020 Registered Direct Offering

Sabby Volatility Warrant Master Fund, Ltd. ("Sabby"), a greater than 5% stockholder, purchased 6,200,000 shares of common stock and pre-funded warrants to purchase up to 2,602,326 shares of common stock for approximately $3,800 in the March 2020 Registered Direct Offering described in Note 9—Stockholders' Equity (Deficit). Sabby's participation in the March 2020 Registered Direct Offering was evaluated and approved pursuant to the Company's existing related party transactions policy.

Joseph Moglia, a greater than 5% stockholder, purchased 1,000,000 shares of common stock for $430 in the March 2020 Registered Direct Offering described in Note 9—Stockholders' Equity (Deficit). Mr. Moglia's participation in the March 2020 Registered Direct Offering was evaluated and approved pursuant to the Company's existing related party transactions policy.

Note 13: Subsequent Events

Exercise of Outstanding Registered Direct Offering Pre-Funded Warrants

As of April 21, 2020, the remaining 3,452,326 RDO Pre-Funded Warrants had been exercised in full, such that there were no more RDO Pre-Funded Warrants outstanding as of such date. See Note 9—Stockholders' Equity (Deficit) for further information regarding the March 2020 Registered Direct Offering.

Paycheck Protection Program

On April 22, 2020, the Company entered into a promissory note (the "Note") evidencing an unsecured loan in the amount of approximately $956 made to the Company (the "Loan") under the Paycheck Protection Program (the "PPP"). The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration (the "SBA"). The Loan to the Company was made through PNC Bank, National Association. Subject to the terms of the Note, the Loan bears interest at a fixed rate of one percent (1%) per annum, with the first six months of interest deferred. Principal and interest are payable monthly commencing on the first day of the next month after the expiration of the initial six-month deferment period and may be prepaid by the Company at any time prior to maturity without penalty. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of loan proceeds for payment of permitted and eligible payroll costs, mortgage interest, rent and utilities. Interest payable on the Note may be forgiven only if the SBA agrees to pay such interest on the forgiven principal amount of the Note. No assurance is provided that the Company will obtain forgiveness of the Loan in whole or in part. The Company will be obligated to repay any portion of the principal amount of the Note that is not forgiven, together with interest accrued and accruing thereon at the rate set forth above, until such unforgiven portion is paid in full.

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, 2019 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 24, 2020, as amended by our Annual Report (Amendment No. 1) on Form 10-K/A filed with the SEC on May 20, 2020 (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. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. These statements are often identified by the use of words such as "believe," "contemplate," "continue," "due," "goal," "objective," "plan," "seek," "target," "expect," "believe," "anticipate," "intend," "may," "will," "would," "could," "should," "potential," "predict," "project," or "estimate," and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. 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 will need substantial additional funding to continue our operating activities and make further advancements in our late-stage clinical development programs. As of March 31, 2020, we had an accumulated deficit of $226.2 million. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our clinical development programs, or eventual commercialization efforts, and/or limit our operations.*
- *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 product candidates and 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 those product candidates.*
- *Ongoing or future product development activities, including preclinical studies, may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of our product candidates.*
- *Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.*
- *Delay or termination of planned clinical trials for our product candidates, including as a result of disruptions caused by the COVID-19 pandemic, could result in unplanned expenses or significantly adversely impact our remaining developmental activities and potential commercial prospects with respect to, and ability to generate potential revenues from, such product candidates.*
- *We may not be able to achieve the objectives described in the section entitled "Overview—Key Product Candidate Development Updates" and "Overview—Business Updates" below. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for any of our product candidates, or regulatory approval 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, our business will be substantially harmed.*
- *We specialize solely in 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.*

- *The issuance of shares in additional equity financings or upon exercise of our outstanding warrants and options may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.*
- *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, 2019 financial statements included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern.*
- *We rely on third parties to conduct some of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or are adversely impacted by the COVID-19 pandemic, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.*
- *We currently manufacture clinical trial materials internally and we intend to utilize third parties, including Orion Corporation, or Orion, to manufacture components of our clinical trial materials and, potentially, commercial supplies of any approved product candidates. If we do not have sufficient quantities of clinical trial materials at acceptable quality levels and within established timelines, it could adversely impact our development and potential future commercialization of any of our product candidates or result in our breaching our obligations to others.*
- *Unexpected delays in our ability to manufacture our NVN1000 active pharmaceutical ingredient, or API, or the associated drug product in a deliverable form, in our facility or at a third-party manufacturer for support of our development and/or commercialization activities could adversely affect our development and commercialization timelines and result in increased costs of our development programs.*
- *We intend to rely on third parties to manufacture raw materials, including our NVN1000 API, and drug product components utilized in clinical trial materials for us and parties with which we contract. Failure to transfer technology and processes to third parties, including our NVN1000 API contract manufacturer and Orion, effectively or failure of those third parties to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities, to provide us with sufficient quantities of raw materials, including API, and drug product components or to provide such raw materials or drug product components at acceptable quality levels or prices could adversely impact our development and potential future commercialization of any of our product candidates or result in our breaching our obligations to others.*
- *Our product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.*
- *Our product candidates, if approved, will face significant competition, and our failure to effectively compete may prevent us from achieving significant market penetration.*
- *If we are unable to obtain and maintain patent protection for our product candidates, 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 and product candidates may be impaired.*
- *If we are unable to establish sales, marketing and distribution capabilities for our product candidates or any future product candidate that receives regulatory approval, either through a commercial partner or internally, we may not be successful in commercializing and generating potential revenues from those product candidates, if approved.*
- *Changes to our leadership team or operational resources could prove disruptive to our operations and have adverse consequences for our business and operating results.*
- *We recently broadened the focus of our product development strategy, and there can be no guarantee that these areas of our platform will be successful or the most profitable.*

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 of our Annual Report and of this Quarterly Report on Form 10-Q.

Novan® is a registered trademark of our company in the United States. This Quarterly Report on Form 10-Q also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q appear without any "™" or "®" symbol, but those references are 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

We are a clinical development-stage biotechnology company focused on leveraging 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 new chemical entities, or 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 advanced strategic development programs in the field of dermatology, while also further expanding the platform into women's health and gastroenterological, or GI, therapeutic areas. We have clinical-stage dermatology drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208) and anti-inflammatory (SB414) mechanisms of action. We recently introduced SB207 as a possible product candidate for additional anti-viral programs, including external genital warts. We are also conducting preclinical work on NCEs and formulations for the treatment of cervical intraepithelial neoplasia, or CIN, caused by high-risk human papilloma virus, or HPV, in the women's health field (WH504 and WH602), inflammatory disorders and diseases in the GI field, and coronaviral infections to include SARS-CoV-2, the virus that causes COVID-19.

During the first quarter of 2020, our primary programmatic focus was on our molluscum contagiosum (SB206) program, and for the remainder of 2020, we intend to focus our clinical-stage development efforts on that program, with all other clinical-stage programs currently on hold. Following the receipt of verbal and minuted feedback from the Type-C meeting with FDA on April 1, 2020, we have sent the proposed protocol to the FDA, manufactured the clinical trial materials at our facility in Morrisville, NC and have begun the planning and start-up phase for B-SIMPLE4, an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum. Further advancement of the molluscum contagiosum (SB206) program beyond the B-SIMPLE4 trial's start-up phase and into the enrollment initiation phase, or advancement of any other late-stage clinical program across our platform, is subject to additional funding or strategic partnering, and has been and may be further impacted by the COVID-19 pandemic. Additional capital may potentially include (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders.

On April 20, 2020, we announced that we have engaged H.C. Wainwright & Co., LLC, or H.C. Wainwright, as a strategic and financial advisor to assist in conducting a comprehensive evaluation of financial and strategic alternatives, intended to maximize stockholder value. Among the strategic and financial alternatives that we are evaluating are strategic transactions and relationships that center on our late-stage assets, our broader dermatology platform and underlying Nitricil technology, as well as evaluating potential sources of financing and other strategic alternatives.

As of March 31, 2020, we had a total cash and cash equivalents balance of $21.8 million and positive working capital of $11.7 million. We believe that our existing cash and cash equivalents balance, including (i) the net proceeds of approximately $15.3 million related to the March 2020 offerings and related warrant exercises described below in "Business Updates" and "Liquidity and Capital Resources", and (ii) expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our operating needs into the second half of 2021, excluding costs associated with the execution of our late-stage clinical development programs, which will require additional funding or strategic partnering in order to complete. Specifically, this operating forecast and related cash projection excludes the potential costs associated with an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum, or B-SIMPLE4, beyond the initial start-up phase, along with any other new late-stage clinical development programs.

If we are unable to secure the additional capital necessary to conduct late-stage clinical trials, including B-SIMPLE4, we would align our business model accordingly to support conduct of early stage research and development and the continued pursuit of strategic alternatives. Our plan and timelines for potential further clinical development of SB206, which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and the related impacts associated with the ongoing COVID-19 pandemic. Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

Key Clinical Stage Product Candidate Development Updates

SB206, a Topical Anti-viral Treatment for Viral Skin Infections

We are developing SB206 as a topical anti-viral gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. Molluscum is a contagious skin infection caused by the molluscipoxvirus. Molluscum affects up to six million people in the U.S. 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 treatment for molluscum. More than half of patients diagnosed with the infection are untreated. The majority of patients that receive treatment are treated with painful procedures and the remaining are often prescribed products indicated for the treatment of external genital warts.

We believed that observational learnings from an in-licensed topical nitric oxide technology study showing clinically meaningful complete clearance rates of baseline molluscum lesions, combined with our SB206 program knowledge, provided a logical pathway for SB206 development in the molluscum indication. We submitted an investigational new drug application, or IND, to the FDA in December 2017 and initiated a Phase 2 clinical trial utilizing SB206 for the treatment of molluscum in the first quarter of 2018. The Phase 2 multi-center, randomized, double-blind, vehicle-controlled, ascending dose clinical trial evaluated the efficacy, safety and tolerability of SB206 in 256 patients, ages 2 and above, with molluscum. Patients were treated with one of three concentrations of SB206 or vehicle for up to 12 weeks. The primary endpoint was the proportion of patients achieving complete clearance of all molluscum lesions at Week 12. We announced top-line results from this Phase 2 clinical trial in the fourth quarter of 2018. SB206 demonstrated statistically significant results in the clearance of all molluscum lesions at Week 12, with signs of efficacy evident as early as Week 2 with the 12% once-daily dose. The safety and tolerability profiles were favorable overall with no serious adverse events reported, including the most effective dose, SB206 12% once-daily.

With the full results from this Phase 2 trial made available, we held an end-of-Phase 2 (Type B) meeting with the FDA in early March 2019. Based on this meeting and the written minutes received, we commenced the Phase 3 development program for molluscum, primarily comprised of two pivotal clinical trials, in the second quarter of 2019 with SB206 12% once-daily as the active treatment arm. The "B-SIMPLE" (Berdazimer Sodium In Molluscum Patients with Lesions) Phase 3 pivotal trials consisted of two (B-SIMPLE1 and B-SIMPLE2) multi-center, randomized, double-blind, vehicle-controlled studies to evaluate the efficacy and safety of SB206 12% once-daily in 707 patients (2:1 active:vehicle randomization), ages 6 months and above, with molluscum. Patients were treated once-daily with SB206 12% or Vehicle Gel once daily for a minimum of 4 weeks and up to 12 weeks to all treatable lesions (baseline and new). There were visits at Screening/Baseline, Week 2, Week 4, Week 8, Week 12 and a safety follow-up at Week 24. The primary endpoint was the proportion of patients achieving complete clearance of all molluscum lesions at Week 12. Both Phase 3 pivotal trials began dosing patients in June 2019 and we completed patient recruitment in August 2019. Top-line efficacy results from the Phase 3 trials were announced in January 2020 with additional efficacy and safety analyses through Week 12 announced in February 2020. SB206 did not achieve statistically significant results in the primary endpoint in both trials, which was the complete clearance of all molluscum lesions at Week 12. In B-SIMPLE2, SB206 was near statistical significance for the primary endpoint ($p=0.062$), and was statistically significant for the secondary endpoint, the complete clearance of all lesions at Week 8 ($p=0.028$), and multiple pre-specified sensitivity analyses. We believe this confirms the robustness of the data in the B-SIMPLE2 trial. While the B-SIMPLE1 trial was not statistically significant for the primary endpoint ($p=0.375$) nor the secondary endpoint ($p=0.202$), all other pre-specified analyses trended in the same direction of improved treatment effect as the B-SIMPLE2 results.

In addition, the results of a statistical test of heterogeneity support that the two pivotal trials are not different from each other. Across both studies, the primary analysis odds ratio and standard error point estimates were similar and in a consistent direction with overlapping 95% confidence intervals. These statistical results are supported by an integrated analysis of the two pivotal trials, which demonstrated statistically significant complete clearance rates at Week 12 for SB206 ($p=0.038$). These additional analyses do not change the outcome of either B-SIMPLE trial, and the FDA may disagree with our conclusions from these analyses. P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of less than 0.050 is generally considered to represent statistical significance, meaning that there is a less than five percent likelihood that the observed results occurred by chance.

The last subject completed their final visit as part of the ongoing safety evaluation through Week 24 in February 2020 and full efficacy and safety data, including data from the safety evaluation through Week 24, were available in March 2020. The safety and tolerability profiles were favorable overall with no serious adverse events reported. Execution of remaining Phase 3 pivotal development program activities for SB206 in molluscum continues in 2020 with the completion of ancillary trials targeted during the second quarter of 2020.

Enrollment was completed in the fourth quarter of 2019 for NI-MC101 (B-SIMPLE3), a Phase 1 open label study assessing the safety, tolerability, and pharmacokinetics of SB206 12% under maximal use conditions in the once daily treatment of molluscum. All patients completed visits for B-SIMPLE3 in the first quarter of 2020. In this open label study, 34 patients with molluscum enrolled, 31 (91%) patients completed the pharmacokinetic assessment phase, and 29 patients (85%) went on to continue study participation for the full 12 weeks of treatment. There were no discontinuations of study drug due to adverse events and there were no reports of serious adverse events. The final study report is expected to be completed in the second quarter of 2020.

Based on the results of the Phase 3 pivotal trials, discussed above, we held a Type C meeting with the FDA on April 1, 2020 seeking feedback on our proposal to conduct one additional, well-controlled confirmatory study of SB206 to support a future NDA. Based on feedback during this meeting and the written minutes received following the meeting, the FDA provided guidance indicating that the FDA will consider one additional pivotal trial, or B-SIMPLE4, that, if successful, can be supported by the previously completed B-SIMPLE2 trial for a future NDA submission. In addition, the FDA provided guidance with regard to both the study design for B-SIMPLE4 and expectations for a future NDA submission.

Preliminary trial design characteristics of B-SIMPLE4 consist of a multi-center, randomized, double-blind, vehicle-controlled study to evaluate the efficacy and safety of SB206 12% once-daily in approximately 750 total patients (1:1 active:vehicle randomization), ages 6 months and above, with molluscum. Patients will be treated once-daily with SB206 12% or Vehicle Gel for a minimum of 4 weeks and up to 12 weeks to all treatable lesions (baseline and new). There will be visits at Screening/Baseline, Week 2, Week 4, Week 8, Week 12 and a safety follow-up at Week 24, with the implementation of additional patient and caregiver training and retention efforts and decentralized visit capabilities for conducting those visits during the COVID-19 pandemic. The primary endpoint will be the proportion of patients achieving complete clearance of all treatable molluscum lesions at Week 12.

We have sent the proposed protocol to the FDA and have begun the planning and start-up phase for B-SIMPLE4. We are targeting enrolling the first patient for B-SIMPLE4 in September 2020 and, if the trial is initiated on this timetable, top-line efficacy results would be expected late in the second quarter of 2021. The initiation and execution of B-SIMPLE4, beyond the start-up phase, is subject to additional funding or strategic partnering, and may be further impacted by the COVID-19 pandemic.

In April 2020, our Japanese development and commercialization partner, Sato Pharmaceutical Co., Ltd., or Sato, informed us of its intention to progress the SB206 development program in Japan with a Phase 1 clinical trial given the observed treatment benefit and favorable safety profile in the B-SIMPLE program.

SB414, a Topical Cream for the Treatment of Inflammatory Skin Diseases

In 2018, we completed two complementary Phase 1b clinical trials with SB414 in patients with atopic dermatitis and psoriasis. The design of these complementary trials was to evaluate the safety, tolerability and pharmacokinetics of SB414. The trials were also designed to assess overall and specific target engagement through a reduction of key inflammatory biomarkers, also known as pharmacodynamic assessment.

Atopic Dermatitis

We initiated a Phase 1b trial with SB414 in adults with mild-to-moderate atopic dermatitis in December 2017. In the Phase 1b trial, 48 adults with mild-to-moderate atopic dermatitis with up to 30% body surface area at baseline, were randomized to receive one of 2% SB414 cream, 6% SB414 cream, or vehicle, twice daily for two weeks. In the complementary Phase 1b trial for mild-to-moderate chronic plaque psoriasis, 36 adults received SB414 6% cream or vehicle twice daily for four weeks.

We received and analyzed the preliminary top line results from the Phase 1b clinical trials during the second and third quarters of 2018. In the atopic dermatitis trial, biomarkers from the Th2, Th17 and Th22 inflammatory pathways known to be highly relevant and indicative of atopic dermatitis, including Interleukin-13, or IL-13, IL-4R, IL-5, IL-17A and IL-22, were downregulated after two weeks of treatment with SB414 2%. The changes in Th2 and Th22 biomarkers and clinical efficacy assessed as the percent change in Eczema Area Severity Index scores were highly correlated in the SB414 2% group.

Additionally, the proportion of patients achieving a greater than or equal to 3-point improvement on the pruritus (itch) numeric rating scale after two weeks of treatment was greater for patients treated with SB414 2% compared to patients treated with vehicle.

The 2% or 6% doses of SB414 in the trial did not result in any serious adverse events, and SB414 2% was more tolerable with no patients discontinuing treatment in the trial due to application site reactions. SB414 at the 6% dose was not consistently effective in reducing biomarkers across both the atopic dermatitis and psoriasis trials. This lack of consistent biomarker movement could potentially be explained by the increased irritation score experienced by patients treated with SB414 6%. Additionally, SB414 6% showed detectable systemic exposure in a subset of patients, which cleared in nearly all affected patients within 12 hours, in both the atopic dermatitis and psoriasis trials. Given the successful downregulation of key biomarkers, favorable tolerability and lack of systemic exposure with SB414 2%, we conducted non-clinical studies and completed our Phase 2 clinical development plan during 2019 to support a potential future Phase 2 clinical program launch. The SB414 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

Psoriasis

We initiated clinical development of SB414, our first use of our nitric oxide platform in the field of immunology by dosing the first patient in October 2017 in a Phase 1b clinical trial to evaluate SB414 in a cream for the treatment of psoriasis. Earlier in 2017, we presented mechanistic evidence for SB414, demonstrating a statistically significant reduction in composite psoriasis scores and an inhibition of IL-17A and IL-17F in an animal model.

In the Phase 1b trial for mild-to-moderate chronic plaque psoriasis, 36 adults received SB414 6% cream or vehicle twice daily for four weeks. We received and analyzed the preliminary top line results from this Phase 1b clinical trial during the second and third quarters of 2018. SB414 at the 6% dose did not result in any serious adverse events, but SB414 at the 6% dose was not consistently effective in reducing biomarkers across the trial. This lack of consistent biomarker movement could potentially be explained by the increased irritation score experienced by patients treated with SB414 6%. Additionally, SB414 6% showed detectable systemic exposure in a subset of patients, which cleared in nearly all affected patients within 12 hours. Based on the results of the Phase 1b trial in psoriasis, we will potentially explore the use of lower doses of SB414 in psoriasis, subject to obtaining additional financing or strategic partnering.

SB204, for the Treatment of Acne Vulgaris

In the second quarter of 2018, we conducted a Type C meeting to further discuss the path forward for our SB204 candidate and possible Phase 3 programs for the treatment of acne vulgaris with the FDA, and the potential for proceeding with a more narrowly defined patient segmentation. In that meeting, our focus was centered specifically on the severe patient population. In the third quarter of 2018, the FDA provided feedback in their minutes on two paths forward for the acne indication, confirming the need for one additional pivotal trial for moderate-to-severe acne patients prior to a NDA submission or, as an alternative, additional preliminary trials for a severe-only patient population.

Following receipt of FDA feedback via written minutes, we have determined that the most pragmatic development pathway for us will be to conduct one additional pivotal Phase 3 trial in moderate-to-severe acne patients. We have completed our clinical development plan for this additional trial, and further advancement of this program is subject to obtaining additional financing or strategic partnering.

Key Preclinical Stage Product Candidate Development Updates

Expansion of Nitric Oxide Platform

We intend to explore the use of our proprietary Nitricil technology to progress a potential topical oral or nasal treatment option for COVID-19, 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 anti-viral indications. We have initiated studies to complete an in vitro assessment of our Nitricil technology, berdazimer sodium (NVN1000), against species within the *Coronaviridae* family, including SARS-CoV-2, the virus that causes COVID-19. We are also exploring the potential for federal grants to support these efforts.

SB207, a Topical Anti-viral Product Candidate

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. The SB207

product candidate incorporates our existing drug substance, berdazimer sodium (NVN1000), with a new formulation specifically engineered for a number of anti-viral programs. In December 2019, we received written responses in response to a pre-IND meeting request with the FDA and, based on such FDA responses, have determined that further advancement of SB207 is subject to further evaluation of clinical plans and securing funding.

Advancement in Women's Health

In February 2020, following the successful progression of a Phase 1 grant received in August 2019, we were awarded a Phase 2 federal grant of approximately $1.0 million from the National Institute of Health, or NIH, that will enable the conduct of IND-enabling toxicology and pharmacology studies and other preclinical activity of a nitric oxide containing intravaginal gel (WH602) designed to treat high-risk HPV infections that can lead to CIN. We may be eligible to receive an additional $0.5 million in funding as part of this Phase 2 grant, subject to availability of NIH funds and satisfactory progress of the project during the initial 12-month term. Under the terms of the aforementioned NIH grant, 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.

This product candidate, in addition to a non-gel formulation product candidate (WH504) supported by a federal grant from the U.S. Department of Defense's, or DoD, Congressionally Directed Medical Research Programs, or CDMRP, currently in development, together represent the core of our Women's Health business unit. This unit has continued to be supported through a collaboration with Health Decisions, Inc., or Health Decisions.

Advancement in GI Disorders

In January 2019, we announced the addition of GI diseases as a therapeutic focus area as part of our overall science and business strategy. This decision was based on the connection between the multi-factorial pathologies of GI diseases and the demonstrable anti-microbial and anti-inflammatory properties of Novan's nitric oxide technology. Nitric oxide produced in the GI tract regulates many of its functions including the secretion of mucous for protection against physical, chemical, and microbial injury, perfusion of blood through the GI tissue, mitigation of white blood cell adherence to GI tissue to protect from injury and the healing and repair of ulcers. We believe that our initial expansion into GI will require minimal investment due to our ability to leverage current technology, experience and assets.

In the fourth quarter of 2019, we received results from our contract research organization, or CRO, partner demonstrating statistically significant improvements in disease activity (i.e., reduced disease activity index scores) with berdazimer sodium (NVN1000) as compared to vehicle in a dextran sulfate sodium (DSS)-induced acute colitis mouse model.

Business Updates

March 2020 Public Offering

On February 27, 2020, we entered into an underwriting agreement with H.C. Wainwright relating to the offering, issuance and sale of 14,000,000 shares of common stock, pre-funded warrants to purchase 4,333,334 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 18,333,334 shares of common stock. We also granted H.C. Wainwright, as underwriter, a 30-day option to purchase up to 2,750,000 additional shares of common stock and/or common warrants to purchase up to an aggregate of 2,750,000 shares of common stock, which H.C. Wainwright partially exercised on March 2, 2020 to purchase 1,498,602 shares of common stock and common warrants to purchase 2,750,000 shares of common stock. The March 2020 Public Offering closed on March 3, 2020. At closing, we also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 594,958 shares of common stock representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in this offering.

Net proceeds from the March 2020 Public Offering were approximately $5.2 million after deducting underwriting discounts and commissions and offering expenses of approximately $0.8 million. As of March 31, 2020, 9,600,000 common stock warrants issued as part of the March 2020 Public Offering have been exercised for an additional $2.9 million of proceeds associated with this offering.

March 2020 Registered Direct Offering

On March 24, 2020, we entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which we agreed to sell and issue in a registered direct offering priced at-the-market under Nasdaq rules, an aggregate of 10,550,000 shares of our common stock and pre-funded warrants to purchase 8,054,652 shares of common stock. The March 2020 Registered Direct Offering closed on March 26, 2020. At closing, we also issued to H.C. Wainwright, as

placement agent, warrants to purchase an aggregate of up to 558,140 shares of common stock representing 3.0% of the aggregate number of shares of common stock and shares of common stock underlying the pre-funded warrants sold in this offering.

Net proceeds from the March 2020 Registered Direct Offering were approximately $7.2 million after deducting the fees and commissions and offering expenses of approximately $0.8 million.

Drug Substance and Drug Product Arrangements; Operational Actions

We have progressed relationships with third-party manufacturers, which are integral to the advancement of our dermatological platform, including our SB206 molluscum program, by us or through partnerships, collaborations, licensing or other strategic relationships. This strategy includes an increased utilization of and reliance upon third-party vendors and strategic partners for the performance of activities, processes and services that (i) do not result in the generation of significant new intellectual property; and (ii) can leverage existing robust infrastructure, systems, and facilities as well as associated subject matter expertise. A parallel and inter-related strategic objective is to reduce our own internal resources, facilities, and infrastructure capabilities that have historically performed such activities, processes and services. As part of our strategic objective to reduce our own internal resources, facilities, and infrastructure capabilities, we took actions in February 2020 that reduced our internal resources from a total of 42 employees as of December 31, 2019 to a total of 28 employees as of April 1, 2020.

On October 15, 2018, we established a strategic alliance with Orion, a Finnish full-scale pharmaceutical company with broad experience in drug manufacturing. The alliance enables Orion to manufacture our topical nitric oxide-releasing product candidates on our behalf and on the behalf of our global strategic partners. We have executed a master contract manufacturing agreement to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with our topical product candidates. We are engaged in the transfer of technology for the manufacture of both SB204 and SB206, and upon its completion intend for Orion to be able to manufacture the drug product, or the finished dosage form of the gel, in accordance with our established manufacturing processes, in compliance with applicable regulatory guidelines, as appropriate for clinical trials and alongside our current internal manufacturing capabilities. A completed manufacturing technology transfer to Orion will enable the manufacture of multiple assets for clinical trial materials and, potentially, commercial quantities. Importantly, this alliance is being structured to support major global markets in which we and our partners pursue regulatory approvals for our product candidates and complements our present internal capability.

In June 2019, we established an operating and business relationship with a full-scale active pharmaceutical ingredient (API) manufacturer, for this manufacturer to become the primary external supplier of our proprietary berdazimer sodium (NVN1000) drug substance. We have executed a master contract manufacturing agreement, which includes the process and analytical method transfer necessary to advance the production of our berdazimer sodium (NVN1000) drug substance for future clinical trials and importantly, upon approval of any of our drug product candidates, for commercial purposes on a global basis. We are engaged in the transfer of the NVN1000 manufacturing technology and upon its completion intend for this API manufacturer to be able to manufacture NVN1000 in accordance with our established manufacturing processes, in compliance with applicable regulatory guidelines, as appropriate for clinical trials and alongside our current internal manufacturing capabilities.

We believe this broad strategy of increasing utilization of and reliance upon third-party vendors and strategic partners for the performance of activities, processes and services can ultimately provide enhanced capabilities and operating efficiencies for us or any potential partnerships, collaborations, licensing or other strategic relationships we may enter. At our request, during the first quarter of 2020, the third-party manufacturers reduced certain near-term activities and extended certain timelines in an effort to reduce our near-term cash utilization. We recently resumed transfer activities with the API manufacturer in April 2020 and are continuing to evaluate when the resumption of activities at Orion may take place. We expect to incur certain incremental and discrete costs to effect this strategy and upon resumption of certain of the manufacturers' transfer activities. Similarly, we expect to incur certain incremental and discrete costs as we seek to reduce our own internal resources, facilities, and infrastructure capabilities, including those actions we took in February 2020 to reduce our internal resources. We will need substantial additional funding to continue our operating activities, including these technical transfer projects and internal cost structure changes, and to make further advancements in our product development programs, as described below in "Liquidity and Capital Resources".

Corporate Updates

Strategic Advisor

In April 2020, we announced that we engaged H.C. Wainwright to assist us in evaluating a range of strategic and financial alternatives, intended to maximize stockholder value. The scope of the review is comprehensive and includes evaluation of

strategic and financial alternatives that can be utilized to advance SB206 for molluscum, the remainder of the dermatology platform and the business as a whole. We have not stated a definitive timeline for completion of this process, and there can be no assurance that this process will result in the Company pursuing any strategic or financial alternatives, or that pursuit of a strategic of financial alternative, if any, would be completed successfully or at all. We do not intend to discuss or disclose developments with respect to this process until the evaluation process has been completed, or our board of directors has concluded that disclosure is appropriate or required.

We believe that our clinical and preclinical data, technology platform and market potential, will provide for a range of opportunities in order to maximize stockholder value.

Nasdaq Listing Matters

As previously disclosed, on February 19, 2020, we received written notice from the staff of the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, indicating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) because the closing bid price for the Company's common stock had closed below $1.00 per share for the previous 30 consecutive business days, or the Minimum Bid Price Requirement.

On April 17, 2020, we received a letter from Nasdaq indicating that, due to extraordinary market conditions, Nasdaq has tolled the compliance period for the Minimum Bid Price Requirement through June 30, 2020, or the tolling period, and that on April 16, 2020, Nasdaq filed an immediately effective rule change with the SEC to implement the tolling period. The new notice indicates that upon expiration of the tolling period and beginning on July 1, 2020, we will receive the balance of days remaining under its currently pending compliance period in effect at the rule change date. Accordingly, upon expiration of the tolling period and beginning on July 1, 2020, we will then have 123 calendar days from July 1, 2020, or until November 2, 2020, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to November 2, 2020.

If we are unable to regain compliance by November 2, 2020, we may be eligible to transfer to the Nasdaq Capital Market and apply for an additional 180 calendar day compliance period to demonstrate compliance with the Minimum Bid Price Requirement. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second 180 calendar day period, Nasdaq will notify us of its determination to delist the Common Stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq Listing Qualifications Panel, or the Panel.

As also previously disclosed, on February 19, 2020 we received notice from the staff of Nasdaq notifying us that, for the previous 30 consecutive business days, the market value of our listed securities had been below the minimum $50.0 million requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(b)(2)(A), or the MVLS Requirement. Nasdaq has not tolled the compliance period for the MVLS Requirement, and accordingly, we have until August 16, 2020, to regain compliance with the MVLS Requirement. If, at any time before August 16, 2020, the market value of our listed securities closes at $50.0 million or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification to us that we comply with the MVLS Requirement.

If we do not regain compliance with the MVLS Requirement by August 16, 2020, Nasdaq will provide written notification to us that our common stock is subject to delisting. At that time, we may either apply for listing on the Nasdaq Capital Market, provided that we meet the continued listing requirements of that market, or appeal the decision to the Panel. In the event of an appeal, our common stock would remain listed on the Nasdaq Global Market pending a decision by the Panel following the hearing. However, there can be no assurance Nasdaq would grant our request for continued listing.

Paycheck Protection Program

On April 22, 2020, we entered into a promissory note for an unsecured loan in the amount of $955,800 under the Paycheck Protection Program, or PPP. The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act and is administered by the U.S. Small Business Administration. The loan to the Company under the PPP was made through PNC Bank, National Association.

Chief Executive Officer Transition

In December 2019, we announced that Paula Brown Stafford, our President and Chief Operating Officer, would succeed G. Kelly Martin as our Chief Executive Officer, effective February 2, 2020. Mr. Martin had a fixed term employment contract that expired on February 1, 2020. Mr. Martin also resigned from our board of directors, effective February 3, 2020. Ms. Stafford remains a member of our board of directors.

Stock Appreciation Rights

Effective December 17, 2019, we entered into an amended and restated employment agreement with Paula Brown Stafford, or the Amended and Restated Stafford Employment Agreement. On January 6, 2020, following our release of top-line results of the Phase 3 molluscum clinical program as provided by the Amended and Restated Stafford Employment Agreement, 600,000 SARs were granted to Ms. Stafford with an exercise price of $0.82 per share, or the Stafford SAR Award. The Stafford SAR Award was granted on a contingent basis and would have been considered irrevocably forfeited and voided in full if sufficient shares of our common stock were not available under the 2016 Plan or if we failed to obtain stockholder approval for amendments to the 2016 Plan at the next annual stockholders' meeting to provide sufficient shares for the Stafford SAR Award. If such contingency were not satisfied, we would have been required to pay Ms. Stafford the cash equivalent of the value of the SARs. Such shares became available under the 2016 Plan on February 1, 2020 and the Stafford SAR Award was no longer considered granted on a contingent basis.

Board of Directors

On January 29, 2020, Dr. Eugene Sun, one of the members of our board of directors, notified us of his resignation from the board and any committees thereof for personal reasons, effective January 29, 2020.

Financial Overview

Since our inception in 2006, we have 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. We conduct these activities in a single operating segment. We have not generated any revenue from product sales and, to date, have funded our operations through a variety of sources described in further detail within the "Liquidity and Capital Resources" section below. From inception through March 31, 2020, we have raised total equity and debt proceeds of $200.5 million to fund our operations, including $5.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the March 2020 Public Offering, $7.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) in the March 2020 Registered Direct Offering and an additional $2.9 million of proceeds associated with exercises through March 31, 2020 of common warrants issued as part of the March 2020 Public Offering. To date, we have focused our funding activities on equity, debt and strategic relationships. However, through March 31, 2020, we have also received funds from licensing and supply arrangements, including $24.2 million through our licensing and supply arrangements with Sato, as well as $12.2 million in government research contracts and grants.

We have never generated revenue from product sales and have incurred net losses in each year since inception. As of March 31, 2020, we had an accumulated deficit of $226.2 million. We incurred net losses of $6.2 million and $6.6 million during the three months ended March 31, 2020 and 2019, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities. We do not expect to generate revenue from product sales unless and until we obtain regulatory approval from the FDA for our clinical-stage product candidates. If we obtain regulatory approval for any of our product candidates, we and/or our commercial partners would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

We believe that our existing cash and cash equivalents balance, including (i) the net proceeds of approximately $15.3 million related to the March 2020 offerings and related warrant exercises described in "Business Updates" and "Liquidity and Capital Resources", and (ii) expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our operating needs into the second half of 2021, excluding costs associated with the execution of our late-stage clinical stage development programs, which will require additional funding or strategic partnering in order to complete. Specifically, this operating forecast and related cash projection excludes the potential costs associated with an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum, or B-SIMPLE4, beyond the initial start-up phase, along with any other new late-stage clinical development programs. Further advancement of the molluscum program beyond the B-SIMPLE4 trial's start-up phase and into the enrollment initiation phase, or advancement of any other late-stage

clinical program across our platform, is subject to additional funding or strategic partnering, and has been and may be further impacted by the COVID-19 pandemic.

If we are unable to secure the additional capital necessary to conduct late-stage clinical trials, including B-SIMPLE4, we would align our business model accordingly to support conduct of early stage research and development and the continued pursuit of strategic alternatives. Our plan and timelines for potential further clinical development of SB206, which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and the related impacts associated with the ongoing COVID-19 pandemic. We will need additional funding to continue our operating activities and make further advancements in our product development programs. Please refer to “Liquidity and Capital Resources” for further discussion of our current liquidity and our future funding needs.

With our existing cash on hand, we expect to incur substantial research and development expenses in 2020 to: (i) advance our SB206 molluscum Phase 3 program, including completing B-SIMPLE1, B-SIMPLE2 and B-SIMPLE3 and supporting activities; (ii) conduct certain API manufacturing capability transfer activities to our external third-party CMO; and (iii) conduct planning and start-up phase activities for an additional confirmatory Phase 3 trial for SB206, B-SIMPLE4, as a treatment for molluscum. We also expect to incur substantial costs in 2020 associated with our research and development personnel and our in-house facility and manufacturing capabilities to support these clinical development activities described in “Key Clinical Stage Product Candidate Development Updates”.

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, our ability to access additional capital, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements and our financial priorities. Additional capital may potentially include (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders.

As a result, we need substantial additional funding to support our planned and future operating activities and make further advancements in our clinical development programs. Adequate future funding may not be available to us on acceptable terms, or at all. The current market value of our common stock may negatively impact funding options and the acceptability of funding terms. Additionally, we expect future advancement of our product candidates to occur after the formation of partnering, collaborations, licensing, grants or other strategic relationships or through equity or debt financings. Our failure to enter into such relationships, or our failure to obtain sufficient additional funds on acceptable terms as and when needed could cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents, such as our current hold on most of our clinical development programs, or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws. Such actions would delay development timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. If we are forced to terminate or eliminate our product development programs, 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. 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. As further discussed in our condensed consolidated financial statements and related footnotes included in this Quarterly Report on Form 10-Q, these matters raise substantial doubt about our ability to continue as a going concern.

We have engaged H.C. Wainwright as a strategic and financial advisor to assist in our comprehensive review of strategic and financial alternatives, which include evaluating potential sources of financing and strategic alternatives. We may seek to engage in one or more potential transactions, such as the sale of the Company, or sale 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 or on terms that are favorable to us.

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

Components of our Results of Operations

Revenue

License and collaboration revenue consists of the amortization of certain fixed and variable consideration under the Sato license agreement that was entered into during the first quarter of 2017, as amended in October 2018, or the Amended Sato Agreement, that (i) has been received to date in the form of upfront and milestone payments; or (ii) are future, non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events. This consideration is being recognized on a straight-line basis over the estimated performance period of approximately 7.5 years, from February 2017 through the third quarter of 2024. We monitor and reassess the estimated performance period for purposes of revenue recognition during each reporting period. We expect to reassess the estimated performance period during the second quarter of 2020, as we consider how the combined SB204 and SB206 development program timeline in Japan may potentially be affected by various factors, including (i) the results from our SB206 Phase 3 trials conducted to date in the U.S., including but not limited to top-line efficacy results announced in January 2020, (ii) our plans and timelines for potential further clinical development of SB206 in the U.S., which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and have been and may be further impacted by the COVID-19 pandemic, and (iii) our in-house drug manufacturing capabilities and the progression of our manufacturing technology transfer projects with third-party contract manufacturing organizations. Therefore, if the duration of the combined SB204 and SB206 development program timeline is affected by the establishment or subsequent adjustments to a mutually agreed upon SB204 and SB206 development plan in the Japan territory, we will adjust our estimated performance period for revenue recognition purposes accordingly, as needed.

The material terms of the Amended Sato Agreement and related revenue recognition are described within “Note 4—Licensing Arrangements” and “Note 5—Revenue Recognition” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Government 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 the qualifying expenses are incurred.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including 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 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 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 share-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.

From inception through March 31, 2020, we have incurred approximately $167.0 million in research and development expenses to develop, expand or otherwise improve our nitric oxide platform and resulting product candidates, as well as costs incurred to generate research and development services revenue. This amount is net of $9.7 million of aggregate contra-research and development expense, including $1.5 million of contra-research and development expense recorded for the three months ended March 31, 2020, representing amortization of the liability related to the $12.0 million of funding received from Ligand to

pursue the development and regulatory approval of SB206. The calculation used to recognize the ratable amortization of this liability includes an estimate of the total cost to progress the SB206 program to a regulatory approval in the U.S. As of March 31, 2020, we are reassessing the estimated total cost to progress the SB206 program to a potential U.S. regulatory approval, including consideration of how such estimated costs may potentially be affected by various factors, including (i) the results from our SB206 Phase 3 trials conducted to date in the U.S., including but not limited to top-line efficacy results announced in January 2020, (ii) our plans and timelines for potential further clinical development of SB206 in the U.S., which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and have been and may be further impacted by the COVID-19 pandemic, and (iii) our in-house drug manufacturing capabilities and the progression of our manufacturing technology transfer projects with third-party contract manufacturing organizations. This reassessment is expected to continue as we evaluate pathways to secure additional funding or a strategic transaction to enable the conduct of further clinical development activities.

For additional information about the Funding Agreement with Ligand, please see “Note 6—Research and Development Arrangements” of the accompanying condensed consolidated financial statements.

The table below sets forth our research and development expenses incurred for external clinical programs and the related product candidates, and other research and development expenses for the three months ended March 31, 2020 and 2019.

Other research and development expenses include: (i) all preclinical program and development costs, including WH504 and WH602, (ii) manufacturing capability and campaign costs, (iii) external costs to establish drug substance and drug product manufacturing capabilities at third-party CMOs, (iv) facility and infrastructure costs, and (v) costs related to all research and development salaries and related personnel costs.

	Three Months Ended March 31,			
	2020		2019	
	(in thousands)			
External clinical programs:				
SB204	$ 9		$ 77	
SB206	902	(1)	649	
SB208	—		7	
SB414	239	(2)	39	
Other research and development	3,766		4,055	
Total research and development expenses	$ 4,916		$ 4,827	

(1) Amount shown net of $1.5 million of contra-research and development expense recorded for the three months ended March 31, 2020, respectively, related to the Funding Agreement with Ligand described in “Note 6—Research and Development Arrangements” to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

(2) Amounts relate to the completion of Phase 2-enabling non-clinical studies and wind-down costs associated with the Phase 2 trial that we placed on indefinite hold in January 2020.

During the first quarter of 2020, our major clinical development activities were primarily associated with the continued conduct of our current SB206 Phase 3 clinical program activities. We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on the completion of our current Phase 3 clinical program activities related to SB206 (B-SIMPLE1, B-SIMPLE2 and B-SIMPLE3), and certain planning and start-up phase costs for an additional confirmatory Phase 3 trial for SB206 (B-SIMPLE4). Our plan and timelines for potential further clinical development of SB206, which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and have been and may be further impacted by the COVID-19 pandemic.

The successful development 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 and in this Quarterly Report on Form 10-Q, for a discussion of the risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including share-based compensation expenses for personnel in our executive, finance, corporate development and other administrative functions. Other general and administrative expenses include 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 general and administrative expenses in 2020 in support of our operating activities and as necessary to operate in a public company environment. Significant general and administrative expenses associated with operations in a public company environment include legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors' and officers' liability insurance premiums and investor relations activities.

Other Income (Expense), net

Other income (expense), net consists primarily of (i) interest income earned on cash and cash equivalents and (ii) other miscellaneous income and expenses.

Results of Operations

Comparison of Three Months Ended March 31, 2020 and 2019

The following table sets forth our results of operations for the periods indicated:

	Three Months Ended March 31,			
	2020	2019	$ Change	% Change
	(in thousands, except percentages)			
License and collaboration revenue	$ 1,024	$ 1,100	$ (76)	(7)%
Government research contracts and grants revenue	189	—	189	100 %
Total revenue	1,213	1,100	113	10 %
Operating expenses:				
Research and development	4,916	4,827	89	2 %
General and administrative	2,507	2,994	(487)	(16)%
Total operating expenses	7,423	7,821	(398)	(5)%
Operating loss	(6,210)	(6,721)	511	(8)%
Other income, net:				
Interest income	35	28	7	25 %
Other income, net	8	56	(48)	(86)%
Total other income, net	43	84	(41)	(49)%
Net loss and comprehensive loss	$ (6,167)	$ (6,637)	$ 470	(7)%

Revenue

License and collaboration revenue of $1.0 million and $1.1 million for the three months ended March 31, 2020 and 2019, respectively, was associated with our performance during the period and the related amortization of the non-refundable upfront and expected milestone payments under the Amended Sato Agreement.

Government research contracts and grants revenue of $0.2 million for the three months ended March 31, 2020 primarily includes $0.2 million of revenue recognized related to the $1.1 million grant we received in September 2019 from the DoD's CDMRP as part of its Peer Reviewed Cancer Research Program.

For additional information regarding our accounting for revenue-generating contracts and agreements, see "Note 5-Revenue Recognition" to the accompanying condensed consolidated financial statements.

Research and development expenses

Research and development expenses were $4.9 million for the three months ended March 31, 2020, compared to $4.8 million for the three months ended March 31, 2019. We experienced a $0.1 million decrease in our SB204 program due to the completion of certain chemistry, manufacturing, and control activities that took place during the comparative period, and a $0.3 million decrease in other research and development expenses. These decreases were partially offset by a $0.3 million increase in the SB206 program, and a $0.2 million increase in our SB414 program due to the incurrence of costs during the first quarter of 2020 associated with the completion of Phase 2-enabling non-clinical studies and wind-down costs associated with the Phase 2 trial that we placed on indefinite hold in January 2020.

In the SB206 program, we experienced a $1.8 million increase in gross costs incurred due to the continued conduct of two Phase 3 pivotal trials and other Phase 3 development activities, including ancillary supporting trials and studies, for the molluscum indication during the first quarter of 2020. This gross increase was primarily offset by $1.5 million of contra-research and development expense recorded during the first quarter of 2020 representing the amortization of the liability related to the Funding Agreement with Ligand, which contributed to the clinical development and regulatory approval of SB206 for the treatment of molluscum.

The $0.3 million decrease in other research and development expenses was primarily driven by a $0.3 million net decrease in research and development personnel costs and a $0.3 million decrease in manufacturing materials and support costs at our Morrisville, NC facility, partially offset by a $0.3 million increase in costs associated with our manufacturing technology transfer projects to third-party manufacturers.

The $0.3 million net decrease in research and development personnel costs is primarily due to (i) $0.5 million in discrete charges during the first quarter of 2019 primarily related to severance and one-time payments associated with the departure of our former chief scientific officer in January 2019 and (ii) a $0.3 million decrease in recurring salary and benefits costs due to a reduced number of research and development personnel between the two comparative periods. These decreases were partially offset by (i) $0.4 million in discrete severance charges and retention incentive compensation associated with business realignment and personnel reduction actions taken during the first quarter of 2020 and (ii) a $0.1 million increase in non-cash stock option related compensation expense.

General and administrative expenses

General and administrative expenses were $2.5 million for the three months ended March 31, 2020, compared to $3.0 million for the three months ended March 31, 2019. The decrease of approximately $0.5 million, or 16%, was primarily due to (i) a $0.3 million decrease in general and administrative personnel and related costs and (ii) a $0.2 million decrease in other general and administrative expenses.

The $0.3 million decrease in general and administrative personnel and related costs is primarily due to (i) a $0.4 million discrete charge in the first quarter of 2019 primarily related to severance and one-time payments associated with the departure of our former chief business officer in January 2019 and (ii) a $0.1 million decrease in non-cash compensation expense primarily associated with the change in the fair value of our Performance Plan liability. These decreases were partially offset by a $0.2 million increase in salaries and benefits costs for general and administrative personnel, of which $0.1 million was associated with discrete retention incentive compensation and severance charges associated business realignment and personnel reductions occurring in the first quarter of 2020 and $0.1 million is associated with recurring salary and benefits costs incurred, including those pursuant to new or modified employment contract terms.

Other income (expense), net

Other income (expense), net was less than $0.1 million for the three months ended March 31, 2020, compared to $0.1 million income for the three months ended March 31, 2019.

Liquidity and Capital Resources

As of March 31, 2020, we had a total cash and cash equivalents of $21.8 million and positive working capital of $11.7 million.

Since our inception through March 31, 2020, we have raised total equity and debt proceeds of $200.5 million to fund our operations, including $5.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the March 2020 Public Offering, $7.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) in the March 2020 Registered Direct Offering and an additional $2.9 million of proceeds associated with the exercises through March 31, 2020 of common warrants issued as part of the March 2020 Public Offering. To date, we have focused our funding activities on equity, debt and strategic relationships, including the transactions

described below. However, other historical forms of funding have included payments received from licensing and supply arrangements, as well as government research contracts.

We believe that our existing cash and cash equivalents balance, including (i) the net proceeds of approximately $15.3 million related to the March 2020 Public Offering and March 2020 Registered Direct Offering, and related warrant exercises, and (ii) expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our operating needs into the second half of 2021, excluding costs associated with the execution of late-stage clinical stage development programs, which will require additional funding or strategic partnering in order to complete. Specifically, this operating forecast and related cash projection excludes the potential costs associated with an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum, or B-SIMPLE4, beyond the initial start-up phase, along with any other new late-stage clinical development programs. Further advancement of the molluscum program beyond the B-SIMPLE4 trial's start-up phase and into the enrollment initiation phase, or advancement of any other late-stage clinical program across our platform, is subject to additional funding or strategic partnering, and has been and may be further impacted by the COVID-19 pandemic. 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, our ability to access additional capital, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements and our financial priorities.

If we are unable to secure the additional capital necessary to conduct late-stage clinical trials, including B-SIMPLE4, we would align our business model accordingly to support conduct of early stage research and development and the continued pursuit of strategic alternatives. Our plan and timelines for potential further clinical development of SB206, which have been informed by verbal feedback during and meeting minutes received from the FDA following the Type C meeting on April 1, 2020, are subject to additional funding or strategic partnering and the related impacts associated with the ongoing COVID-19 pandemic. We will need additional funding to continue our operating activities and make further advancements in our product development programs.

With our existing cash on hand, we also expect to incur substantial research and development expenses in 2020 to: (i) advance our SB206 molluscum Phase 3 program, including completing B-SIMPLE1, B-SIMPLE2 and B-SIMPLE3 and supporting activities; (ii) conduct certain API manufacturing capability transfer activities to our external third-party CMO; and (iii) conduct planning and start-up phase activities for an additional confirmatory Phase 3 trial for SB206, B-SIMPLE4, as a treatment for molluscum. We also expect to incur substantial costs in 2020 associated with our research and development personnel and our in-house facility and manufacturing capabilities that support the aforementioned external development activities.

Our ability to continue to operate our business, including our ability to advance our development programs, is dependent upon our ability to access additional sources of capital, including, but not limited to (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders. We may revise our development and operating activities or their timing depending on the availability of additional funding, partnership opportunities and our financial priorities. Our assumptions and plans may change and could impact the magnitude and/or timing of development and operating expenses and, therefore, our cash runway. In addition, we have continued to evaluate financial as well as strategic options in order to continue operations and to progress SB206 for the molluscum indication. Alternatively, we may seek to engage in one or more potential transactions, such as the sale of the Company, or sale 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 or on terms that are favorable to us.

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization by a strategic partner or by ourselves. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin any commercialization activities. We are subject to all of the risks inherent 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.

As we continue to endeavor to raise additional capital, 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. Our failure to obtain sufficient additional funds on acceptable terms as and when needed could cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws. Such actions could delay development timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. If

we are forced to terminate or eliminate our product development programs, 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. A failure to obtain sufficient funds on acceptable terms when needed could cause us to alter or reduce our planned operating activities to conserve our cash and cash equivalents, including but not limited to delaying planned activities directly related to or in support of product candidate development. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and have a material adverse effect on our results of operations, financial condition and market valuation. As of March 31, 2020, we had an accumulated deficit of $226.2 million and there is substantial doubt about our ability to continue as a going concern.

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.

Aspire Common Stock Purchase Agreement

On August 30, 2019, we entered into the Aspire Common Stock Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock at our request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement. The aggregate amount that we may raise through sales of common stock under the Aspire Common Stock Purchase Agreement is subject to certain limitations including, but not limited to: (i) the number of shares that may be sold will be limited to 5,211,339 shares, representing 19.99% of our outstanding shares of common stock on August 30, 2019, if the average price paid for all shares issued under the agreement is less than $2.17, which was the closing sale price of our common stock immediately preceding the execution of the Aspire Common Stock Purchase Agreement; and (ii) on any purchase date, the closing sale price of our common stock must be greater than or equal to $0.25. As of March 31, 2020, we had sold an aggregate of 1,000,000 shares of common stock at an average price of $1.19 per share under the Aspire Common Stock Purchase Agreement, since the agreement's inception. These amounts, combined with the 345,622 shares issued as part of the commitment fee related to the agreement's execution, leads to a total of 1,345,622 shares issued to Aspire Capital under the agreement as of March 31, 2020. See "Note 9—Stockholders' Equity (Deficit)" to the accompanying condensed consolidated financial statements for information regarding the Aspire Common Stock Purchase Agreement.

However, in addition to certain limitations on use of the Aspire Capital facility imposed by Nasdaq rules, pursuant to the terms of the securities purchase agreement relating to the March 2020 Registered Direct Offering, we are prohibited from issuing additional securities in a variable rate transaction, including in connection with the Aspire Common Stock Purchase Agreement, for the period of one year, unless, following the 60th day of the date of the securities purchase agreement, the VWAP (as defined in the securities purchase agreement) is greater than the per share purchase price of the March 2020 Registered Direct Offering for five consecutive trading days.

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, we entered into the Purchase Agreement with Reedy Creek, pursuant to which Reedy Creek provided us funding in an initial amount of $25.0 million for us to use primarily to pursue the development, regulatory approval and commercialization (including through out-license agreements and other third-party arrangements) activities for SB206, for the treatment of molluscum, and advancing programmatically other activities with respect to SB414, for atopic dermatitis, and SB204, for acne. Reedy Creek was to provide $10.0 million of additional funding contingent upon our achievement of the primary endpoints in each of the two SB206 Phase 3 clinical trials no later than March 31, 2020. Based on the top line efficacy results from the Phase 3 SB206 program released in January 2020, we understand that Reedy Creek will not be paying us the contingent $10.0 million of additional funding.

Pursuant to the Purchase Agreement, we will pay Reedy Creek ongoing quarterly payments, calculated based on an applicable percentage per product of any upfront fees, milestone payments, royalty payments or equivalent payments received by us pursuant to any out-license agreement for the products in the United States, Mexico or Canada, net of any upfront fees, milestone payments, royalty payments or equivalent payments paid by us to third parties pursuant to any agreements under which we have in-licensed intellectual property with respect to the products.

The applicable percentage used for determining the ongoing quarterly payments, applied to amounts received directly by us pursuant to any out-license agreement for each product, ranges from 10% for SB206 to 20% for SB414 and SB204. However, the agreement provides that the applicable percentage for each product will be 25% for fees or milestone payments received by us (but not royalty payments received by us) until Reedy Creek has received payments under the Purchase Agreement equal to

the total funding amount provided by Reedy Creek under the Purchase Agreement. If we decide to commercialize any product on its own following regulatory approval, as opposed to commercializing through an out-license agreement or other third-party arrangement, we will be obligated to pay Reedy Creek a low single digits royalty on net sales of the products.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

On May 4, 2019, we entered into the Funding Agreement with Ligand, pursuant to which Ligand provided us funding of $12.0 million for us to use to pursue the development and regulatory approval of SB206, for the treatment of molluscum.

Pursuant to the Funding Agreement, we will pay Ligand up to $20.0 million in milestone payments upon the achievement by us of certain regulatory and commercial milestones associated with SB206 or any product that incorporates or uses NVN1000, the active pharmaceutical ingredient for our clinical stage product candidates, for the treatment of molluscum. In addition to the milestone payments, we will pay Ligand tiered royalties ranging from 7% to 10% based on annual aggregate net sales of the products in the United States, Mexico or Canada.

Expansion of Partnership with Sato in Japanese Territory

On October 5, 2018, we and Sato entered into the second amendment to the initial license agreement dated January 12, 2017, or the Sato Amendment. The initial license agreement had focused on the development and commercialization of SB204 for the treatment of acne vulgaris in Japan. The Sato Amendment also provides Sato with the exclusive rights to develop and commercialize SB206 and related dosage forms for the treatment of viral skin infections, including but not limited to molluscum contagiosum and external genital warts, in Japan. We have received approximately $24.2 million from Sato beginning January 2017 through March 31, 2020 under the Amended Sato Agreement, including (i) a $10.8 million upfront payment received following the execution of the agreement in January 2017; (ii) a $2.2 million payment related to the initiation of a Phase 1 trial in Japan in the third quarter of 2018; and (iii) $11.2 million of installment payments received following the October 2018 amendment to our amended license agreement with Sato. Under the terms of the Sato Amendment, we received an upfront payment from Sato totaling 1.25 billion JPY (approximately $11.2 million USD) to be paid in three installments over a 12 months period. We received the first installment of 0.25 billion JPY (approximately $2.2 million USD) in October 2018, the second installment of 0.5 billion JPY (approximately $4.5 million USD) in March 2019 and the third installment of 0.5 billion JPY (approximately $4.6 million USD) in November 2019. The Sato Amendment also provides for an aggregate of 1.0 billion JPY in additional non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events.

Primary Facility Lease Financing

Our approximately 51,000 square foot leased facility in Morrisville, North Carolina serves as our corporate headquarters and sole research, development and manufacturing facility. We entered into the ten-year, non-cancellable lease agreement in 2016, currently have approximately 6.25 years remaining under the lease term and currently have approximately $8.2 million in remaining minimum lease payments.

As part of our broader strategic plan to shift our operating cost structure characteristics from fixed to variable, we are actively pursuing efforts to reduce or offset our remaining fixed lease obligation. We have engaged a commercial real estate broker and are currently marketing our Morrisville, North Carolina headquarters facility for sublease or assignment.

We assess the carrying value of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. As of March 31, 2020, we concluded there were no such events or changes in circumstances requiring review of the carrying amount of the Company’s long-lived assets.

Cash Flows

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (7,438)	$ (2,110)
Investing activities	(337)	(17)
Financing activities	15,848	10
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 8,073	$ (2,117)

Net Cash Used in Operating Activities

During the three months ended March 31, 2020, net cash used in operating activities was $7.4 million and consisted primarily of a net loss of $6.2 million, with adjustments for non-cash amounts related primarily to depreciation expense of $0.5 million, share-based compensation expense of $0.3 million, a loss on disposal of equipment of less than $0.1 million, and a $2.1 million net decrease in other operating assets and liabilities. The net decrease in assets and liabilities was primarily due to a $1.5 million decrease in research and development service obligation liabilities related to the amortization of the Ligand Funding Agreement liability, a $1.1 million decrease in deferred revenue associated with our performance under, and revenue recognition of, the Amended Sato Agreement during the first quarter of 2020, a $0.5 million decrease in accrued legal and professional fees, and a $0.7 million decrease in accounts payable. These decreases were partially offset by (i) a $0.9 million increase in accrued outside research and development services and (ii) a $0.7 million increase in accrued compensation, of which $0.5 million was associated with discrete severance charges and retention incentive compensation that were settled through cash payments made during the early second quarter of 2020. The changes in accounts payable and accrued outside research and development services balances during the first quarter of 2020 were primarily related to timing of invoice receipts and payments associated with the SB206 Phase 3 development program.

During the three months ended March 31, 2019, net cash used in operating activities was $2.1 million and consisted primarily of a net loss of $6.6 million, with adjustments for non-cash amounts related primarily to depreciation expense of $0.5 million, share-based compensation expense for both equity-based and liability-based awards of $0.2 million and a $3.8 million favorable change in other operating assets and liabilities. The favorable net change in assets and liabilities was primarily due to (i) a $3.4 million increase in deferred revenue following the receipt of an additional upfront installment payment under the Amended Sato Agreement during the first quarter of 2019; and (ii) a $0.6 million increase in accrued compensation associated with severance obligations to two former officers who resigned during the first quarter of 2019. These changes were partially offset by a $0.2 million net decrease in accounts payable and accrued expenses associated with the timing between the incurrence of service fees and the contractual invoicing and payment terms for such services. Our total accrued compensation balance was $2.0 million as of March 31, 2019, which was reduced over the remainder of 2019 as we made payments of approximately $0.7 million for accrued fiscal year 2018 employee bonuses and approximately $0.6 million for remaining severance payments to former officers.

Net Cash Used in Investing Activities

During the three months ended March 31, 2020, the $0.3 million of net cash used in investing activities was primarily related to installment payments made to a drug delivery device technology manufacturing vendor in connection with an ongoing drug delivery device technology enhancement project.

During the three months ended March 31, 2019, net cash used in investing activities was minimal and consisted of purchases of laboratory and manufacturing equipment.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2020, net cash provided by financing activities was $15.8 million and consisted primarily of $5.3 million of proceeds, net of underwriting fees, from closing of our March 2020 Public Offering, $2.9 million of proceeds from the exercise of common stock warrants, $7.3 million of proceeds, net of placement agent fees, from our March 2020 Registered Direct Offering, and $0.4 million of proceeds from the sale of our common stock pursuant to the Aspire Common Stock Purchase Agreement. These financing cash inflows were partially offset by less than $0.1 million of other offering costs, including legal and professional fees, directly associated with the March 2020 Public Offering, March 2020

Registered Direct Offering and the February 2020 shelf registration statement filing. Additional offering costs recorded in accounts payable or accrued expenses as of March 31, 2020 totaling approximately $0.2 million are expected to be paid during the second quarter of 2020.

During the three months ended March 31, 2019, net cash provided by financing activities was less than $0.1 million and consisted primarily of proceeds from the exercise of stock options.

Capital Requirements

As of March 31, 2020, we had a total cash and cash equivalents balance of $21.8 million and positive working capital of $11.7 million. We believe that our existing cash and cash equivalents balance, including (i) the net proceeds of approximately $15.3 million related to the March 2020 offerings and related warrant exercises, and (ii) expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our operating needs into the second half of 2021, excluding costs associated with the execution of late-stage clinical development programs, which will require additional funding or strategic partnering in order to complete. Specifically, this operating forecast and related cash projection excludes the potential costs associated with an additional confirmatory Phase 3 trial for SB206 as a treatment for molluscum, or B-SIMPLE4, beyond the initial start-up phase, along with any other new late-stage clinical development programs. Further advancement of the molluscum program beyond the B-SIMPLE4 trial's start-up phase and into the enrollment initiation phase, or advancement of any other late-stage clinical program across our platform, is subject to additional funding or strategic partnering, and has been and may be further impacted by the COVID-19 pandemic.

We are utilizing our existing capital resources to fund the ongoing and near-term operating and development activities, as described in the "Overview" section above. We will need substantial additional funding to continue our operating activities and make further advancements in our product development programs, including to conduct the B-SIMPLE4 trial. As we continue to attempt to raise additional capital, there can be no assurance that we will be able to obtain it on terms acceptable to us, on a timely basis, or at all. The current market value of our common stock may negatively impact funding options and the acceptability of funding terms. Additionally, we expect future advancement of our product candidates to occur after the formation of partnering, collaborations, licensing, grants or other strategic relationships or through equity or debt financings. Our failure to enter into such relationships, or our failure to obtain sufficient additional funds on acceptable terms as and when needed could cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws. Such actions could delay development timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. If we are forced to terminate or eliminate our product development programs, 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. 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. Alternatively, we may seek to engage in one or more potential transactions, such as the sale of the Company, or sale 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 or on terms that are favorable to us.

Our ability to continue to operate our business, including our ability to advance our development programs, is dependent upon our ability to access additional sources of capital, including, but not limited to (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders. We may revise our development and operating activities or their timing depending on the availability of additional funding, partnership opportunities and our financial priorities. Our assumptions and plans may change and could impact the magnitude and/or timing of development and operating expenses and therefore our cash runway. We continue to explore other potential non-dilutive business development activities around the developmental and commercial rights to the clinical-stage assets in our platform, including various geographic and indication-specific opportunities.

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization by a strategic partner or by ourselves. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin any commercialization activities. We

are subject to all of the risks inherent 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.

As we continue to attempt to raise additional capital, there can be no assurance that we will be able to obtain it on terms acceptable to us, on a timely basis, or at all. A failure to obtain sufficient funds on acceptable terms when needed could cause us to alter or reduce our planned operating activities to conserve our cash and cash equivalents, including but not limited to delaying planned activities directly related to or in support of product candidate development. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and have a material adverse effect on our results of operations, financial condition and market valuation. As of March 31, 2020, we had an accumulated deficit of $226.2 million and there is substantial doubt about our ability to continue as a going concern.

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:

- 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;
- 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 current manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204 and SB206 in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies; and
- subject to receipt of marketing approval, revenue received from commercial sales or out licensing of our product candidates.

Contractual Obligations and Contingent Liabilities

Except for compensatory obligations described in “Note 8—Commitments and Contingencies” to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there were no material changes during the three months ended March 31, 2020 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.

Jumpstart Our Business Startups Act of 2012 (JOBS Act)

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. We have chosen to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company" we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items, such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. We may remain an emerging growth company until the last day of 2021. However, if certain events occur prior to such date, including if we become a "large accelerated filer," our annual gross revenue equals or exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to such date.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these 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 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. 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. 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, 2020, 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 the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures*

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to

ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, cannot provide absolute assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive and financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020, the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based upon such evaluation, our principal executive and financial officers have concluded because of the material weakness in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective as of such date at the reasonable assurance level.

Material Weakness

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal control over financial reporting will prevent all error and all fraud. Management conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission, or the 2013 Framework. Based on our evaluation under the 2013 Framework, management concluded that we did not maintain effective internal control over financial reporting as of March 31, 2020 because of a material weakness in our internal control over financial reporting related to the accounting for a significant and unusual transaction related to the warrants we issued in connection with the January 2018 Offering.

To respond to this material weakness, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our consolidated financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Restatement of Previously Issued Financial Statements

On May 14, 2020, we revised our prior position on accounting for warrants and concluded that our previously issued consolidated financial statements for the year ended December 31, 2018, and all quarterly periods of 2019 and 2018, or the Affected Periods, should not be relied upon because of a misapplication in the guidance on warrant accounting. On May 20, 2020, we restated our consolidated financial statements for all Affected Periods in our Annual Report on Form 10-K/A (Amendment No. 1) for the fiscal year ended December 31, 2019.

(b) *Changes in Internal Controls Over Financial Reporting*

There have been no significant changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the first quarter ended March 31, 2020 that have materially affected, or are 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 or threatened against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial statements. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

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

We have restated our consolidated financial statements for the year ended December 31, 2018, and all quarterly periods of 2019 and 2018, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our stock price.

On May 14, 2020, we concluded that, because of a misapplication of the accounting guidance applicable to the warrants we issued in January 2018, our previously issued consolidated financial statements for the Affected Periods should no longer be relied upon. As such, we determined that we would restate our consolidated financial statements for each of the Affected Periods and that we would revise our consolidated financial statements for the year ended December 31, 2019 in connection with the restatement of our consolidated financial statements for the Affected Periods, which we did on May 20, 2020. As a result of these events, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with the restatement and the remediation of our ineffective disclosure controls and procedures and material weakness in internal control over financial reporting. In addition, the attention of our management team has been diverted by these efforts. We could be subject to additional stockholder, regulatory or other actions in connection with the restatement or other matters. If any such actions occur, they will, regardless of the outcome, consume a significant amount of management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay substantial damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our counterparties to lose confidence in us. Each of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We identified a material weakness in our internal control over financial reporting related to the accounting for a significant and unusual transaction related to the warrants we issued in connection with the January 2018 Offering. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of March 31, 2020. This material weakness resulted in a material misstatement of our warrant liability, change in fair value of warrant liability, additional paid-in capital, accumulated deficit and related financial disclosures for the Affected Periods.

To respond to this material weakness, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our consolidated financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects. For a discussion of management's consideration of the material weakness identified related to the accounting for a significant and unusual transaction related to the warrants we issued in

connection with the January 2018 Offering, see Part I, Item 4: Controls and Procedures included in this Quarterly Report on Form 10-Q.

Any failure to maintain such internal control could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In either case, there could result a material adverse effect on our business. Failure to timely file will cause us to be ineligible to utilize short form registration statements on Form S-3 or Form S-4, which may impair our ability to obtain capital in a timely fashion to execute our business strategies or issue shares to effect an acquisition. Inferior internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

Our operations have been impacted by and we may face further business disruption and related risks resulting from the COVID-19 pandemic which could have a material adverse effect on our business.

The novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes novel coronavirus disease 2019, or COVID-19, continues to spread globally and has resulted in authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter in place orders, and shutdowns. The COVID-19 pandemic, and the mitigation measures and uncertainty resulting from it, have had and will likely continue to have an adverse impact on economic, public health and behavioral conditions in the United States and worldwide, which in each case could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed or on terms that are favorable to us.

The timetable for development of our product candidates has been impacted and may face further disruption and our business could be further adversely affected by the outbreak of COVID-19. We are still assessing our business plans and the impact COVID-19 may have on our daily operations, our ability to conduct our planned preclinical studies and clinical trials, which also remain subject to available funding, including our ability to recruit patients to participate in clinical trials and access sites and investigators to conduct our clinical trials, and our ability to rely on our current and future third-party relationships (including with third-party manufacturers, vendors, and strategic partners). There can be no assurance that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. In particular, COVID-19 has impacted the trial execution plans of our B-SIMPLE4 Phase 3 trial for SB206, and we are assessing any further impact of COVID-19 on the B-SIMPLE4 Phase 3 trial for SB206, which is also subject to additional funding, including delay, postponement or other impacts to the trial. We may face difficulties and/or delays with site initiation and patient enrollment for the B-SIMPLE4 Phase 3 trial for SB206 or our other planned pre-clinical or clinical trials if (i) the prevalence of molluscum contagiosum is reduced as a result of the various measures implemented by authorities to try to contain COVID-19, (ii) the patient populations that are eligible for our planned clinical trials are impacted by the COVID-19 pandemic, or (iii) if healthcare resources continue to be prioritized toward the COVID-19 pandemic. Because the greatest incidence of molluscum is in children aged one to 14 years, school and child care center closures or reliance on virtual learning could impact our ability to conduct the B-SIMPLE4 Phase 3 trial for SB206. Moreover, the COVID-19 pandemic may continue to affect the business of the FDA or other health authorities, which could result in delays in our interactions with the FDA related to our planned clinical trials.

If we or any future third-parties with whom we partner (including manufacturers, vendors, strategic partners, clinical trial sites, and CROs), or the FDA or other health authorities, experience delays or other disruptions associated with the COVID-19 pandemic, our ability to conduct our business and operations could be further adversely affected, which could prevent or delay us continuing development of our product candidates, and ultimately of reviews and approvals of our product candidates. The extent to which COVID-19 and global efforts to contain its spread will impact our business including our operations, preclinical studies, clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity, and scope of the pandemic and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19.

Our evaluation and potential pursuit of strategic and financial alternatives may result in significant transaction expenses and could adversely impact our business and our stock price.

On April 20, 2020, we announced that we are evaluating strategic and financial alternatives focused on maximizing stockholder value, and we have engaged H.C. Wainwright to assist in that process. We have not stated a definitive timeline for completion of the this process, and there can be no assurance that this process will result in the Company pursuing any strategic or financial alternatives, or that a strategic or financial alternative, if any, would be completed successfully or at all. Moreover, there can be no assurance that any such strategic or financial alternative, if completed, will yield additional stockholder value. Our board of directors may determine to suspend or terminate our evaluation of strategic or financial alternatives, or any pursuit of such alternatives, at any time due to various factors. In addition, our evaluation and pursuit of any strategic or financial alternatives is dependent upon a number of factors that may be beyond our control, including among other factors, market conditions, travel restrictions, industry trends, regulatory limitations, the interest of third parties in our business and the availability of financing to potential strategic partners on reasonable terms.

Further, the process of evaluating and pursuing strategic and financial alternatives, the public announcement of such process or any decision or transaction resulting from such process could adversely impact our business and our stock price. We may devote a significant amount of time and resources to evaluating and pursuing potential strategic and financial alternatives, which could result in the diversion of management's attention from our existing business and focus on our current strategy. In connection with the evaluation and potential pursuit of any strategic and/or financial alternatives, we may incur significant transaction expenses (including equity compensation, severance pay and legal, accounting and financial advisory fees); fail to retain or attract key personnel; or fail to strengthen or maintain our business and relationships with our existing partners and vendors. As a result, we may fail to achieve objectives related to the development of our clinical product candidates or other operational objectives, which may have a material adverse effect on our business.

We do not intend to discuss or disclose developments or provide updates on the progress or status of this process unless and until it has been completed, or our board of directors has concluded that disclosure is appropriate or required. As such, perceived uncertainties related to the future of the Company and speculation regarding the evaluation and potential pursuit of any strategic and/or financial alternatives and related developments may make it more difficult for us to attract and retain key personnel and business partners or cause our stock price to fluctuate significantly.

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

Unregistered Sales of Equity Securities

During the quarter ended March 31, 2020, we sold an aggregate of 700,000 shares of common stock to Aspire Capital under the Aspire Common Stock Purchase Agreement, generating aggregate proceeds of $0.4 million. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(a)(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(a)(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. Such shares are registered for re-sale by Aspire Capital on our Registration Statement on Form S-1 (File No. 333-233632) registering 7,032,630 shares of common stock that have been or may be offered to Aspire Capital from time to time under the Aspire Common Stock Purchase Agreement.

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

2020 Annual Meeting

Pursuant to Rule 14a-8 under the Exchange Act, stockholders may present proper proposals for inclusion in the proxy statement for consideration at our next annual meeting of stockholders. The 2020 Annual Meeting of Stockholders, or the 2020 Annual

Meeting, has been scheduled to be held on July 28, 2020. Because the date of the 2020 Annual Meeting will be held on a date that is more than 30 days after the tentative date of the 2020 Annual Meeting announced in the Company's Quarterly Report on Form 10-Q filed on August 13, 2019, we are informing stockholders in accordance with Rule 14a-5(f) under the Exchange Act that June 1, 2020 is the new deadline for receipt of any stockholder proposals for inclusion in the Company's proxy statement for the 2020 Annual Meeting pursuant to Rule 14a-8 under the Exchange Act.

In accordance with Rule 14a-8 under the Exchange Act, proposals of stockholders for the 2020 Annual Meeting will not be included in the proxy statement for the 2020 Annual Meeting unless the proposal is proper for inclusion in the proxy statement and is received by us at our principal executive offices not later than the date set forth above. While our board will consider stockholder proposals, we reserve the right to omit from the proxy statement stockholder proposals that we are not required to include under the Exchange Act, including Rule 14a-8.

Item 6. Exhibits

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

			INCORPORATED BY REFERENCE			
EXHIBIT NO.	DESCRIPTION	Filed Herewith	FORM	File No.	Exhibit	Filing Date
4.1	Form of March 2020 Public Offering Common Warrant		8-K	001-37880	4.1	March 3, 2020
4.2	Form of March 2020 Public Offering Pre-Funded Warrant		8-K	001-37880	4.2	March 3, 2020
4.3	Form of March 2020 Public Offering Underwriter Warrant		8-K	001-37880	4.3	March 3, 2020
4.4	Form of March 2020 Registered Direct Offering Pre-Funded Warrant		8-K	001-37880	4.1	March 26, 2020
4.5	Form of March 2020 Registered Direct Offering Placement Agent Warrant		8-K	001-37880	4.2	March 26, 2020
10.1	Form of Securities Purchase Agreement, dated March 24, 2020, by and between the Company and each Purchaser thereto		8-K	001-37880	10.1	March 26, 2020
10.2	Paycheck Protection Program Term Note, dated April 22, 2020, in favor of PNC Bank, National Association		8-K	001-37880	10.1	April 23, 2020
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	XBRL Instance Document.	X				
101.SCH	XBRL Taxonomy Extension Schema Document.	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	XBRL Taxonomy Extension Definition Document.	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X				

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
President and Chief Executive Officer
(Principal Executive Officer)

/s/ John M. Gay

John M. Gay
Vice President, Finance and Corporate Controller
(Principal Financial Officer)

/s/ Andrew J. Novak

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

Date: May 20, 2020

Exhibit 31.1

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

I, Paula Brown Stafford, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 20, 2020

/s/ Paula Brown Stafford

Paula Brown Stafford

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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

I, John M. Gay, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 20, 2020

/s/ John M. Gay

John M. Gay

Vice President, Finance and Corporate Controller

(Principal Financial Officer)

Exhibit 32.1

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2020 (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 20, 2020

/s/ Paula Brown Stafford

Paula Brown Stafford
Chief Executive Officer
(Principal Executive Officer)

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

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

Exhibit 32.2

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

I, John M. Gay, Vice President, Finance and Corporate Controller 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, 2020 (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 20, 2020

/s/ John M. Gay

John M. Gay
Vice President, Finance and Corporate Controller
(Principal Financial Officer)

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

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