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

FORM 10-Q

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

For the quarterly period ended September 30, 2021

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37880

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

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

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

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

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

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

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

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

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

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

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

As of November 3, 2021, there were 18,815,892 shares of the registrant's Common Stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,960	$ 35,879
Contracts and grants receivable	121	4,863
Prepaid insurance	40	1,818
Prepaid expenses and other current assets	974	1,333
Other current asset related to leasing arrangement, net	419	—
Assets held for sale	—	114
Total current assets	61,514	44,007
Restricted cash	472	—
Intangible assets	75	75
Other assets	294	341
Property and equipment, net	10,189	2,406
Right-of-use lease assets	1,343	—
Total assets	$ 73,887	$ 46,829
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,919	$ 1,192
Accrued compensation	1,068	1,154
Accrued outside research and development services	182	930
Accrued legal and professional fees	272	168
Other accrued expenses	4,081	801
Deferred revenue, current portion	2,586	2,990
Paycheck Protection Program loan, current portion	—	478
Research and development service obligation liability, current portion	1,558	987
Total current liabilities	12,666	8,700
Deferred revenue, net of current portion	6,818	8,238
Paycheck Protection Program loan, net of current portion	—	478
Noncurrent operating lease liabilities	2,973	—
Research and development service obligation liability, net of current portion	171	649
Research and development funding arrangement liability	25,000	25,000
Other long-term liabilities	74	787
Total liabilities	47,702	43,852
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock $0.0001 par value; 200,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 18,816,092 and 14,570,959 shares issued as of September 30, 2021 and December 31, 2020, respectively; 18,815,142 and 14,570,009 shares outstanding as of September 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	297,074	252,408
Treasury stock at cost, 950 shares as of September 30, 2021 and December 31, 2020	(155)	(155)
Accumulated deficit	(270,736)	(249,277)
Total stockholders' equity	26,185	2,977
Total liabilities and stockholders' equity	$ 73,887	$ 46,829

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License and collaboration revenue	$ 680	$ 1,100	$ 2,174	$ 3,224
Government research contracts and grants revenue	57	217	129	627
Total revenue	737	1,317	2,303	3,851
Operating expenses:				
Research and development	4,251	4,836	15,926	13,513
General and administrative	2,969	3,108	8,086	8,847
Impairment loss on long-lived assets	—	—	114	2,421
Loss on facility asset group disposition	—	1,772	—	1,772
Total operating expenses	7,220	9,716	24,126	26,553
Operating loss	(6,483)	(8,399)	(21,823)	(22,702)
Other income (expense), net:				
Interest income	4	2	10	47
Gain on debt extinguishment	—	—	956	—
Other income (expense)	(5)	(8)	(602)	(3)
Total other income (expense), net	(1)	(6)	364	44
Net loss and comprehensive loss	$ (6,484)	$ (8,405)	$ (21,459)	$ (22,658)
Net loss per share, basic and diluted	$ (0.34)	$ (0.63)	$ (1.30)	$ (2.70)
Weighted-average common shares outstanding, basic and diluted	18,813,653	13,368,965	16,476,235	8,396,106

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

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

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

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

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

	Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2019	2,673,480	$ —	$ 197,856	$ (155)	$ (219,984)	$ (22,283)
Stock-based compensation	—	—	385	—	—	385
Common stock and pre-funded warrants issued pursuant to public offering, net	1,549,860	—	5,158	—	—	5,158
Exercise of pre-funded warrants related to public offering	433,333	—	—	—	—	—
Common stock and pre-funded warrants issued pursuant to registered direct offering, net	1,055,000	1	7,224	—	—	7,225
Exercise of pre-funded warrants related to registered direct offering	460,233	—	—	—	—	—
Exercise of common stock warrants	960,000	—	2,880	—	—	2,880
Common stock issued pursuant to common stock purchase agreement	70,000	—	442	—	—	442
Net loss	—	—	—	—	(6,167)	(6,167)
Balance as of March 31, 2020	7,201,906	$ 1	$ 213,945	$ (155)	$ (226,151)	$ (12,360)
Stock-based compensation	—	—	335	—	—	335
Exercise of pre-funded warrants related to registered direct offering	345,233	—	—	—	—	—
Exercise of common stock warrants	861,067	—	2,583	—	—	2,583
Common stock issued pursuant to common stock purchase agreements	3,533,999	—	17,491	—	—	17,491
Net loss	—	—	—	—	(8,086)	(8,086)
Balance as of June 30, 2020	11,942,205	$ 1	$ 234,354	$ (155)	$ (234,237)	$ (37)
Stock-based compensation	—	—	147	—	—	147
Exercise of common stock warrants	24,850	—	75	—	—	75
Exercise of stock options	1,150	—	5	—	—	5
Common stock issued pursuant to common stock purchase agreements	2,183,174	—	15,668	—	—	15,668
Net loss	—	—	—	—	(8,405)	(8,405)
Balance as of September 30, 2020	14,151,379	$ 1	$ 250,249	$ (155)	$ (242,642)	$ 7,453

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

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flow from operating activities:		
Net loss	$ (21,459)	$ (22,658)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	242	1,107
Impairment loss on long-lived assets	114	2,421
Non-cash loss on facility asset group disposition	—	767
Stock-based compensation	(84)	832
Non-cash cost of shares issued to Aspire Capital as commitment fee	—	1,695
Foreign currency transaction loss	676	—
Gain on debt extinguishment	(956)	—
Loss on disposal and write-offs of property and equipment	—	66
Changes in operating assets and liabilities:		
Contracts and grants receivable	4,399	262
Prepaid insurance, prepaid expenses and other current assets	2,137	744
Accounts payable	(45)	(1,441)
Accrued compensation	(86)	346
Accrued outside research and development services	(748)	39
Accrued legal and professional fees	104	(297)
Other accrued expenses	1,550	82
Deferred revenue	(2,174)	(3,343)
Research and development service obligation liabilities	93	(2,166)
Other long-term assets and liabilities	201	(324)
Net cash used in operating activities	(16,036)	(21,868)
Cash flow from investing activities:		
Purchases of property and equipment	(4,515)	(415)
Landlord reimbursement of tenant improvement allowance	1,015	—
Proceeds from the sale of property and equipment	—	325
Net cash used in investing activities	(3,500)	(90)
Cash flow from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net of underwriting fees and commissions	37,600	12,577
Proceeds from exercise of common stock warrants	461	5,538
Proceeds from Paycheck Protection Program loan	—	956
Proceeds from issuance of common stock under common stock purchase agreement	6,334	31,906
Payments related to public offering costs	(364)	(178)
Payments of offering costs related to registration statement	—	(25)
Proceeds from exercise of stock options	58	5
Net cash provided by financing activities	44,089	50,779
Net increase in cash, cash equivalents and restricted cash	24,553	28,821
Cash, cash equivalents and restricted cash as of beginning of period	35,879	14,251
Cash, cash equivalents and restricted cash as of end of period	$ 60,432	$ 43,072
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment with accounts payable and accrued expenses	$ 3,892	$ 56
Right-of-use assets obtained in exchange for lease liabilities	$ 1,343	$ —
Non-cash gain on debt extinguishment from forgiveness of Paycheck Protection Program loan	$ 956	$ —
Deferred offering costs reclassified to additional paid-in capital	$ 364	$ 16
Reconciliation to condensed consolidated balance sheets:		
Cash and cash equivalents	$ 59,960	$ 43,072
Restricted cash included in noncurrent assets	$ 472	$ —
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 60,432	$ 43,072

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 pre-commercial nitric oxide-based pharmaceutical company focused on dermatology and anti-infective therapies. The Company leverages its proprietary nitric oxide based technology platform, NITRICIL™ to generate macromolecular new chemical entities. 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, 2020 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's report for the December 31, 2020 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.

Reverse Stock Split

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

All disclosures of shares and per share data in the condensed consolidated financial statements and related notes have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented, and certain amounts within the condensed consolidated balance sheets and condensed consolidated statements of stockholders' equity (deficit) were reclassified between common stock and additional paid-in capital.

Liquidity and Ability to Continue as a Going Concern

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

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

- The Company has reported a net loss in all fiscal periods since inception and, as of September 30, 2021, the Company had an accumulated deficit of $270,736.

- As of September 30, 2021, the Company had a total cash and cash equivalents balance of $59,960.

- As described in Note 10—Stockholders' Equity (Deficit), in June 2021 the Company completed a public offering of its common stock pursuant to the Company's shelf registration statement (the "June 2021 Public Offering"). Net proceeds from the offering were approximately $37,236 after deducting underwriting discounts and commissions and offering expenses of approximately $2,764.

- As described in Note 10—Stockholders' Equity (Deficit), in July 2020 the Company entered into a common stock purchase agreement (the "July 2020 Aspire CSPA") with Aspire Capital Fund, LLC ("Aspire Capital"). The July 2020 Aspire CSPA replaced the prior common stock purchase agreement, dated as of June 15, 2020, between the Company and Aspire Capital (the "June 2020 Aspire CSPA"), which was fully utilized. During the nine months ended September 30, 2021, the Company received aggregate net proceeds of $6,334 from sales under the July 2020 Aspire CSPA and, as of September 30, 2021, had $12,005 in remaining availability for sales of its common stock under the July 2020 Aspire CSPA.

- As described in Note 10—Stockholders' Equity (Deficit), in early 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 exercise of common warrants issued in the March 2020 Public Offering of approximately $5,568 through September 30, 2021.

- As described in Note 10—Stockholders' Equity (Deficit), in late 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.

- The Company anticipates that it will continue to generate losses for the foreseeable future, and it expects the losses to increase as it continues the development of, and seeks regulatory approvals for, its product candidates and begins activities to prepare for potential commercialization.

- The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company, coupled with its current forecasts, including costs associated with implementing the SB206 prelaunch strategy and commercial preparation, raise substantial doubt about its ability to continue as a going concern.

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

The Company believes that its existing cash and cash equivalents balance as of September 30, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its planned operating needs into the fourth quarter of 2022. This operating forecast and related cash projection includes: (i) costs through the completion of the B-SIMPLE4 Phase 3 trial, including final data accumulation and reporting in addition to other supporting activities; (ii) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum; (iii) costs associated with the completion of the build-out of its new corporate headquarters and manufacturing capability necessary to support small-scale drug substance and drug product manufacturing; (iv) conducting drug manufacturing capability transfer activities to external third-party contract manufacturing organizations, or CMOs, including a drug delivery

device technology enhancement project; (v) developmental and regulatory activities for its SB019 program (Coronaviridae (COVID-19)), including a Phase 1 study, targeted for initiation in 2022; (vi) preparatory activities for a potential Phase 3 trial, targeted for initiation in 2023, related to SB204 as a treatment for acne; and (vii) initial efforts to support potential commercialization of SB206, but excludes: (a) any potential costs associated with other late-stage clinical programs, including executing the potentially registrational Phase 3 trial of SB204 for acne; (b) progression of the SB019 program subsequent to execution of a Phase 1 study; (c) operating costs that could occur between a potential NDA submission for SB206 through NDA approval, specifically including marketing and commercialization efforts to achieve potential launch of SB206; and (d) proceeds from any potential future sales of common stock under the July 2020 Aspire CSPA. The Company may decide to revise its development and operating plans or the related timing, depending on information it learns through its research and development activities, including regulatory submission efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, its ability to enter into strategic arrangements, its ability to access additional capital and its financial priorities. The Company will need significant additional funding to continue its operating activities, make further advancements in its product development programs and potentially commercialize any of its product candidates beyond those activities currently included in its operating forecast and related cash projection.

The Company does not currently have sufficient funds to commercialize any of its product candidates, if approved, and its funding needs will largely be determined by its commercialization strategy for SB206, subject to NDA submission timing and the regulatory approval process. The Company has engaged Syneos Health, a fully integrated biopharmaceutical solutions organization, as its commercial solutions provider for SB206. The Company's relationship with Syneos Health will focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by commercial sales of SB206, if approved by the U.S. Food and Drug Administration.

The inability of the Company to obtain significant additional funding on acceptable terms, including through the utilization of the remaining amount available under the July 2020 Aspire CSPA, 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 may pursue additional capital through equity or debt financings, including potential sales under the July 2020 Aspire CSPA, or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. The Company's equity issuances during the year ended December 31, 2020, and the nine months ended September 30, 2021, have resulted in significant dilution to its existing stockholders. Any future additional issuances of equity, or debt convertible into equity, would result in further significant dilution to the Company's existing stockholders. Alternatively, the Company may seek to engage in one or more potential transactions, which could include 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.

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 ("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 its variant strains, and domestic 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, the availability and effectiveness of vaccines in preventing the spread of COVID-19 (and its variants), and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19 and its variants.

During the pandemic, the timetable for development of the Company's product candidates has been impacted and may face further disruption and the Company's business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of the Company's B-SIMPLE4 Phase 3 trial. The Company continues to assess any further impact of COVID-19 on the Company's operations.

In addition, the Company currently relies on third-party suppliers to provide the raw materials that are used by the Company or its third-party manufacturers in the manufacture of its product candidates. There are a limited number of suppliers for raw materials, including nitric oxide, that the Company uses to manufacture its product candidates. The Company also relies on third-party logistics vendors to transport its raw materials, active pharmaceutical ingredient ("API"), and drug products through its supply chain. Certain materials, including the Company's API, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials with

such hazard classifications from time to time, especially in light of the pandemic and related global supply chain constraints, which could adversely impact the timing or cost of the Company's manufacturing supply chain activities or other associated development activities.

The Company continues to assess any further impact of COVID-19 on its supply chain and related vendors, and the impact of global supply chain constraints across various industries, including interruption of, or delays in receiving, supplies of raw materials, API or drug product from third-party manufacturers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems. The Company is also continuing to evaluate the impacts of COVID-19 and global supply chain constraints on its work to build-out its new facility. The Company expects to complete the construction of its new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product, by the end of 2021. Once the build-out is completed and occupied, the Company will proceed with the related preparatory activities associated with qualifying, commissioning and validating the manufacturing equipment for use in API production.

Despite disruptions to the Company's business operations and the business operations of third parties on which the Company relies, the COVID-19 pandemic has not significantly impacted the Company's operating results and financial condition to date. However, at this time, the extent to which COVID-19 and its variants may impact the Company's financial condition or results of operations in the future is uncertain.

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 of a normal, recurring nature that are necessary for the fair statement of the Company's financial position and its results of operations and cash flows. The results of operations for interim periods are not necessarily indicative of the results expected for the full fiscal year or any future period. These interim financial statements should be read in conjunction with the consolidated financial statements and notes set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on February 24, 2021.

Reclassifications

Certain amounts in the Company's consolidated balance sheet as of December 31, 2020 have been reclassified to conform to current presentation related to deferred offering costs in the amount of $58 being included with prepaid expenses and other current assets. These reclassifications had no impact on the Company's consolidated current assets or on the consolidated statements of operations and comprehensive loss or cash flows for the year ended December 31, 2020.

Certain amounts in the Company's consolidated balance sheet as of December 31, 2020 have been reclassified to conform with the May 25, 2021 Reverse Stock Split. The reclassified amount between common stock and additional paid-in capital was $13 as of December 31, 2020. These reclassifications had no impact on the Company's consolidated stockholders' equity or on the consolidated statements of operations and comprehensive loss or cash flows for the year ended December 31, 2020.

Restricted Cash

Restricted cash as of September 30, 2021 includes funds maintained in a deposit account to secure a letter of credit for the benefit of the TBC Landlord (as defined below). See Note 8—Commitments and Contingencies for further information regarding the letter of credit and the TBC Lease (as defined below).

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.

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

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding for the three and nine months ended September 30, 2021 and September 30, 2020 because the effect is anti-dilutive due to the net loss reported in each of those periods. All share amounts presented in the table below represent the total number outstanding as of the end of each period.

	September 30,	
	2021	2020
Warrants to purchase common stock (Note 10)	1,274,176	1,377,727
Stock options outstanding under the 2008 and 2016 Plans (Note 11)	392,058	199,530
Stock appreciation rights outstanding under the 2016 Plan (Note 11)	60,000	61,000
Inducement stock options outstanding (Note 11)	1,250	9,183

Segment and Geographic Information

The Company has determined that it operates in one segment. The Company uses its proprietary nitric oxide based technology platform to generate macromolecular new chemical entities and develops product candidates to treat multiple indications. 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 with Sato Pharmaceutical Co., Ltd. ("Sato"). Substantially 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 $680, or 92% of total revenue, and $2,174, or approximately 94% of total revenue, during the three and nine months ended September 30, 2021, respectively. During the three and nine months ended September 30, 2020, the Company generated revenue from its licensing partner in Japan of $1,100, or approximately 84% of total revenue, and $3,224, or 84% of total revenue, respectively.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* This guidance is intended to improve consistent application of 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. This ASU was effective for the Company as of January 1, 2021. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* This guidance is intended to simplify the accounting for certain financial instruments with characteristics of liabilities and equity. This standard is effective for annual reporting periods beginning after December 15, 2021, including interim reporting periods within those annual reporting periods. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The adoption of this new accounting guidance, as of January 1, 2021, did not have a material impact on the Company's condensed consolidated financial statements.

Accounting Pronouncements Being evaluated

In May 2021, the FASB issued ASU No. 2021-04, *Earnings per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.* This guidance is intended to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options, such as warrants, that remain equity classified after modification or exchange. This standard is effective for annual reporting periods beginning after December 15, 2021, 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 but does not expect the adoption of this new standard to have a material impact on the Company's condensed 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 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 United States and foreign patents and patent applications that were controlled by the Company as of December 29, 2015 or that became controlled by the Company between that date and December 29, 2018, directed towards nitric-oxide releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds and other nitric oxide-based therapeutics.

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the "KNOW Bio Sublicense Agreements" and together with the KNOW Bio License Agreement, the "Original KNOW Bio Agreements"). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the United States and foreign patents and patent applications exclusively licensed to the Company from 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 nine months ended September 30, 2021 and 2020.

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 United States and foreign patents and patent applications controlled by the Company as of December 29, 2015, and that became controlled by the Company between December 29, 2015 and December 29, 2018, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses (the "Oncovirus Field").

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

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

The rights granted to the Company in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Original KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and the Company that are set forth in the Original KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

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

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

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 United States, 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, 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 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 was 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, of which the Company received a payment of 0.5 billion JPY (approximately $4,572 USD) during the second quarter of 2021.
- 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 United States; (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 framework in the Sato Agreement is representative of a stand-alone selling price for the supply of API and does not represent a discount. Therefore, this contract provision is not considered to be a promise to deliver goods or services and is not a performance obligation or part of the combined single performance obligation described above.

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 September 30, 2021; 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. On May 20, 2021, the Company received one such non-contingent milestone payment in the form of a payment of 0.5 billion JPY (approximately $4,572 USD) related to achievement of a time-based developmental milestone.

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

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

	Contract Asset	Contract Liability	Net Deferred Revenue
December 31, 2020	$ 4,843	$ 16,071	$ 11,228
September 30, 2021	$ 4,494	$ 13,898	$ 9,404

	Short-term Deferred Revenue	Long-term Deferred Revenue	Net Deferred Revenue
December 31, 2020	$ 2,990	$ 8,238	$ 11,228
September 30, 2021	$ 2,586	$ 6,818	$ 9,404

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 and nine months ended September 30, 2021 was associated with (i) the recognition of license and collaboration revenue associated with the Company's performance during the period (continued amortization of deferred revenue); and (ii) the impact of foreign currency exchange rate fluctuations. As of December 31, 2020, the Company had an unconditional right to receive consideration of $4,843, based on a time-based developmental milestone payment that became due and payable as of December 31, 2020. Therefore, as of December 31, 2020, the Company presented this milestone payment in contracts and grants receivable within its condensed consolidated balance sheets. During the nine months ended September 30, 2021, the Company received payment of $4,572 related to achievement of this time-based developmental milestone, with the difference between the amount received and the balance presented as of December 31, 2020 being due to foreign currency fluctuations.

During the three and nine months ended September 30, 2021, the Company recognized $680 and $2,174, respectively, in license and collaboration revenue under this agreement. During the three and nine months ended September 30, 2020, the Company recognized $1,100 and $3,224, respectively, in license and collaboration revenue under this agreement.

During the three and nine months ended September 30, 2021, the Company recognized income of $7 and expense of $621, respectively, related to foreign currency adjustments related to the contract asset and contract receivable, presented within other income (expense), net within the accompanying condensed consolidated statements of operations and comprehensive loss.

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 September 30, 2021 and therefore, is currently fully constrained and excluded from the transaction price.

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

The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. During the third quarter of 2020, Sato prepared, and the Company reviewed, an SB206 Japanese development program timeline that supported a 7.5 year performance period estimate completing in the third quarter of 2024. The SB204 Japanese development plan and program timeline was not presented by Sato and remains under evaluation by the Company and Sato. Currently, the Company understands that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato's comprehensive asset developmental program, including SB206.

In November of 2020, Sato determined its initial Japanese Phase 1 study for SB206 would require an amended design, including evaluation of potential lower dose strengths, to further refine dose tolerability in a subsequent Phase 1 study. Based upon (i) the need for an additional Phase 1 study; (ii) Sato's estimated comprehensive developmental schedule for SB206, including additional post-Phase 1 clinical trials; and (iii) current and future Japanese clinical trial material manufacturing and technical transfer considerations, the Company concluded that a prospective delay in Sato's overall SB206 Japanese development plan had occurred. The Company estimates the program timeline to be extended by 1.75 years from its previous estimate, and a corresponding extension of the performance period estimate to 9.25 years, completing in the second quarter of 2026.

In late July 2021, Sato communicated an updated plan regarding its amended design for its additional Japanese Phase 1 study for SB206. The amended study design includes evaluation of potential lower dose strengths, including potential further refinement in a subsequent dose tolerability study. As part of the communication regarding these Phase 1 studies, Sato also communicated an updated comprehensive timeline for the Japanese SB206 program. The updated timeline assumes that the 12% formulation is appropriate to proceed for development in Japan, and is to be reassessed based on the findings of the Phase 1 study.

Based upon (i) the expected timing of the additional Phase 1 study, including a subsequent dose tolerability study; (ii) Sato's estimated comprehensive developmental schedule for SB206, including additional post-Phase 1 clinical trials; and (iii) current and future Japanese clinical trial material manufacturing and technical transfer considerations, including the manufacturing site for drug product, the Company concluded that a prospective delay in Sato's overall SB206 Japanese development plan had occurred. The Company estimates the program timeline to be extended by 0.75 years from its previous estimate, and a corresponding extension of the performance period estimate to 10 years, completing in the first quarter of 2027. The Company understands that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato's comprehensive asset developmental program, including SB206.

The change in estimate related to the expected duration of the combined SB204 and SB206 development program timeline that occurred in July 2021 resulted in a decrease of $34 in monthly license and collaboration revenue, as compared to amounts that would have been recorded under the previous timeline.

Based on the timing of this change in estimate, beginning in the third quarter of 2021, the Company recognized a lower amount of license and collaboration revenue, as compared to the first and second quarter of 2021. Prospective periods will reflect the impact of this change in estimate that occurred in July 2021, as compared to the previous timeline, based on the current timeline and the effective difference in monthly revenue recognized under the Amended Sato Agreement.

The estimated timeline remains subject to prospective reassessment and adjustment based upon Sato's interaction with the Japanese regulatory authorities and other developmental and timing considerations. The combined SB204 and SB206 development program timeline in Japan is continuously reevaluated by Sato and the Company, and may potentially be further

affected by various factors, including: (i) the analyses, assessments and decisions made by the joint development committee and the applicable regulatory authorities, which will influence and establish the combined SB204 and SB206 Japan development program plan; (ii) the remaining timeline and completion of the B-SIMPLE4 Phase 3 trial in the United States, which has been and may be further impacted by the COVID-19 pandemic; (iii) the API and drug product supply chain progression, including the Company's build-out of further in-house drug manufacturing capabilities; (iv) the Company's manufacturing technology transfer projects with third-party CMOs; and (v) a drug delivery device technology enhancement project with a technology manufacturing vendor.

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

In future periods, the Company 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—Amended 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 that 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 Amended 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 Amended Sato Agreement

The net amount of existing performance obligations under long-term contracts unsatisfied as of September 30, 2021 was $9,404. The Company expects to recognize approximately 19% 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.

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 was awarded additional funding of $126 in March 2021 and may be eligible to receive additional funding as part of the NIH Phase 2 Grant, all of which was or will be subject to availability of NIH funds and satisfactory progress of the project. Revenue recognized under the NIH Phase 1 Grant and NIH Phase 2 Grant was $57 and $119 during the three and nine months ended September 30, 2021, respectively. Revenue recognized under the NIH Phase 1 Grant and NIH Phase 2 Grant was $104 and $133 during the three and nine months ended September 30, 2020, respectively.

In September 2019, the Company received a grant from the United States Department of Defense’s Congressionally Directed Medical Research Programs of approximately $1,113 as part of its Peer Reviewed Cancer Research Program. The grant supports 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 supports 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 $0 and $10 during the three and nine months ended September 30, 2021, respectively. Revenue recognized under this grant was $113 and $494 during the three and nine months ended September 30, 2020, respectively.

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 gel with anti-viral properties being developed as a treatment for molluscum, and advancing programmatically such activities with respect to SB204, a once-daily, topical monotherapy being developed for the treatment of acne vulgaris, and SB414, a topical cream-based product candidate being developed for the treatment of atopic dermatitis.

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 only 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 Accounting Standards Codification (“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 at the time of entry into the Purchase Agreement.

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 milestone or other payments 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 gel with anti-viral properties being developed as a treatment for molluscum.

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 API for the Company's clinical stage product candidates, as a treatment for molluscum. In addition to the milestone payments, the Company will pay Ligand tiered royalties ranging from 7% to 10% based on annual aggregate net sales of such products in the United States, Mexico or Canada.

The Company determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. 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 condensed 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 United States. The ratable Ligand funding is presented within the accompanying condensed consolidated statements of operations and comprehensive loss within research and development expenses associated with the SB206 program.

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.

During the three months ended June 30, 2020, the Company completed a reassessment of the estimated total cost to progress the SB206 program to a potential United States regulatory approval, including consideration of how such estimated costs may potentially be affected by various regulatory, clinical development, and drug manufacturing and supply factors. During this reassessment, the Company concluded that the incremental costs associated with the conduct of the B-SIMPLE4 Phase 3 trial would be excluded from the total cost basis used to amortize the liability because they were not contemplated within the Funding Agreement. The reassessment also concluded that the other projected costs to progress SB206 to a planned regulatory approval in the United States, most of which are regulatory costs associated with the NDA submission process, did not materially change and did not have a material effect on the amortization of the liability.

During the three months ended June 30, 2021, after the announcement of the B-SIMPLE4 positive top-line results on June 11, 2021, the Company reassessed and identified additional estimated costs necessary to progress the SB206 program to a potential United States regulatory approval. As such, the estimated regulatory costs subject to the Ligand funding has increased from prior periods. Therefore, the Company noted that for the three and six months period ended June 30, 2021, the Company reflected this change in estimate and recorded accretion of the liability associated with the Ligand Funding Agreement. The Company will continue to monitor and adjust its estimated regulatory cost, through approval, as needed.

For the three and nine months ended September 30, 2021, related to the SB206 developmental program, the Company recorded in research and development expense $117 and $93, respectively, related to the amortization and accretion, respectively, of the Ligand Funding Agreement amount. For the three and nine months ended September 30, 2020, the Company recorded $284 and $2,166, respectively, as contra-research and development expense related to the SB206 developmental program, related to amortization of the Ligand Funding Agreement amount.

Note 7: Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2021	December 31, 2020
Computer equipment	$ 58	$ 67
Furniture and fixtures	23	34
Laboratory equipment	4,091	2,930
Office equipment	183	72
Leasehold improvements	7,314	562
Property and equipment, gross	11,669	3,665
Less: Accumulated depreciation and amortization	(1,480)	(1,259)
Total property and equipment, net	$ 10,189	$ 2,406

Depreciation and amortization expense was $104 and $242 for the three and nine months ended September 30, 2021, respectively, and $120 and $1,107 for the three and nine months ended September 30, 2020, respectively.

During the second quarter of 2020, the Company met the relevant criteria for reporting certain property and equipment as held for sale on June 29, 2020, and as a result, the Company stopped recording depreciation expense on that date, assessed the property and equipment assets for impairment pursuant to FASB Topic 360, *Property, Plant, and Equipment*, and reclassified the remaining carrying value of the assets held for sale as current assets in its condensed consolidated balance sheets as of June 30, 2020. Certain events and transactions occurred during the third quarter of 2020 that resulted in the disposition of assets and liabilities within the Company's various disposal and asset groups, including the disposition of all assets and liabilities within the Company's facility asset group on July 16, 2020 in conjunction with the lease termination transaction described in Note 8—Commitments and Contingencies.

As of December 31, 2020, the Company had $114 of disposal group carrying value remaining, which was classified as assets held for sale in the accompanying condensed consolidated balance sheets. This disposal group and related assets consisted of certain manufacturing and laboratory equipment associated with the Company's previous large scale drug manufacturing capability, which was being sold over time through a consignment seller. During the second quarter of 2021, the Company assessed the disposal group for recoverability and determined that the remaining carrying value of the disposal group had no fair value. As a result of this assessment, the Company recorded an impairment charge of $114 during the three months ended June 30, 2021.

As of September 30, 2021 and December 31, 2020, the Company had goods and services associated with the planning, design and build-out of its new facility of $1,789 and $17, respectively, included in accounts payable and $2,103 and $365, respectively, included in other accrued expenses in other current liabilities in the accompanying condensed consolidated financial statements.

Note 8: Commitments and Contingencies

Lease Obligations

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

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

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

Hopson Road 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 "Hopson Road Facility Lease").

On July 16, 2020, the Company entered into a Lease Termination Agreement (the "Termination Agreement") with Durham Hopson, LLC (as successor-in-interest to Durham Hopson Road, LLC) (the "Landlord"), which provided for the early termination of the Hopson Road Facility Lease, subject to certain conditions. Pursuant to the terms of the Termination Agreement, the Hopson Road Facility Lease was terminated in connection with the Landlord entering into a lease with an unrelated third party (the "New Tenant") for the premises in the building covered by the Hopson Road Facility Lease (the "New Tenant Lease"), which commenced on July 16, 2020.

In connection with the termination of the Hopson Road Facility Lease pursuant to the Termination Agreement, the Company entered into a sublease agreement, which was effective upon the termination of the Hopson Road Facility Lease and the commencement of the New Tenant Lease, through which the Company began to sublease from the New Tenant approximately 12,000 square feet (reduced to approximately 10,000 square feet after August 31, 2020) in the building that was covered by the Hopson Road Facility Lease (the "Sublease"). The New Tenant and the Landlord entering into the New Tenant Lease was a condition precedent to the effectiveness of the termination of the Hopson Road Facility Lease pursuant to the Termination Agreement, and, in connection with the termination of the Hopson Road Facility Lease, the Landlord consented to the Sublease. The Company decommissioned and physically exited the premises covered by the Sublease during the three months ended March 31, 2021, and the Sublease's material terms expired on March 31, 2021.

Triangle Business Center Facility Lease

On January 18, 2021, the Company entered into a Lease, dated as of January 18, 2021, as amended as of March 18, 2021 (the "TBC Lease"), by and between the Company and Copper II 2020, LLC (the "TBC Landlord"), pursuant to which the Company is leasing 15,623 rentable square feet located at a new location (the "Premises"). The Premises will serve as the Company's new corporate headquarters. The Company is building out the Premises to support various cGMP activities, including research and development and small-scale manufacturing capabilities. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a primary, or secondary backup, component of a potential future commercial supply chain.

The TBC Lease commenced on January 18, 2021 (the "Lease Commencement Date"). Rent under the TBC Lease commences on the earlier of (i) the date the Company occupies a certain portion of the Premises, as specified in the TBC Lease, for the purposes of conducting business therein, or (ii) nine months after the Lease Commencement Date, provided that the date for purposes of (ii) is subject to extension for any delay in the TBC Landlord's delivery of the Premises to the Company in accordance with certain specifications set forth in the TBC Lease (the "Rent Commencement Date"). The term of the TBC Lease expires on the last day of the one hundred twenty-third calendar month after the Rent Commencement Date (and if the Rent Commencement Date does not occur on the first day of a calendar month, the period from the Rent Commencement Date to the first day of the next calendar month shall be included in the first such month for purposes of determining the duration of the term of the TBC Lease). The TBC Lease provides the Company with one option to extend the term of the TBC Lease for a period of five years, which would commence upon the expiration of the original term of the TBC Lease, with base rent of a market rate determined according to the TBC Lease; however, the renewal period was not included in the calculation of the lease obligation as the Company determined it was not reasonably certain to exercise the renewal option.

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

The TBC Landlord has agreed to provide the Company with a tenant improvement allowance in an amount not to exceed $130 per rentable square foot, totaling approximately $2,031. The tenant improvement allowance will be paid over four equal installments corresponding with work performed by the Company. Pursuant to the terms of the TBC Lease, the Company

delivered to the TBC Landlord a letter of credit in the amount of $472 as collateral for the full performance by the Company of all of its obligations under the TBC Lease and for all losses and damages the TBC Landlord may suffer as a result of any default by the Company under the TBC Lease. Cash funds maintained in a separate deposit account at the Company's financial institution to fully secure the letter of credit are presented as restricted cash in non-current assets on the accompanying condensed consolidated balance sheets.

Rent expense, including both short-term and variable lease components associated with the Hopson Road Facility Lease and the TBC Lease, as applicable, was $100 and $356 for the three and nine months ended September 30, 2021, respectively, and $53 and $448 for the three and nine months ended September 30, 2020, respectively.

The weighted average remaining lease term for the TBC Lease and weighted average discount rate for the TBC Lease are 10.42 years and 8.35%, respectively, as of September 30, 2021.

Future net minimum lease payments as of September 30, 2021 were as follows:

Maturity of Lease Liabilities	**Operating Lease**
2021	$ (508)
2022	(69)
2023	493
2024	508
2025	523
2026 and beyond	3,542
Total future undiscounted lease payments	$ 4,489
Add: reclassification of discounted net cash inflows to other current assets	$ 419
Less: imputed interest	$ (1,935)
Total reported lease liability	$ 2,973

The table above reflects payments for an operating lease with a remaining term of one year or more, but does not include obligations for short-term leases. In addition, the net cash inflow related to the 2021 and 2022 fiscal year presented above relates to the expected timing of the tenant improvement allowance of $2,031 being funded by the TBC Landlord, which the Company reasonably expects to receive within the next twelve months, partially offset by expected lease payments for the corresponding period.

Components of lease assets and liabilities as of September 30, 2021 were as follows:

	As of September 30, 2021
Leases	
Assets	
Other current asset related to leasing arrangement, net	$ 419
Right-of-use lease assets	1,343
Total assets	$ 1,762
Liabilities	
Noncurrent operating lease liabilities	$ 2,973
Total lease liabilities	$ 2,973

During the three month period ended September 30, 2021, the Company received $1,015 related to payments as part of the total TBC Landlord funded tenant improvement allowance. The effective discounted value of the remaining tenant improvement allowance payments, of the total tenant improvement allowance of $2,031 being funded by the TBC Landlord, partially offset by the expected lease payments by the Company within the next twelve months results in a net balance of $419. This net amount is presented within the condensed consolidated balance sheets as other current asset related to leasing arrangement, net as of September 30, 2021. Furthermore, this amount is also included in long-term lease liabilities within the condensed consolidated balance sheets as of September 30, 2021.

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, in addition to potential third-party manufacturers for the manufacture of our product candidates. 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 September 30, 2021.

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 10—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.

Development Services Agreement

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

Legal Proceedings

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

Compensatory Obligations

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.

See Note 11—Stock-Based Compensation regarding stock options and stock appreciation rights.

See Note 12—Tangible Stockholder Return Plan regarding the Tangible Stockholder Return Plan adopted in August 2018, as amended and restated on May 25, 2021.

Note 9: Paycheck Protection Program

On April 22, 2020, the Company entered into a promissory note, which was subsequently amended (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 United States Small Business Administration (the "SBA"). The Loan 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.

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 program-eligible expenses. 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.

The Company previously applied for and during the second quarter of 2021 received notification of forgiveness of the entire loan balance, including any accrued interest. Based upon the Notice of Paycheck Protection Program Forgiveness Payment received by the Company from the SBA, as of June 14, 2021, the forgiveness of the principal balance of $956 is presented within the condensed consolidated statements of operations as a gain on debt extinguishment.

Note 10: Stockholders' Equity (Deficit)

Capital Structure

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

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

June 2021 Public Offering

On June 17, 2021, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell an aggregate of 3,636,364 shares of the Company's common stock at a price to the public of $11.00 per share, less underwriting discounts and commissions. The Company also granted the underwriter a 30-day option (the "Underwriter Option") to purchase up to an additional 545,454 shares of common stock at the public offering price, less underwriting discounts and commissions. The June 2021 Public Offering closed on June 21, 2021, and the Underwriter Option expired unexercised in July 2021.

Net proceeds from the June 2021 Public Offering were approximately $37,236 after deducting underwriting discounts and commissions and offering expenses of approximately $2,764. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

The June 2021 Public Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (No. 333-236583), filed with the Securities and Exchange Commission ("SEC") and declared effective by the SEC on April 10, 2020, including a prospectus contained therein dated as of April 10, 2020, as supplemented by a prospectus supplement, dated June 17, 2021.

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 1,400,000 shares of common stock, pre-funded warrants to purchase 433,333 shares of common stock (the "CMPO Pre-Funded Warrants"), and accompanying common warrants to purchase up to an aggregate of 1,833,333 shares of common stock (the "firm warrants"). The Company also granted H.C. Wainwright, as underwriter, a 30-day option to purchase up to 275,000 additional shares of common stock and/or common warrants to purchase up to an aggregate of 275,000 shares of common stock, which H.C. Wainwright partially exercised on March 2, 2020 to purchase 149,860 shares of common stock and common warrants to purchase 275,000 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 $3.00, and the combined price to the public in this offering for each pre-funded warrant and accompanying common warrant was $2.999. 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 59,496 shares of common stock (the "CMPO UW Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in the March 2020 Public Offering. 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.

During the first quarter of 2020, all of the CMPO Pre-Funded Warrants were exercised in full, such that there were no more of the CMPO Pre-Funded Warrants outstanding as of March 31, 2020. The CMPO Pre-Funded Warrants had an exercise price of $0.001 per share.

The CMPO Common Warrants have an exercise price of $3.00 per share and expire five years from the date of issuance. During the nine months ended September 30, 2021, warrant holders exercised 10,000 of the CMPO Common Warrants for total proceeds of approximately $30. From the March 3, 2020 closing date of the March 2020 public offering through September 30, 2021, warrant holders exercised a total of 1,855,917 of the CMPO Common Warrants for total proceeds of approximately $5,568. There were 252,417 of the CMPO Common Warrants outstanding as of September 30, 2021.

The CMPO UW Warrants have an exercise price of $3.75 per share and expire five years from the date of issuance. During the nine months ended September 30, 2021, warrant holders exercised 48,192 of the CMPO UW Warrants for total proceeds of approximately $181. None of the CMPO UW Warrants were exercised during 2020. There were 11,304 of the CMPO UW Warrants outstanding as of September 30, 2021.

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 assessed the CMPO Common Warrants and the CMPO UW Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy. During this assessment, the Company determined (i) the CMPO Common Warrants and the CMPO UW Warrants did not constitute a liability under ASC 480; (ii) the CMPO Common Warrants and the CMPO UW Warrants met the definition of a derivative under ASC 815; (iii) the warrant holder's option to

receive a net cash settlement payment under the 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 met all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the CMPO Common Warrants and the CMPO UW Warrants are freestanding equity-linked derivative instruments that met the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, the CMPO Common Warrants and the CMPO UW Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

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

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

March 2020 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 1,055,000 shares of the Company's common stock and pre-funded warrants to purchase 805,465 shares of common stock (the "RDO Pre-Funded Warrants"). The purchase price for each share of common stock was $4.30, and the price for each pre-funded warrant was $4.299. 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 55,814 shares of common stock (the "RDO PA Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying 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.

During the first nine months of 2020, warrant holders exercised all of the 805,465 of the RDO Pre-Funded Warrants, and none of the RDO Pre-Funded Warrants were outstanding as of September 30, 2021. The RDO Pre-Funded Warrants had an exercise price of $0.001 per share.

The RDO PA Warrants have an exercise price of $5.375 per share and expire five years from the date of issuance. None of the RDO PA Warrants were exercised during the year ended December 31, 2020. During the nine months ended September 30, 2021, warrant holders exercised 45,209 of the RDO PA Warrants for total proceeds of approximately $243, and there were 10,605 of the RDO PA Warrants outstanding as of September 30, 2021.

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. 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 met the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, the RDO PA Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

Pre-funded warrants. The RDO Pre-Funded Warrants contained substantially similar terms as the CMPO Pre-Funded Warrants, including fundamental transaction settlement provisions that did not provide the warrant holders with the option to settle any unexercised warrants for cash in the event of any fundamental transactions; rather, in all fundamental transaction scenarios, the warrant holder was only entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that 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. 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 were freestanding equity-linked financial instruments that met the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the RDO Pre-Funded Warrants were classified as equity and were 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 then-effective shelf registration statement (the "January 2018 Offering"), pursuant to which it sold an aggregate of 1,000,000 shares of common stock and warrants to purchase up to 1,000,000 shares of the Company's common stock at a public offering price of $38.00 per share of common stock and accompanying warrant. The warrant exercise price is $46.60 per share and will expire four years from the date of issuance. Based on the results of the Company's assessment of the warrants for appropriate equity or liability classification, the Company determined that the warrants issued in connection with the January 2018 Offering are freestanding equity-linked derivative instruments that met the criteria for the own-equity scope exception to derivative accounting under ASC 815. Accordingly, such warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

During the nine months ended September 30, 2021, warrant holders exercised 150 of the warrants issued in the January 2018 Offering. There were no exercises of warrants issued in the January 2018 Offering during the nine months ended September 30, 2020.

The following table presents outstanding warrants to purchase the Company's common stock for the periods indicated.

	September 30, 2021	December 31, 2020	Exercise Price Per Share
Warrants to purchase common stock issued in the January 2018 Offering	999,850	1,000,000	$ 46.60
Warrants to purchase common stock issued in the March 2020 Public Offering	252,417	262,417	3.00
Underwriter warrants to purchase common stock associated with the March 2020 Public Offering	11,304	59,496	3.75
Placement agent warrants to purchase common stock issued in the March 2020 Registered Direct Offering	10,605	55,814	5.375
	1,274,176	1,377,727	

The weighted average exercise price per share for warrants outstanding as of September 30, 2021 and December 31, 2020 was $37.24 and $34.77, respectively.

July 2020 Aspire Common Stock Purchase Agreement

On July 21, 2020, the Company entered into the July 2020 Aspire CSPA, 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 $30,000 of shares of the Company's common stock at the Company's request from time to time during the 30-month term of the July 2020 Aspire CSPA. Upon execution of the July 2020 Aspire CSPA, the Company agreed to sell to Aspire Capital 555,555 shares of its common stock at $9.00 per share for proceeds of $5,000. In consideration for entering into the July 2020 Aspire CSPA, upon satisfaction of certain conditions under the July 2020 Aspire CSPA, the Company issued to Aspire Capital 100,000 shares of the Company's common stock (the "July 2020 Commitment Shares"). The July 2020 Commitment Shares, valued at approximately $847, were recorded in July 2020 as non-cash costs of equity financing and included within general and administrative expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. The July 2020 Aspire CSPA replaced the June 2020 Aspire CSPA, which was terminated under the terms of the July 2020 Aspire CSPA.

Concurrently with entering into the July 2020 Aspire CSPA, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file with the SEC one or more registration statements, as necessary, and to the extent permissible and subject to certain exceptions, to register under the Securities Act of 1933, as amended, the sale of the shares of the Company's common stock that may be issued to Aspire Capital under the July 2020 Aspire CSPA. On July 23, 2020, the Company filed with the SEC a prospectus supplement to the Company's effective shelf Registration Statement on Form S-3 (File No. 333-236583) registering all of the shares of common stock that may be offered to Aspire Capital from time to time.

Under the terms of the July 2020 Aspire CSPA, 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 "July 2020 Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 30,000 shares of the Company's common stock per business day, up to an aggregate of $30,000 (including the initial purchase shares) of the Company's common stock in the aggregate at a per share price (the "July 2020 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, unless otherwise mutually agreed. The parties may mutually agree to increase the number of shares of the Company's common stock that may be purchased per trading day pursuant to the terms of the July 2020 Aspire CSPA to up to 200,000 shares.

In addition, on any date on which the Company submits a July 2020 Purchase Notice to Aspire Capital in an amount equal to 30,000 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 "July 2020 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 "July 2020 VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such July 2020 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 July 2020 VWAP Purchase Date.

The July 2020 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 July 2020 Purchase Price. The Company may deliver multiple July 2020 Purchase Notices and July 2020 VWAP Purchase Notices to Aspire Capital from time to time during the term of the July 2020 Aspire CSPA, so long as the most recent purchase has been completed.

The July 2020 Aspire CSPA provides that the Company and Aspire Capital shall not effect any sales under the July 2020 Aspire CSPA on any purchase date where the closing sale price of the Company's common stock is less than $0.15. There are no trading volume requirements or restrictions under the July 2020 Aspire CSPA, 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 July 2020 Aspire CSPA. 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 July 2020 Aspire CSPA. The July 2020 Aspire CSPA 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 July 2020 Aspire CSPA. Any proceeds the Company receives under the July 2020 Aspire CSPA are expected to be used for working capital and general corporate purposes.

The July 2020 Aspire CSPA provides that the number of shares that may be sold pursuant to the July 2020 Aspire CSPA will be limited to 2,543,364 shares (the "July 2020 Exchange Cap"), which represents 19.99% of the Company's outstanding shares of common stock on July 21, 2020, unless stockholder approval or an exception pursuant to the rules of the Company's principal market, currently the Nasdaq Capital Market, is obtained to issue more than 19.99%. This limitation will not apply if, at any time the July 2020 Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the July 2020 Aspire CSPA is equal to or greater than $5.907, which is the arithmetic average of the five closing sale prices of the Company's common stock immediately preceding the execution of the July 2020 Aspire CSPA. The Company is not required or permitted to issue any shares of common stock under the July 2020 Aspire CSPA if such issuance would breach its obligations under the rules or regulations of the Nasdaq Capital 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 Capital Market.

During the nine months ended September 30, 2021, the Company sold 493,163 shares of its common stock at an average price of $12.84 for total proceeds of $6,334. From the inception of the July 2020 Aspire CSPA, as of September 30, 2021, the Company has sold 2,221,040 shares of its common stock at an average price of $8.10 per share, including 555,555 shares of its common stock at $9.00 which the Company agreed to sell to Aspire Capital upon execution of the July 2020 Aspire CSPA, for total proceeds of $17,995. As of September 30, 2021, the Company had $12,005 in remaining availability for sales of its common stock under the July 2020 Aspire CSPA.

In addition to the limitations noted above, pursuant to the underwriting agreement relating to the June 2021 Public Offering, the Company is prohibited from issuing securities, including under the July 2020 Aspire CSPA, for a period until the 60th day after the date of the underwriting agreement (other than under certain circumstances set forth in the underwriting agreement).

Common Stock

The Company's common stock has a par value of $0.0001 per share and consists of 200,000,000 authorized shares as of September 30, 2021 and December 31, 2020. There were 18,815,142 and 14,570,009 shares of voting common stock outstanding as of September 30, 2021 and December 31, 2020, respectively.

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

	September 30, 2021	December 31, 2020
Outstanding warrants to purchase common stock	1,274,176	1,377,727
Outstanding stock options (Note 11)	393,308	199,199
Outstanding stock appreciation rights (Note 11)	60,000	61,000
For possible future issuance under the 2016 Stock Plan (Note 11)	1,339,219	52,378
	3,066,703	1,690,304

Preferred Stock

The Company's restated certificate of incorporation provides the Company's board of directors with the authority to issue $0.0001 par value preferred stock from time to time in one or more series by adopting a resolution and filing a certificate of designations. Voting powers, designations, preferences, dividend rights, conversion rights and liquidation preferences shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and no shares outstanding as of September 30, 2021 and December 31, 2020.

Note 11: Stock-Based Compensation

2016 Stock Plan

During the nine months ended September 30, 2021, 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, to increase the number of shares reserved under the 2016 Plan by 100,000 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.

At the Company's Annual Meeting of Stockholders held on May 4, 2021, the Company's stockholders approved an amendment to the 2016 Plan ("the 2016 Plan Amendment"), to increase the aggregate number of shares of the Company's common stock authorized for issuance thereunder by 1,500,000 shares. This amendment was approved by the Company's board of directors on March 10, 2021.

The approval by the Company's stockholders of the 2016 Plan Amendment was contingent upon the occurrence of certain other events, including that the 2016 Plan Amendment would become effective at the effective time of a certificate of amendment to the Company's certificate of incorporation filed with the Secretary of State of the State of Delaware in relation to a potential reverse stock split pursuant to the authority previously granted to the Company's board of directors by the Company's stockholders at the 2020 Annual Meeting. The Certificate of Amendment filed in connection with the Reverse Stock Split became effective at 5:00pm on May 25, 2021, and thus, the 2016 Plan Amendment became effective on May 25, 2021.

Stock Appreciation Rights

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, 60,000 stock appreciation rights ("SARs") were granted to Ms. Stafford with an exercise price of $8.20 per share (the fair market value of the Company's common stock on the grant date) and with a ten year term (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 SARs were no longer considered granted on a contingent basis and were classified as equity-based awards. The Stafford SAR Award vests quarterly and will vest in full on December 31, 2021, subject to Ms. Stafford's continuous service as an employee or consultant of the Company through the vesting period.

On August 18, 2020, the Company granted 1,000 SARs to a consultant of the Company with an exercise price of $5.31 per share (the fair market value of the Company's common stock on the grant date) with a ten year term.

As of September 30, 2021, there were a total of 60,000 SARs outstanding, 52,500 of which were exercisable.

Stock Compensation Expense

During the three and nine months ended September 30, 2021, the Company recorded stock-based compensation expense, including fair value adjustments of the Tangible Stockholder Return Plan, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	$ 298	$ 116	$ 491	$ 745
Stock appreciation rights	29	31	87	122
Tangible Stockholder Return Plan (Note 12)	(150)	(6)	(662)	(35)
Total	$ 177	$ 141	$ (84)	$ 832

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ (13)	$ 74	$ (325)	$ 585
General and administrative	190	67	241	247
Total	$ 177	$ 141	$ (84)	$ 832

Stock option activity for the nine months ended September 30, 2021 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, 2020	199,199	$ 30.71		
Options granted	255,285	9.92		
Options forfeited	(49,084)	28.16		
Options exercised	(12,092)	4.74		
Options outstanding as of September 30, 2021	393,308	$ 18.33	8.59	$ 106

As of September 30, 2021, there were a total of 393,308 stock options outstanding and there were 1,339,219 shares available for future issuance under the 2016 Plan.

Note 12: 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 was adjusted on May 25, 2021 as a result of the 1-for-10 Reverse Stock Split, which correspondingly adjusted the two share price goals.

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. As adjusted for the Reverse Stock Split, the share price target for the first tranche and related bonus pool are $111.70 per share and $25,000, respectively. As adjusted for the Reverse Stock Split, the share price target for the second tranche and related bonus pool are $254.50 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 accompanying 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 accompanying 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 stock-based compensation expense within operating expenses in the accompanying condensed consolidated statements of operations and comprehensive loss, 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, adjusted for certain market considerations and other factors. The fair value of the underlying common stock is the published closing market price on the Company's principal market, which is currently the Nasdaq Capital Market, as of each reporting date, as adjusted for significant results, as necessary (if applicable). The risk-free interest rate is based on the United States 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.

See Note 11—Stock-Based Compensation regarding compensatory expense and fair value adjustments related to the Performance Plan.

Note 13: Related Party Transactions

Members of the Company's board of directors held 100,497 and 110,474 shares of the Company's common stock as of September 30, 2021 and December 31, 2020, respectively.

Health Decisions

On October 25, 2018, the Company announced a foundational collaboration with Health Decisions, Inc. ("Health Decisions"). Health Decisions, which was acquired by Premier Research in July of 2021, is a full-service contract research organization specializing in clinical studies of therapeutics for women's health indications. The Company's Chairman, President and Chief Executive Officer, Paula Brown Stafford, was a stockholder and previously served on the board of directors of Health Decisions.

Reedy Creek

Reedy Creek beneficially owned greater than 5% of the Company's outstanding common stock and held approximately 395,000 warrants, all of which were acquired during the January 2018 Offering, and, accordingly, was a related party of the Company at the time the Company entered into the Purchase Agreement with Reedy Creek, described in Note 6—Research and Development Arrangements. The Purchase Agreement with Reedy Creek was evaluated and approved pursuant to the Company's existing related party transactions policy. Based solely on information reported in a Schedule 13D/A filed with the SEC on June 24, 2021, Reedy Creek is no longer a greater than 5% stockholder of the Company.

2020 Registered Direct Offering

Sabby Volatility Warrant Master Fund, Ltd. ("Sabby"), while a greater than 5% stockholder of the Company, purchased 620,000 shares of common stock and pre-funded warrants to purchase up to 260,233 shares of common stock for approximately $3,800 in the March 2020 Registered Direct Offering described in Note 10—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. Based solely on information reported in a Schedule 13G/A filed with the SEC on January 5, 2021, Sabby no longer held any of the Company's common stock or pre-funded warrants to purchase shares of the Company's common stock.

Joseph Moglia, while a greater than 5% stockholder of the Company, purchased 100,000 shares of common stock for $430 in the March 2020 Registered Direct Offering described in Note 10—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. Based solely on information reported in a Schedule 13D/A filed with the SEC on January 27, 2021, Mr. Moglia is no longer a greater than 5% stockholder of the Company.

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, 2020 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 24, 2021 (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 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 have incurred net losses since our incorporation and anticipate that we will continue to incur net losses for the foreseeable future. We will need significant additional funding to continue our operating activities and for the advancement of our product development programs, including potential commercialization efforts, beyond what is currently included in our operating forecast and related cash projection. As of September 30, 2021, we had an accumulated deficit of $270.7 million. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs, or our commercialization efforts.*
- *Raising additional capital, including through the issuance of shares of our common stock to Aspire Capital Fund, LLC, or Aspire Capital, pursuant to the common stock purchase agreement that we entered into with Aspire Capital on July 21, 2020, or the July 2020 Aspire CSPA, may reduce the trading price of our common stock. Our equity issuances during the year ended December 31, 2020 and the nine months ended September 30, 2021, have resulted in significant dilution to our existing stockholders. Any future additional issuances of equity, or debt convertible into equity, may result in significant dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.*
- *The price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for our existing stockholders.*
- *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.*
- *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. Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for any of our product candidates, or regulatory approval of our product candidates. Ongoing or future product development activities may not be successful, including in that our preclinical studies may not prove successful in demonstrating proof-of concept or may show adverse toxicological findings, and our clinical trials may not show the requisite safety and efficacy of our product candidates. The regulatory approval processes of the Food and Drug Administration, or FDA, are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis or at all, our business will be substantially harmed.*

- *Delays or disruptions in the qualification of manufacturing facilities and processes or in the manufacture of our (i) active pharmaceutical ingredients, or APIs, including NVN1000 or any other NITRICIL™ new chemical entities, or NCEs, or (ii) clinical trial materials or commercial supplies of any approved product candidates, whether by us or any third-party manufacturer with whom we contract, including any delays in the upfit of our new facility under the TBC Lease (as defined below) or in the transfer of technology to third-party manufacturers, could adversely affect our development and commercialization timelines and result in increased costs of our development programs or in our breaching our obligations to others.*
- *We currently rely on third-party suppliers to provide the raw materials and equipment that are used by us or our third-party manufacturers in the manufacture of our product candidates. There are a limited number of suppliers for raw materials, including nitric oxide, and the equipment used to manufacture our product candidates. Any delay or disruption, especially in light of current global supply chain constraints, could adversely impact the timing or cost of our manufacturing activities or other associated development activities.*
- *We currently rely on third-party logistics vendors to transport our raw materials, API, and drug products through our supply chain. Certain materials, including our API, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, which could adversely impact the timing or cost of our manufacturing activities or other associated development activities.*
- *We currently rely on third-party suppliers and the usage of third-party vendors to supply goods, materials and equipment in connection with our business, including in connection with the build-out of our new facility that we began to occupy earlier in 2021. We expect to complete the build-out of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product, by the end of 2021. We continue to assess global supply chain constraints, including any further impact of the COVID-19 pandemic, on our related suppliers and vendors. Any further delay or disruption could adversely impact the timing for completing the build-out of our new facility, which would cause us to rely solely on other third parties for any small-scale manufacturing or other research and development and cGMP activities.*
- *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.*
- *We rely on third parties to conduct some of our preclinical studies, clinical trials, stability and analytical testing, and regulatory activities. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or are adversely impacted by the COVID-19 pandemic, we may be unable to obtain regulatory approval for or commercialize any of our product candidates as planned or at all.*
- *Delay or termination of planned clinical trials for our product candidates, including as a result of disruptions caused by the COVID-19 pandemic, would result in unplanned expenses and adversely impact our remaining developmental activities and potential commercial prospects with respect to, and ability to generate potential revenues from, such product candidates.*
- *If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities would be delayed or otherwise adversely affected.*
- *We may expend our limited resources to pursue one or more product candidates or indications within our product development strategy, which may change over time, and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*
- *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.*
- *Changes to our leadership team or operational resources could prove disruptive to our operations and have adverse consequences for our business and operating results.*

- *If we are unable to obtain and maintain patent protection for our product candidates, 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.*
- *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, 2020 financial statements included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern.*
- *We may not be able to achieve the objectives described in the sections entitled "Priority Development Pipeline," "Pipeline Expansion Opportunities," "Manufacturing and Supplies," "Business Updates" and "Corporate Updates" below.*

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

Novan® is a registered trademark of our company in the United States. This Quarterly Report on Form 10-Q also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q 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 pre-commercial nitric oxide-based pharmaceutical company focused on dermatology and anti-infective therapies. Our vision is to create the world's leader in nitric oxide-based science, technology, and clinical translation in support of delivering safe and efficacious therapies using our proprietary nitric oxide-based technology platform, NITRICIL™ to generate macromolecular NCEs.

Our proprietary technology platform leverages nitric oxide's naturally occurring anti-viral, anti-bacterial, anti-fungal and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated product candidates.

The two key components of our nitric oxide platform are our proprietary Nitricil technology, which drives the creation of NCEs, and our formulation science, both of which we use to tune our product candidates for specific indications. Our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of diseases.

We have advanced strategic development programs in the field of dermatology, while also further expanding the platform into infectious diseases, men's and women's health, and various other medical conditions with significant unmet needs. This decision was based on the connection between the multi-factorial pathologies of diseases in these areas and the demonstrable anti-microbial, anti-viral and anti-inflammatory properties of Novan's nitric oxide technology.

We have clinical-stage dermatology and anti-infective drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208) and anti-inflammatory (SB414) mechanisms of action. We have also introduced a possible anti-viral product candidate for treatment of external genital warts (SB207). We have or are currently conducting preclinical work on NCEs, including berdazimer sodium, and formulations for the potential treatment of (i) SARS-CoV-2, the virus that causes COVID-19 (SB019); (ii) antimicrobial indications for the adjacent companion animal health market (NVN4100); (iii) cervical intraepithelial neoplasia caused by high-risk human papilloma virus in the men's and women's health field (WH504 and WH602); and (iv) inflammatory disorders.

We are currently focusing our efforts and resources on our priority development pipeline candidates, which include (i) progressing our lead program, SB206, as a treatment for molluscum contagiosum, or molluscum, including preparing for and seeking U.S. regulatory approval, and implementing prelaunch strategy and U.S. commercial preparation; (ii) advancing our late-stage product candidate, SB204, for the treatment of acne vulgaris, or acne, within the U.S., as our second lead program toward a registrational Phase 3 study, based on two prior Phase 3 trials; and (iii) progressing our SB019 development program into a Phase 1 trial for a potential intranasal prophylaxis or therapeutic for mild-to-moderate COVID-19 infection.

Business Updates

During 2021, our primary programmatic focus has been on our molluscum product candidate, SB206, and we intend to continue to focus our near term development efforts on this program. Following the positive top-line results from the B-SIMPLE4 trial announced on June 11, 2021 and the comprehensive B-SIMPLE4 safety data announced on September 23, 2021, we are targeting a potential NDA submission of SB206 for molluscum during the third quarter of 2022.

Thus, we are preparing for regulatory submission and potential approval of SB206 as a treatment for molluscum. The timing of the targeted NDA submission is dependent upon: (i) completion of the B-SIMPLE 4 clinical study report; (ii) completion of our new manufacturing facility to have the infrastructure and capability necessary to produce cGMP API registration batches; (iii) continued technical transfer activities to our drug product contract manufacturing organization, or CMO, and preparing the necessary registration batches of drug product; (iv) preparatory activities and data accumulation related to the NDA submission including conducting customary drug substance and drug product stability protocols; and (v) regulatory and quality documentation compilation related to our preclinical, clinical and chemistry, manufacturing and control, or CMC, data related to the B-SIMPLE trials, and our drug manufacturing and related processes.

We have also selected Syneos Health, a fully integrated biopharmaceutical solutions organization, as our commercial solutions provider for SB206 as a treatment for molluscum. Our relationship with Syneos Health will focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by commercial sales of SB206, if approved by the FDA.

In September 2021, we also announced our updated strategic priorities and outlined potential key milestones. In addition to the regulatory progression of SB206, including implementing prelaunch strategy and commercial preparation, we also announced our intention to progress (a) SB204, a topical monotherapy for the treatment of acne, by (i) preparing for a pivotal Phase 3 study during 2022; (ii) targeting the conduct of a potential pivotal Phase 3 trial in 2023; and (iii) targeting a potential NDA submission of SB204 for acne in 2024; and (b) SB019, as a potential intranasal treatment option for COVID-19, by (i) initiating a Phase 1 study in healthy volunteers targeted for the first half of 2022; (ii) targeting the conduct of a potential Phase 2/3 study(s) in 2023; and (iii) targeting a potential NDA submission of SB019 for COVID-19 in 2024. The progression of the SB019 program, subsequent to the execution of a Phase 1 study, and the progression of the SB204 program, including the execution of the potentially registrational SB204 Phase 3 trial, is subject to obtaining additional financing or strategic partnering.

Further advancement of our molluscum program beyond the potential NDA submission of SB206, or advancement of any other early-stage or late-stage clinical program across our platform, has been and may be further impacted by the COVID-19 pandemic and is subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) equity or debt financings, including through sales under the July 2020 Aspire CSPA; or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Our equity issuances during the year ended December 31, 2020, and the nine months ended September 30, 2021, have resulted in significant dilution to our existing stockholders. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

Working Capital and Additional Capital Needs

As of September 30, 2021, we had a total cash and cash equivalents balance of $60.0 million and positive working capital of $48.8 million. As of September 30, 2021, we had $12.0 million in remaining availability for sales of our common stock under the July 2020 Aspire CSPA.

We believe that our existing cash and cash equivalents balance as of September 30, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our planned operating needs into the fourth quarter of 2022. This operating forecast and related cash projection includes: (i) costs through the completion of the B-SIMPLE4 Phase 3 trial, including final data accumulation and reporting in addition to other supporting activities; (ii) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum; (iii) costs associated with the completion of the build-out of our new corporate headquarters and manufacturing capability necessary to support small-scale drug substance and drug product manufacturing; (iv) conducting drug manufacturing capability transfer activities to external third-party CMOs, including a drug delivery device technology enhancement project; (v) developmental and regulatory activities for our SB019 program (Coronaviridae (COVID-19)), including a Phase 1 study, targeted for initiation in 2022; (vi) preparatory activities for a potential Phase 3 trial, targeted for initiation in 2023, related to SB204 as a treatment for acne; and (vii) initial efforts to support potential commercialization of SB206, but excludes: (a) any potential costs associated with other late-stage clinical programs, including executing the potentially registrational Phase 3 trial of SB204 for acne; (b) progression of the SB019 program subsequent to execution of a Phase 1 study; (c) operating costs that

could occur between a potential NDA submission for SB206 through NDA approval, specifically including marketing and commercialization efforts to achieve potential launch of SB206; and (d) proceeds from any potential future sales of common stock under the July 2020 Aspire CSPA. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

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

COVID-19 Overview

While certain COVID-19 vaccines have been approved and are now available for use in the United States and certain other countries, we are unable to predict how widely utilized the vaccines will be, whether they will be effective in preventing the spread of COVID-19 (including its variant strains), and when or if normal economic activity and business operations will resume. Vaccine resistance, coupled with the emergence of fast-spreading variants have introduced renewed uncertainty into whether additional measures will be implemented to combat the spread of COVID-19 including in the locations where we do business. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, disrupted clinical trials and created significant volatility in and disruption of financial markets. The full extent of the pandemic, related business and travel restrictions and changes to behavior intended to reduce its spread remain uncertain as the pandemic and the potential impact of variants of the virus that causes COVID-19 continue to evolve globally.

We have continued to closely monitor and rapidly respond to the ongoing impact of the COVID-19 pandemic on our employees, our community and our business operations. We have worked to continue our critical business functions, including continued operation of our development efforts, and we have adopted a series of precautionary measures and will continue to do so as the circumstances warrant, including increased sanitization of our facilities, use of personal protective equipment, as appropriate, and physical distancing practices to help protect our employees’ health and safety as they continue to advance important research related to our product candidates.

The timetable for development of our product candidates has been impacted and may face further disruption and our business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of our B-SIMPLE4 Phase 3 trial. Therefore, we continue to assess any potential further impact of COVID-19 on our operations.

Despite disruptions to our business operations and the business operations of third parties on which we rely, the COVID-19 pandemic has not significantly impacted our operating results and financial condition to date. Although it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic has had or will have on our business, operations and employees, our CMOs, our contract research organizations, or CROs, our partners, our collaborators in clinical research, and our contractors, suppliers and vendors supporting our ongoing facility build-out and cGMP manufacturing capability project, any continued spread of COVID-19 and its variants, measures taken by governments, actions taken to protect employees from the pandemic, and the broad impact of the pandemic on all business activities and financial markets may materially and adversely affect our business, results of operations and financial condition and stock price. Please refer to “Results of Operations” for further discussion of these items. Due to numerous uncertainties surrounding the COVID-19 pandemic, we are unable to predict the nature and extent of the future impacts that the pandemic will have on our financial condition and operating results. These uncertainties include, among other things, the ultimate severity and duration of the pandemic, including the efficacy or availability of a treatment or vaccine for COVID-19 and its variants; governmental, business or other actions that have been, or will be, taken in response to the pandemic, including continued restrictions on travel and mobility, business closures and operating restrictions and imposition of social distancing measures; impacts of the pandemic on the conduct of our previous or potential future clinical trials, including with respect to availability of investigators and clinical trial sites, patients’ ability to complete the necessary visits and clinical trial site operations, and monitoring of clinical trial data; impacts of the pandemic on regulatory authorities; and impacts of the pandemic on the United States and global economies more broadly. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see the “Risk Factors” section in our Annual Report.

Supply Chain

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

We continue to assess any further impact of COVID-19 on our supply chain and related vendors and global supply chain constraints across various industries, including interruption of, or delays in receiving, supplies of raw materials, API or drug product from third-party manufacturers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems. We are also continuing to evaluate the impacts of COVID-19 and global supply chain constraints on our work to build-out our new facility. We expect to complete the construction of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product, by the end of 2021. Once the build-out is completed and occupied, we will proceed with the related preparatory activities associated with qualifying, commissioning and validating the manufacturing equipment for use in API production.

Priority Development Pipeline

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

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

As discussed below, the 12% dose of berdazimer sodium, our drug substance (NVN1000), being used in the development of SB206 for molluscum is comprised of 10.3% berdazimer. We refer to 12% berdazimer sodium, or 10.3% berdazimer, interchangeably.

Based on the results of our initial Phase 3 trials for SB206 (referred to as B-SIMPLE1 and B-SIMPLE2), announced in January 2020, we held a Type C meeting with the FDA on April 1, 2020 seeking feedback on our proposal to conduct one additional, well-controlled pivotal study of SB206 to support a future NDA. Based on feedback, the FDA provided guidance indicating that the FDA would consider one additional pivotal trial, the B-SIMPLE4 Phase 3 trial, that, if successful, could 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 the B-SIMPLE4 Phase 3 trial and expectations for a future NDA submission.

B-SIMPLE4 was designed as a multi-center, randomized, double-blind, vehicle-controlled study to evaluate the efficacy and safety of SB206 12% once daily that exceeded its enrollment target by randomizing 891 total patients (1:1 active:vehicle randomization), ages 6 months and above, with molluscum, across 55 clinical sites. Patients were 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 were visits at Screening/Baseline, Week 2, Week 4, Week 8 and Week 12, and a safety follow-up at Week 24. As part of B-SIMPLE4's study design, we also implemented additional patient and caregiver training and patient engagement efforts and offered decentralized visit capabilities for conducting visits during the COVID-19 pandemic. The primary endpoint for B-SIMPLE4 was the proportion of patients achieving complete clearance of all treatable molluscum lesions at Week 12.

We initiated the B-SIMPLE4 trial in August 2020, the first patient was enrolled and dosed in September 2020, the trial completed patient enrollment during the first quarter of 2021 and the final patient completed their last Week-12 visit in late April 2021. We announced positive top-line efficacy and safety results on June 11, 2021. In the B-SIMPLE4 trial, 32.4% of patients experienced total clearance at Week 12 and 43.5% experienced total clearance or one remaining lesion at Week 12. B-SIMPLE4 achieved statistical significance for the primary endpoint with a p-value less than 0.0001. B-SIMPLE4 also achieved statistical significance for all secondary endpoints. 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 there is less than five percent likelihood that the observed results occurred by chance. We announced the B-SIMPLE4 trial's

last patient visit in late July 2021 and the final safety profile through Week 24 was released in the third quarter of 2021. The comprehensive safety data readout demonstrated a favorable safety profile, consistent with previous studies and met our expectations. Based on these data, we believe that SB206, if approved, can provide a powerful treatment option for children and adults with molluscum. We are targeting submitting a potential NDA submission of SB206 for molluscum during the third quarter of 2022 and are preparing for regulatory submission and potential approval of SB206 as a treatment for molluscum.

Amended Sato Agreement

In 2018, we licensed rights to Sato Pharmaceutical Co., Ltd., or Sato, to develop, use, and sell SB206 in certain topical dosage forms in Japan for the treatment of viral skin infections, and to manufacture the finished form of SB206 for sale in Japan, which are in addition to the rights granted to Sato related to SB204 for the treatment of acne vulgaris. The significant terms and the related accounting considerations of our licensing arrangement with Sato are further described in “Note 4—Licensing Arrangements” to the accompanying condensed consolidated financial statements.

In April 2020, 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. In November of 2020, Sato determined its initial Japanese Phase 1 study for SB206 would require an amended design, including evaluation of potential lower dose strengths, to further refine dose tolerability in a subsequent Phase 1 study. In the fourth quarter of 2020 we concluded that a prospective delay in Sato’s overall SB206 development plan had occurred and we estimated the program timeline to be extended by 1.75 years from our previous estimate, and a corresponding extension of the performance period estimate to 9.25 years, completing in the second quarter of 2026.

In late July 2021, Sato communicated an updated plan regarding its amended design for its additional Japanese Phase 1 study for SB206. The amended study design includes evaluation of potential lower dose strengths, including potential further refinement in a subsequent dose tolerability study. As part of the communication regarding these Phase 1 studies, Sato also communicated an updated comprehensive timeline for the Japanese SB206 program. The updated timeline assumes that the 12% formulation is appropriate to proceed for development in Japan, and is to be reassessed based on the findings of the Phase 1 study.

Based upon (i) the expected timing of the additional Phase 1 study, including a subsequent dose tolerability study; (ii) Sato’s estimated comprehensive developmental schedule for SB206, including additional post-Phase 1 clinical trials; and (iii) current and future Japanese clinical trial material manufacturing and technical transfer considerations, including the manufacturing site for drug product, we concluded that a prospective delay in Sato’s overall SB206 Japanese development plan had occurred in July 2021. We estimate the program timeline to be extended by 0.75 years from our previous estimate, and a corresponding extension of the performance period estimate to 10 years, completing in the first quarter of 2027. We understand that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato’s comprehensive asset developmental program, including SB206. This estimated timeline remains subject to prospective reassessment and adjustment based upon Sato’s interaction with the Japanese regulatory authorities and other developmental and timing considerations. The details of this development are further described in “Note 5—Revenue Recognition” to the accompanying condensed consolidated financial statements.

SB204, for the Treatment of Acne Vulgaris

SB204 is a product candidate designed as a once-daily, topical monotherapy for the treatment of acne vulgaris, a multi-factorial disease with multiple aspects of the disease pathology (anti-inflammatory and anti-bacterial). Acne vulgaris is the most common skin condition in the United States. The disease ranges in severity from mild to severe cystic acne and causes both physical and psychological effects, including permanent scarring, anxiety, depression and poor self-esteem. Acne is a multi-factorial disease with several mechanistic contributors to the disease pathology, often requiring treatments that address more than one of the major causes of acne pathogenesis. Localized nitric oxide delivery may provide anti-inflammatory and anti-bacterial mechanisms of action from a single active ingredient.

We believe that acne continues to be characterized as an unmet medical need due to the difficulty of balancing efficacy, systemic safety and cutaneous tolerability, as well as the growing concerns with anti-bacterial resistance with existing therapies. In our SB204 clinical development program, topical application of SB204 has been well-tolerated with no significant safety concerns identified. In maximal-use pharmacokinetic trials that we have conducted in adult and pediatric patients with acne vulgaris, we observed no detectable systemic exposure from SB204 following its topical application.

In the first quarter of 2017, we reported top-line results from two identically designed Phase 3 pivotal clinical trials for SB204. SB204 demonstrated statistical significance compared to vehicle on all three co-primary endpoints in one of the trials but demonstrated statistical significance on only one of three co-primary endpoints in the other trial. We conducted an in-depth examination of the full data sets from these trials, including post hoc analyses in pooled and sub populations, with extensive assistance from third-party expert consultants in biostatistics and regulatory affairs. In mid-2017 we completed our 40-week long term safety trial in eligible patients with acne who had previously completed 12 weeks of treatment in the related Phase 3 pivotal trials of SB204. No serious adverse events were observed with over 400 patients followed for six months and over 200 patients followed for one year.

We have had several interactions with the FDA since mid-2017 regarding SB204 and the acne indication. In September 2017, we conducted a guidance meeting with the FDA to obtain clinical and regulatory guidance by reviewing the previously completed parallel Phase 3 pivotal trials in patients with moderate-to-severe acne. The FDA's specific feedback noted that there were no additional safety requirements and that one additional pivotal trial, in moderate-to-severe acne, would be required for submission of an NDA. In the third quarter of 2018, the FDA provided feedback on two potential paths forward for the acne indication, confirming the need for one additional pivotal trial for moderate-to-severe acne patients prior to an NDA submission.

Based on the recent positive pivotal Phase 3 results in the SB206 molluscum development program, we believe we can optimize the trial design of a pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal trial to support an NDA submission. As such, we plan to prepare for a pivotal Phase 3 study during 2022; target the conduct of a potential pivotal Phase 3 trial in 2023, subject to obtaining additional financing or strategic partnering; and target a potential NDA submission of SB204 for acne in 2024.

In January 2017, we licensed rights to Sato to develop, use, and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris, and to manufacture the finished form of SB204 for sale in Japan. The significant terms and the related accounting considerations of our licensing arrangement with Sato are further described in "Note 4—Licensing Arrangements" to the accompanying condensed consolidated financial statements. For further information regarding the current status of the Japanese SB204 program see "Note 5—Revenue Recognition" to the accompanying condensed consolidated financial statements.

SB019, an intranasal treatment option for Coronaviridae (COVID-19)

We continue to explore the use of our proprietary Nitricil technology to progress SB019, a potential intranasal 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 other anti-viral indications. Based on the scientific literature and data available to-date related to berdazimer sodium and SB206, we believe that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

In October 2020, we announced positive in vitro results showing the potential efficacy of our Nitricil platform technology, berdazimer sodium (NVN1000), as an anti-viral against SARS-CoV-2, the virus that causes COVID-19. To evaluate the ability of our Nitricil platform technology as a potential nasal treatment option for COVID-19, we initiated *in vitro* assessments targeting the reduction of viral burden in differentiated normal human bronchial epithelial cells. The studies were conducted at the Institute for Antiviral Research at Utah State University, and these results demonstrate the first instance of an anti-viral effect from a nitric oxide-based medicine in a 3-D tissue model that has similar structure to the human airway epithelium. The results from the *in vitro* assessment of concentrations as low as 0.75 mg/mL demonstrated that berdazimer sodium reduced 90% of virus after repeat dosing, once daily.

In December 2020, we entered into a Master Services Agreement with Catalent, Inc., a leading global provider of integrated services, delivery technologies and manufacturing solutions, relating to our COVID-19 program. This agreement includes work to support CMC activities and development of an intranasal formulation of berdazimer sodium for use in that program.
To further evaluate the potential of our Nitricil platform technology as an intranasal treatment option for COVID-19, we initiated preliminary preclinical *in vivo* studies to evaluate the efficacy of berdazimer sodium in reducing viral burden in infected animals and to deter viral transmission to uninfected animals.

In June 2021, we announced positive results from two separate studies that independently demonstrated the ability of berdazimer sodium to prevent progression of infection into the lungs after transmission, significantly limiting severity of

disease in this model. The intranasal treatment was well-tolerated during these studies, and no treatment-related adverse effects were observed.

In November 2021, we announced favorable results of a Good Laboratory Practices, or GLP, 14-day repeat dose intranasal study. The preclinical safety data indicated that intranasal administration of SB019 formulation is well tolerated and safe. The GLP study evaluated repeated dosing with the SB019 product candidate (i.e., 5 times daily) for a period of 14 days and concluded with a 7-day recovery period without drug exposure. There were no treatment-related adverse events up to the highest dose tested of 14 mg/day berdazimer sodium, and the SB019 formulation was concluded to be well-tolerated under the conditions of this study.

Based on the positive preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, as well as the public health need to reduce breakthrough infections and transmission, we plan to advance our SB019 product candidate. Pre-investigational new drug, or IND, application activities are underway with a target of an IND submission no later than Q2 2022. Subject to regulatory guidance, our targeted timeline includes (i) initiating a Phase 1 study in healthy volunteers in the first half of 2022; (ii) conducting a potential Phase 2/3 study(s) in 2023, subject to obtaining additional financing or strategic partnering; and (iii) a potential NDA submission of SB019 for COVID-19 in 2024.

Pipeline Expansion Opportunities

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

SB414 is a product candidate designed as a topical cream-based gel for the treatment of inflammatory skin diseases, with a focus on the treatment of atopic dermatitis and psoriasis. 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 as a cream for the treatment of psoriasis. 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. 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 could potentially explore the use of lower doses of SB414 in psoriasis, subject to obtaining additional financing or strategic partnering.

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

SB208 is a product candidate designed as a topical broad-spectrum anti-fungal gel for the potential treatment of fungal infections of the skin and nails, including athlete's foot (tinea pedis) and fungal nail infections (onychomycosis). Studies have demonstrated enhanced efficacy when tinea pedis and onychomycosis are treated concurrently, suggesting that an effective topical treatment, suitable for simultaneous application to the nail plate and skin, may lead to lower rates of recurrence and enhanced efficacy.

We conducted a Phase 2 proof-of-concept trial in patients with clinical signs and symptoms of tinea pedis and announced top-line results in the second quarter of 2017. SB208 demonstrated a statistically significant effect compared to vehicle in (i) the primary endpoint of achieving negative fungal culture at day 14; and (ii) the secondary endpoint of achieving mycological cure at day 14 (mycological cure is defined by having a negative laboratory culture and negative fungal clinical diagnosis). At the end of a 4-week post treatment follow-up period, mycological cure was maintained at day 42 in both dose groups.

We conducted a Phase 1, single-center, double-blinded, randomized clinical trial in 32 adult females to evaluate the rate of fingernail growth associated with SB208 16% cream and the local tolerability of the gel when used over the course of 29 days. SB208 16% cream demonstrated a statistically significant greater mean daily nail growth rate for the treatment period when compared to the same patient's own growth rate in the run-in period and was well tolerated by patients.

The SB208 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB207, for the Treatment of External Genital Warts

Genital warts are among the world's most common sexually transmitted diseases. We have previously evaluated SB206's anti-viral activity in a Phase 2 randomized, double-blinded, vehicle-controlled clinical trial in 107 patients with genital warts caused by HPV. We announced top-line results from this Phase 2 clinical trial in the fourth quarter of 2016. SB206 demonstrated statistically significant results in the clearance of external genital and perianal warts. Once-daily treatment arms were generally well-tolerated, including the most effective dose, SB206 12% once-daily. With the full results from this Phase 2 trial made available, a Type B meeting was held with the FDA in the second quarter of 2017 with minutes received shortly thereafter.

In response to our identification of targeted viral opportunities of high unmet need where we believe our nitric oxide releasing technology could provide clinical benefit to patients, we developed SB207, a new anti-viral product candidate for the treatment of external genital warts. The SB207 product candidate incorporates our existing drug substance, berdazimer sodium (NVN1000), including the nitric oxide release profile of SB206, in a new formulation specifically tailored for external genital warts. Following the FDA's December 2019 feedback from a pre-IND meeting request with the FDA, we have determined that further advancement of SB207 is subject to further evaluation of clinical plans and developmental timelines, as well as obtaining additional financing or strategic partnering.

Advancement in Men's and Women's Health

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 cervical intraepithelial neoplasias, or CIN. In March 2021, we were awarded additional funding of $0.1 million as part of this Phase 2 grant. 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 Men's and Women's Health business unit. This unit has continued to be supported through a collaboration with Health Decisions, Inc., or Health Decisions, a Premier Research company.

Companion Animal Health

We have initiated exploratory work to evaluate our new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. On June 7, 2021, we announced positive proof-of-concept *in vitro* results and informative *in vivo* results with NVN4100. This program is currently on hold, pending the engagement of potential collaborators or strategic partners to progress this asset, including the conduct of additional studies and formulation work.

Manufacturing and Supplies

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

Drug Substance

Upon successful completion of the required technology transfer, we intend for a new third-party API manufacturer to be able to manufacture berdazimer sodium in compliance with established manufacturing processes, applicable regulatory guidelines and as appropriate for potential large-scale commercial quantities.

In June 2019, we established an operating and business relationship with a third-party full-scale API manufacturer, with the goal being for this third-party API manufacturer to become the primary external supplier of our proprietary berdazimer sodium (NVN1000) drug substance. We executed a master contract manufacturing agreement, which included the process and analytical method transfer necessary to advance the production of our drug substance for future clinical trials and potentially for commercial purposes on a global basis if any of our product candidates are approved.

Through January 2021, we remained engaged in technical transfer efforts with this third-party API manufacturer. However, in February 2021, based on progress to date, including timing considerations relating to top-line results for the B-SIMPLE4 Phase 3 trial, we terminated our existing work orders related to technical transfer activities with this third-party API manufacturer. The master services agreement remains in place with this third-party API manufacturer for potential longer term needs.

We recently entered into development services agreements with third-party full-scale API manufacturers for certain manufacturing process feasibility services including process familiarization, safety assessments, preliminary engineering studies, and initial process and analytical methods determination. Following the successful completion of such preliminary activities with a third-party API manufacturer and other preparatory activities, we would then proceed with a third-party API manufacturer beyond the initial stages noted above, in which case we would expect to incur substantial costs associated with technical transfer efforts, capital expenditures, manufacturing capabilities, and ultimately, potential large-scale commercial quantities of our drug substance.

Internal Capability

We manufactured the API necessary for the B-SIMPLE4 Phase 3 trial using internal manufacturing capabilities at our former facility. In addition, we currently have an inventory of API that allows us to continue certain preclinical and/or developmental activities.

With the B-SIMPLE4 Phase 3 trial positive top-line efficacy results, we are targeting a potential NDA submission of SB206 for molluscum in the third quarter of 2022. In order to ensure that we have the API necessary to enable the SB206 NDA submission on our targeted timeline, we are preparing our new facility to have the infrastructure necessary to produce cGMP API registration batches, among other manufacturing capabilities. We are in the process of building out our new facility, which we expect to complete by the end of 2021, to support various research and development and cGMP activities, including the production of cGMP API registration batches necessary to support the SB206 NDA submission as well as other small-scale manufacturing capabilities for API and drug product. Once the build-out is completed and occupied, we will proceed with the

related preparatory activities associated with qualifying, commissioning and validating the manufacturing equipment for use in API production.

The anticipated additional manufacturing capabilities include the ability to act as a supportive, or potentially primary, component of, or as a back up to, elements of a potential future commercial supply chain, and the ability to produce limited quantities of clinical trial materials. We believe the new facility, once completed, will have the capability to support our planned potential NDA submission for SB206 and potential commercial launch quantities of API for SB206. The timing of our efforts to submit an NDA and to have a third-party full-scale API manufacturer ready for production are expected to inform our future decisions on the expected duration and utilization level of the capabilities of our new facility.

We expect to continue to work toward completion of technical transfer activities with a third-party full-scale API manufacturer to provide the API needed for long-term commercial supply of drug substance, if any of our product candidates are approved. We believe this 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 of our potential partnerships, collaborations, licensing or other strategic relationships. At the same time, we are attempting to balance the need to have internal capabilities to allow flexibility for the progression of our product development programs on our targeted timelines.

Drug Product

On October 15, 2018, we established a strategic alliance with Orion Corporation, or 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 completion, we 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 and as appropriate for clinical trials. A completed manufacturing technology transfer to Orion will enable the manufacture of multiple assets for supply of clinical trial materials and, potentially, commercial quantities if any of our product candidates are approved. Importantly, this alliance is being structured to support major global markets in which we and our partners pursue regulatory approvals for our product candidates.

Based on the results of the B-SIMPLE1 and B-SIMPLE2 clinical trials in January 2020, during the first quarter of 2020, at our request, Orion reduced certain near-term activities and extended certain timelines in an effort to reduce our near-term cash utilization at that time. We resumed technical transfer efforts with Orion during the third quarter of 2020. We will continue to work toward completion of technical transfer and manufacturing activities to provide the necessary regulatory registration batches of drug product for our planned NDA submission of SB206 for molluscum, and if any of our product candidates are approved, commercial supply of drug product.

As we move forward with these initiatives, we will need significant additional funding to continue our operating activities, including these technical transfer projects, potential utilization and development of internal capabilities and cost structure changes, and to make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection, as described below in “Liquidity and Capital Resources”.

Corporate Updates

Commercial Solutions Provider

In September 2021, we announced that we engaged Syneos Health, a fully integrated biopharmaceutical solutions organization, as our commercial solutions provider for SB206 as a treatment for molluscum. This relationship with Syneos Health, structured as a fee-for-service arrangement, will focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by commercial sales of SB206, if approved by the FDA.

Chief Medical Officer

On August 24, 2021, Tomoko Maeda-Chubachi, MD, PhD, MBA was appointed as our Chief Medical Officer after previously serving as our Senior Vice President, Medical since March of 2021 and our Vice President, Medical Dermatology since joining us in September of 2017.

June 2021 Public Offering

On June 17, 2021, we entered into an underwriting agreement with Cantor Fitzgerald & Co. relating to the offering, issuance and sale of 3,636,364 shares of common stock. We also granted Cantor Fitzgerald & Co., as underwriter, a 30-day option to purchase up to 545,454 additional shares of common stock, which was not exercised. The June 2021 Public Offering closed on June 21, 2021.

Net proceeds from the June 2021 Public Offering were approximately $37.2 million after deducting underwriting discounts and commissions and offering expenses of approximately $2.8 million.

See “Note 10—Stockholders’ Equity (Deficit)” to the accompanying condensed consolidated financial statements for additional information regarding the June 2021 Public Offering.

Reverse Stock Split

As previously disclosed, on July 28, 2020, our stockholders approved a proposal to amend our restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of not less than one-for-two and not more than one-for-fifteen, with such ratio and the implementation and timing of such reverse stock split to be determined by our board of directors in its sole discretion. On May 18, 2021, our board of directors approved a one-for-ten reverse stock split of our issued and outstanding common stock, or the Reverse Stock Split. On May 24, 2021, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Restated Certificate of Incorporation in order to effect the Reverse Stock Split, or the Charter Amendment. The Reverse Stock Split became effective at 5:00 pm Eastern Time on May 25, 2021. Pursuant to the Charter Amendment, on the effective date thereof, each outstanding ten (10) shares of common stock combined into and became one (1) share of common stock and the number of our issued and outstanding shares of common stock was reduced to 15,170,678. The new CUSIP number for our common stock is 66988N205.

All references to numbers of shares of common stock and per-share information in this Quarterly Report on Form 10-Q have been adjusted retroactively, as appropriate, to reflect the Reverse Stock Split.

Paycheck Protection Program

On April 22, 2020, we entered into a promissory note for an unsecured loan in the amount of approximately $1.0 million 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. We previously applied for and during the second quarter of 2021 received notification of forgiveness of the entire loan balance, including any accrued interest.

Triangle Business Center Facility Lease

On January 18, 2021, we entered into a Lease dated as of January 18, 2021, as amended as of March 18, 2021, or the TBC Lease, by and between us and Copper II 2020, LLC, pursuant to which we are leasing 15,623 rentable square feet located at a new location, or the Premises. The Premises serves as our new corporate headquarters. We are building out the Premises to support various cGMP activities, including research and development and small-scale manufacturing capabilities. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a component of, or as a back up to, elements of a potential future commercial supply chain. See “Note 8—Commitments and Contingencies” to the accompanying condensed consolidated financial statements for a further discussion of the terms of the TBC Lease.

Financial Overview

Since our incorporation 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. To date, we have focused our funding activities primarily on equity financings, while generating additional liquidity and capital through other sources, including payments received from licensing and supply arrangements, strategic arrangements and government research contracts.

We have never generated revenue from product sales and have incurred net losses in each year since our incorporation. As of September 30, 2021, we had an accumulated deficit of $270.7 million, and we incurred net losses of $6.5 million and $21.5 million during the three and nine months ended September 30, 2021, respectively, and $8.4 million and $22.7 million during the three and nine months ended September 30, 2020, 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.

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.

In November of 2020, Sato determined its initial Japanese Phase 1 study for SB206 would require an amended design, including evaluation of potential lower dose strengths, to further refine dose tolerability in a subsequent Phase 1 study. Based upon (i) the need for an additional Phase 1 study; (ii) Sato’s estimated comprehensive developmental schedule for SB206 including additional post-Phase 1 clinical trials; and (iii) current and future Japanese clinical trial material manufacturing and technical transfer considerations, we concluded that a prospective delay in Sato’s overall SB206 development plan had occurred. We estimated the program timeline to be extended by 1.75 years from our previous estimate, and a corresponding extension of the performance period estimate to 9.25 years, completing in the second quarter of 2026.

In late July 2021, Sato communicated an updated plan regarding its amended design for its additional Japanese Phase 1 study for SB206. The amended study design includes evaluation of potential lower dose strengths, including potential further refinement in a subsequent dose tolerability study. As part of the communication regarding these Phase 1 studies, Sato also communicated an updated comprehensive timeline for the Japanese SB206 program. The updated timeline assumes that the 12% formulation is appropriate to proceed for development in Japan, and is to be reassessed based on the findings of the Phase 1 study.

Based upon (i) the expected timing of the additional Phase 1 study, including a subsequent dose tolerability study; (ii) Sato’s estimated comprehensive developmental schedule for SB206, including additional post-Phase 1 clinical trials; and (iii) current and future Japanese clinical trial material manufacturing and technical transfer considerations, including the manufacturing site for drug product, we concluded that a prospective delay in Sato’s overall SB206 Japanese development plan had occurred in July 2021. We estimate the program timeline to be extended by 0.75 years from our previous estimate, and a corresponding extension of the performance period estimate to 10 years, completing in the first quarter of 2027. We understand that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato’s comprehensive asset developmental program, including SB206. This estimated timeline remains subject to prospective reassessment and adjustment based upon Sato’s interaction with the Japanese regulatory authorities and other developmental and timing considerations.

The material terms of the Amended Sato Agreement and related revenue recognition are described in “Note 4—Licensing Arrangements” and “Note 5—Revenue Recognition” to the accompanying condensed consolidated financial statements.

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 qualifying expenses are incurred.

Research and Development Expenses

Since our incorporation, 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 CMOs and to enhance drug delivery device technologies through partnerships with technology manufacturing vendors;
- legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- salaries and related costs, including stock-based compensation, for personnel in our research and development functions; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, utilities, equipment and other supplies.

From our incorporation through September 30, 2021, we have incurred approximately $197.8 million in research and development expenses to develop, expand or otherwise improve our nitric oxide platform and resulting product candidates. This amount is net of $10.3 million of aggregate contra-research and development expense representing amortization of the liability related to the $12.0 million of funding received from Ligand Pharmaceuticals Incorporated, or Ligand, to pursue the development and regulatory approval of SB206. For the three and nine months ended September 30, 2021, we recognized accretion, or a decrease in contra-research and development expense of $0.1 million and amortization, or an increase in contra-research and development expense of $0.1 million, respectively. For the three and nine months ended September 30, 2020, we recognized amortization of $0.3 million and $2.2 million, respectively. For a description of the methodology and assumptions used to recognize the ratable amortization of this liability, as well as other information about the development funding and royalties agreement, or the Funding Agreement, with Ligand, please see “Note 6—Research and Development Arrangements” to the accompanying condensed consolidated financial statements.

For the nine months ended September 30, 2021 and 2020, our total research and development expense was $15.9 million and $13.5 million, respectively. During the first nine months of 2021, our major clinical development activities were primarily associated with the continued conduct of our current SB206 Phase 3 clinical program. The total external clinical program expense related to the SB206 program was $8.3 million and $4.3 million for the nine months ended September 30, 2021 and 2020, respectively.

In addition, other research and development expenses were $7.6 million and $9.0 million for the nine months ended September 30, 2021 and 2020, respectively. Other research and development expenses include: (i) all preclinical program and development costs, including WH504, WH602 and SB019; (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.

Our plan and timelines for further clinical development of SB206 have been and may be further impacted by the COVID-19 pandemic. We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on: (i) costs through the completion of the B-SIMPLE4 Phase 3 trial, including final data accumulation and reporting in addition to other supporting activities; (ii) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum; (iii) conducting drug manufacturing capability transfer activities to external third-party CMOs, including a drug delivery device technology enhancement project; (iv) developmental and regulatory activities for our SB019 program (Coronaviridae (COVID-19)), including a Phase 1 study, targeted for initiation in 2022; and (v) preparatory activities for a potential Phase 3 trial, targeted for initiation in 2023, related to SB204 as a treatment for acne.

We also expect to incur substantial costs in 2021 associated with our research and development personnel, and certain manufacturing capability costs related to the infrastructure build-out necessary to support small-scale drug substance and drug product manufacturing operations at our new corporate headquarters, including capital costs subject to depreciation and various ongoing operating costs. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential SB206 commercialization strategies developed in conjunction with Syneos Health, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

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

General and Administrative Expenses

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

We expect to continue to incur substantial general and administrative expenses in 2021 in support of our prelaunch strategy and commercial preparation activities for SB206. We may decide to revise our plans or the related timing associated with our prelaunch strategy and commercial preparation activities for SB206, depending on information we learn through our regulatory submission process and potential SB206 commercialization strategies developed in conjunction with Syneos Health.

We also expect to continue to incur substantial general and administrative expenses in 2021 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.

Impairment loss on long-lived assets

As of June 29, 2020, we evaluated all of our long-lived assets for potential held for sale classification, and assessed our remaining long-lived assets classified as held and used for potential impairment pursuant to our accounting policies described in “Note 1—Organization and Significant Accounting Policies” to our audited consolidated financial statements contained in our Annual Report. This evaluation and assessment was triggered by the decommissioning of our large scale drug manufacturing capability at our former Morrisville, North Carolina facility and by preparatory actions taken in connection with the planned lease termination transaction for the facility that was executed in July 2020. In connection with this evaluation and impairment assessment, during the three months ended June 30, 2020, we recognized an impairment loss on long-lived assets that represented the carrying value in excess of fair value of assets held and used or the carrying value in excess of fair value less cost to sell for assets held for sale.

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

Loss on facility asset group disposition

In conjunction with the lease termination transaction executed in July 2020, as described above, all assets and liabilities within the related facility asset group were disposed of on July 16, 2020. As of the disposition date, the net aggregate carrying value of

the assets and liabilities was written off, combined with certain other direct costs incurred in connection with the lease termination transaction, which resulted in a loss on disposition.

Other Income (Expense), net

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

Results of Operations

Comparison of Three Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,			
	2021	2020	$ Change	% Change
	(in thousands, except percentages)			
License and collaboration revenue	$ 680	$ 1,100	$ (420)	(38)%
Government research contracts and grants revenue	57	217	(160)	(74)%
Total revenue	737	1,317	(580)	(44)%
Operating expenses:				
Research and development	4,251	4,836	(585)	(12)%
General and administrative	2,969	3,108	(139)	(4)%
Loss on facility asset group disposition	—	1,772	(1,772)	(100)%
Total operating expenses	7,220	9,716	(2,496)	(26)%
Operating loss	(6,483)	(8,399)	1,916	(23)%
Other income (expense), net:				
Interest income	4	2	2	100 %
Other income (expense)	(5)	(8)	3	(38)%
Total other income (expense), net	(1)	(6)	5	(83)%
Net loss and comprehensive loss	$ (6,484)	$ (8,405)	$ 1,921	(23)%

Revenue

License and collaboration revenue of $0.7 million and $1.1 million for the three months ended September 30, 2021 and 2020, 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 totaled $0.1 million and $0.2 million for the three months ended September 30, 2021 and 2020, respectively. For the three months ended September 30, 2021 and 2020, we recognized no and $0.1 million of revenue, respectively, related to the grant we received in September 2019 from the DoD's CDMRP as part of its Peer Reviewed Cancer Research Program and $0.1 million and $0.1 million related to the grant we received in February 2020 from the NIH.

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 $4.3 million for the three months ended September 30, 2021, compared to $4.8 million for the three months ended September 30, 2020. The net decrease of $0.6 million, or 12%, was primarily related to a $1.1 million net decrease in the SB206 program; partially offset by a $0.5 million increase in other research and development expenses.

In the SB206 program, we experienced (i) a $1.8 million decrease in gross costs incurred due primarily to the completion and wind down of the B-SIMPLE4 Phase 3 trial during the third quarter of 2021, compared to relatively higher costs for B-

SIMPLE4 Phase 3 trial start-up activities and certain B-SIMPLE 1 and B-SIMPLE 2 Phase 3 trial wind down activities conducted during the comparative period in 2020, (ii) a $0.5 million increase in regulatory consulting services, stability and other analytical testing services, and chemistry, manufacturing and controls consulting services and materials in support of our planned SB206 NDA submission and (iii) a $0.2 million decrease in contra-research and development expense from the ratable amortization of the Funding Agreement with Ligand liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum.

The $0.5 million increase in other research and development expenses was primarily due to (i) an increase of $0.5 million related to costs incurred during the third quarter of 2021 related to our *in vitro* and *in vivo* studies to evaluate our SB019 product candidate as an intranasal treatment option for COVID-19, (ii) a $0.1 million net increase in external drug manufacturing technology transfer projects ongoing with our contract manufacturing partners, (iii) a $0.1 million net increase in rent expenses as we transitioned into our new facility in Durham, North Carolina, and (iv) a $0.3 million net increase in other facility preparation and operating service costs; partially offset by (i) a $0.2 million decrease in research and development personnel costs, (ii) a $0.2 million decrease in our preclinical, grant-funded WH602 and WH604 programs, and (iii) $0.1 million of discrete facility decommissioning costs incurred in the third quarter of 2020 associated with our former Morrisville, North Carolina facility.

The $0.2 million net decrease in research and development personnel costs was primarily due to (i) a $0.1 million net decrease in recurring salary, cash bonus and benefits costs due to changes in the composition of our research and development personnel between the two comparative periods and (ii) the decrease in non-cash compensation expense related to the change in the fair value of our Tangible Stockholder Return Plan, or our Performance Plan, liability, which is a long-term incentive plan that expires on March 1, 2022.

General and administrative expenses

General and administrative expenses were $3.0 million for the three months ended September 30, 2021, compared to $3.1 million for the three months ended September 30, 2020. The net $0.1 million decrease in general and administrative expenses for the three months ended September 30, 2021 was primarily due to (i) a $0.3 million increase in insurance premium expenses associated with our directors' and officers' liability policies, (ii) a $0.2 million net increase in general and administrative personnel and related costs, (iii) a $0.3 million increase in SB206 prelaunch strategy and commercial preparation costs, and (iv) a $0.1 million increase in intellectual property and related legal costs; partially offset by a $0.8 million non-cash expense recognized in the third quarter of 2020 related to the issuance of commitment shares in consideration for entering into the July 2020 Aspire CSPA.

The $0.2 million net increase in general and administrative personnel and related costs is primarily due to (i) a $0.1 million increase in recurring salary and benefits costs, and (ii) a $0.1 million net increase in non-cash stock-based incentive compensation expense.

Loss on facility asset group disposition

For the three months ended September 30, 2020 we reported a $1.8 million loss on facility group disposition, in conjunction with a lease termination transaction executed in July 2020, as described above. All assets and liabilities within the related facility asset group were disposed of on July 16, 2020. As of the disposition date, the net aggregate carrying value of the assets and liabilities was written off, combined with certain other direct costs incurred in connection with the lease termination transaction.

Comparison of Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
	(in thousands, except percentages)			
License and collaboration revenue	$ 2,174	$ 3,224	$ (1,050)	(33)%
Government research contracts and grants revenue	129	627	(498)	(79)%
Total revenue	2,303	3,851	(1,548)	(40)%
Operating expenses:				
Research and development	15,926	13,513	2,413	18 %
General and administrative	8,086	8,847	(761)	(9)%
Impairment loss on long-lived assets	114	2,421	(2,307)	(95)%
Loss on facility asset group disposition	—	1,772	(1,772)	(100)%
Total operating expenses	24,126	26,553	(2,427)	(9)%
Operating loss	(21,823)	(22,702)	879	(4)%
Other income (expense), net:				
Interest income	10	47	(37)	(79)%
Gain on debt extinguishment	956	—	956	100 %
Other (expense) income	(602)	(3)	(599)	*
Total other income (expense), net	364	44	320	*
Net loss	$ (21,459)	$ (22,658)	$ 1,199	(5)%

** Not meaningful*

Revenue

License and collaboration revenue of $2.2 million and $3.2 million for the nine months ended September 30, 2021 and 2020, 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 totaled $0.1 million and $0.6 million for the nine months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, we recognized no and $0.5 million of revenue, respectively, related to the grant we received in September 2019 from the DoD's CDMRP as part of its Peer Reviewed Cancer Research Program and $0.1 million and $0.1 million, respectively, related to the grant we received in February 2020 from the NIH.

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 $15.9 million for the nine months ended September 30, 2021, compared to $13.5 million for the nine months ended September 30, 2020. The net increase of $2.4 million, or 18%, was primarily related to a $4.1 million net increase in the SB206 program; partially offset by (i) a $1.4 million decrease in other research and development expenses, and (ii) a $0.3 million decrease in our SB414 program.

In the SB206 program, we experienced (i) a $0.8 million increase in gross costs incurred primarily due to the conduct and completion of the B-SIMPLE4 Phase 3 trial during the first nine months of 2021, compared to the relatively lower cost of B-SIMPLE4 Phase 3 trial start-up activities and B-SIMPLE 1 and B-SIMPLE 2 Phase 3 trial wind down activities during the comparative period in 2020, (ii) a $1.0 million increase in regulatory consulting services, stability and other analytical testing services, and chemistry, manufacturing and controls consulting services and materials in support of our planned SB206 NDA submission, and (iii) a $2.3 million decrease in contra-research and development expense from the ratable amortization of the Ligand Funding Agreement liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum. The SB206 clinical development activities conducted during the comparative period in 2020, including but not limited to the B-SIMPLE 1 and B-SIMPLE 2 Phase 3 trials, were eligible for Ligand contribution and associated amortized contra-research and development expense recognition, but the B-SIMPLE 4 Phase 3 trial conducted during the current period in 2021 was not eligible for Ligand contributions and therefore no contra-research and development expense was recognized against the gross B-SIMPLE 4 trial costs. During the nine months ended September 30, 2021, we recorded a $0.1 million reduction to contra-research and development expense related to the Ligand SB206 developmental program, related to accretion of the Funding Agreement with Ligand liability, based on our reassessment of the estimated total cost to progress the SB206 program to a potential United States regulatory approval. Further information regarding our reassessment of the SB206 program is described in "Note 6—Research and Development Arrangements" to the accompanying condensed consolidated financial statements.

The $1.4 million decrease in other research and development expenses was primarily driven by (i) a $1.6 million net decrease in research and development personnel costs, (ii) a $0.8 million net decrease in rent and depreciation expense following the reduction of our real estate footprint due to the exit and the lease termination of our former Morrisville, North Carolina facility completed in the third quarter of 2020, (iii) $0.3 million of discrete facility decommissioning costs incurred in the second and third quarters of 2020 associated with our former Morrisville, North Carolina facility, and (iv) a $0.6 million decrease in our preclinical, grant-funded WH602 and WH604 programs; partially offset by (i) $1.0 million costs incurred during the first nine months of 2021 related to our *in vitro* and *in vivo* studies to evaluate our SB2019 product candidate as an intranasal treatment option for COVID-19, (ii) a $0.5 million net increase in external drug manufacturing technology transfer projects ongoing with our contract manufacturing partners, (iii) a $0.3 million net increase in other facility preparation and operating service costs, and (iv) $0.1 million costs incurred during the first nine months of 2021 associated with exploratory work to evaluate our new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health.

The $1.6 million net decrease in research and development personnel costs is primarily due to (i) a $0.5 million decrease in non-cash compensation expense related to the change in the fair value of our Tangible Stockholder Return Plan, (ii) a $0.4 million decrease in non-cash compensation expense associated with stock option compensation, (iii) a $0.4 million decrease in discrete severance charges and retention incentive compensation associated with business realignment and personnel reduction actions taken during the first quarter of 2020, and (iv) 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.

General and administrative expenses

General and administrative expenses were $8.1 million for the nine months ended September 30, 2021, compared to $8.8 million for the nine months ended September 30, 2020. The decrease of approximately $0.8 million, or 9%, was primarily due to $1.7 million of aggregate non-cash expense recognized during the nine months ended September 30, 2020 related to the issuance of commitment shares in consideration for entering into the June 2020 Aspire CSPA and July 2020 Aspire CSPA. In addition we experienced (i) a $0.9 million increase in insurance premium expenses associated with our directors' and officers' liability policies, (ii) a $0.2 million net increase in general and administrative personnel and related costs, and (iii) a $0.3 million increase in SB206 prelaunch strategy and commercial preparation costs; partially offset by a $0.3 million decrease in rent and depreciation expense following the reduction of our real estate footprint within our Morrisville, North Carolina facility after the lease termination completed in the third quarter of 2020.

The $0.2 million net increase in general and administrative personnel and related costs includes (i) a $0.3 million increase in cash-based compensation expenses related, in part, to a success bonus paid to all employees following the announcement of the positive top-line results of our B-SIMPLE 4 study, (ii) a $0.1 million decrease in non-cash compensation expenses related to the change in the fair value of our Performance Plan liability, which was offset by a $0.1 million increase in non-cash compensation expense associated with stock option compensation, and (iii) a $0.1 million decrease in recurring salary and benefits costs.

Impairment loss on long-lived assets

As of June 29, 2020, we evaluated all of our long-lived assets for potential held for sale classification, and assessed our remaining long-lived assets classified as held and used for potential impairment pursuant to our accounting policies. Our evaluation resulted in a $2.4 million non-cash impairment loss on long-lived assets for the nine months ended September 30, 2020.

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

Loss on facility asset group disposition

For the nine months ended September 30, 2020 we reported a $1.8 million loss on facility group disposition, in conjunction with a lease termination transaction executed in July 2020, as described above. All assets and liabilities within the related facility asset group were disposed of on July 16, 2020. As of the disposition date, the net aggregate carrying value of the assets and liabilities was written off, combined with certain other direct costs incurred in connection with the lease termination transaction.

Other income (expense), net

Other income (expense), net was $0.4 million income for the nine months ended September 30, 2021, and was negligible for the nine months ended September 30, 2020. During the second quarter of 2021, we experienced a $1.0 million gain on debt extinguishment related to the forgiveness of our PPP loan in June 2021. This gain was partially offset by $0.6 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to the Amended Sato Agreement.

Liquidity and Capital Resources

As of September 30, 2021, we had an accumulated deficit of $270.7 million. We incurred net losses of $6.5 million and $21.5 million during the three and nine months ended September 30, 2021, respectively, and $8.4 million and $22.7 million during the three and nine months ended September 30, 2020, respectively, and there is substantial doubt about our ability to continue as a going concern. 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 potentially begin 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. 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 and commercial solutions providers would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

As of September 30, 2021, we had total cash and cash equivalents of $60.0 million and positive working capital of $48.8 million. As of September 30, 2021, we had $12.0 million in remaining availability for sales of our common stock under the July 2020 Aspire CSPA, subject to certain limitations.

From January 1, 2019 through September 30, 2021, we have raised total equity and debt proceeds of $97.7 million to fund our operations, including (i) $37.2 million in net proceeds from the sale of common stock in the June 2021 public offering (as defined below); (ii) $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 (as defined below); (iii) $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 (as defined below); (iv) an additional $6.0 million of proceeds associated with exercises through September 30, 2021 of common warrants issued as part of the March 2020 Public Offering and March 2020 Registered Direct Offering; (v) $41.0 million in proceeds from the sale of common stock under our August 2019 and June 2020 common stock purchase agreements with Aspire Capital and the July 2020 Aspire CSPA; and (vi) less than $0.1 million of proceeds from the exercise of stock options. We also obtained a loan under the PPP (as defined below) of approximately $1.0 million in April 2020 to support certain qualified expenses, including payroll and rental expense, which is described below. The PPP loan was forgiven in June 2021.

To date, we have focused our funding activities primarily on equity financings, while generating additional liquidity and capital through other sources, including: (i) governmental research contracts and grants totaling $12.9 million; (ii) our licensing and supply arrangements with Sato, totaling $28.8 million; and (iii) $25.0 million and $12.0 million in proceeds from two funding transactions during the second quarter of 2019 with Reedy Creek Investments LLC, or Reedy Creek, and Ligand, respectively, as described below.

We believe that our existing cash and cash equivalents balance as of September 30, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide us with adequate liquidity to fund our planned operating needs into the fourth quarter of 2022. This operating forecast and related cash projection includes: (i) costs through the completion of the B-SIMPLE4 Phase 3 trial, including final data accumulation and reporting in addition to other supporting activities; (ii) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum; (iii) costs associated with the completion of the build-out of our new corporate headquarters and manufacturing capability necessary to support small-scale drug substance and drug product manufacturing; (iv) conducting drug manufacturing capability transfer activities to external third-party CMOs, including a drug delivery device technology enhancement project; (v) developmental and regulatory activities for our SB019 program (Coronaviridae (COVID-19)), including a Phase 1 study, targeted for initiation in 2022; (vi) preparatory activities for a potential Phase 3 trial, targeted for initiation in 2023, related to SB204 as a treatment for acne; and (vii) initial efforts to support potential commercialization of SB206, but excludes: (a) any potential costs associated with other late-stage clinical programs, including executing the potentially registrational Phase 3 trial of SB204 for acne; (b) progression of the SB019 program subsequent to execution of a Phase 1 study; (c) operating costs that could occur between a potential NDA submission for SB206 through NDA approval, specifically including marketing and commercialization efforts to achieve potential launch of SB206; and (d) proceeds from any potential future sales of common stock under the July 2020 Aspire CSPA. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

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

We do not currently have sufficient funds to complete commercialization of any of our product candidates, and our funding needs will largely be determined by our commercialization strategy for SB206, subject to the NDA submission timing and the regulatory approval process and outcome. We have selected Syneos Health, a fully integrated biopharmaceutical solutions organization, as our commercial solutions provider for SB206. Our relationship with Syneos Health will focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by commercial sales of SB206, if approved by the FDA.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. We may pursue additional capital through equity or debt financings, including potential sales under the July 2020 Aspire CSPA, or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. Alternatively, we may seek to engage in one or more potential transactions, which could include the sale of the Company, or the 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 on terms that are favorable to us.

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.

Development Services Agreement

In July 2021, we entered into a development services agreement with a third-party full-scale API manufacturer for certain manufacturing process feasibility services including process familiarization, safety assessments, preliminary engineering studies, and initial process and analytical methods determination. Following the successful completion of certain preliminary activities with this third-party API manufacturer and other preparatory activities, we would then proceed with the third-party

API manufacturer beyond the initial stages noted above, in which case we expect to incur substantial costs associated with technical transfer efforts, capital expenditures, manufacturing capabilities, and certain quantities of our drug substance.

Purchase Agreements with Aspire Capital

Prior Aspire Common Stock Purchase Agreements

On August 30, 2019, we entered into a common stock purchase agreement with Aspire Capital, or the 2019 Aspire CSPA, and on June 15, 2020, we entered into a common stock purchase agreement with Aspire Capital, or the June 2020 Aspire CSPA, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $25.0 million and $20.0 million, respectively, of shares of our common stock at our request from time to time during the 30-month term of each agreement. The June 2020 Aspire CSPA replaced the 2019 Aspire CSPA, which was terminated under the terms of the June 2020 Aspire CSPA. On July 21, 2020, the June 2020 Aspire CSPA was replaced by the July 2020 Aspire CSPA described below.

From the inception through the termination of the 2019 Aspire CSPA, we sold 486,571 shares of common stock at an average price of $6.22 per share under such agreement. These amounts, combined with the 34,562 shares issued as part of the commitment fee related to the agreement's execution, resulted in a total of 521,133 shares issued to Aspire Capital under that agreement as of September 30, 2021. From the inception through the termination of the June 2020 Aspire CSPA, we sold 3,776,428 shares of common stock at an average price of $5.30 per share under that agreement. These amounts, combined with the 144,927 shares issued as part of the commitment fee related to the agreement's execution, resulted in a total of 3,921,355 shares issued to Aspire Capital under the agreement, which was fully utilized prior to entry into the July 2020 Aspire CSPA. The 2019 Aspire CSPA and June 2020 Aspire CSPA had substantially similar terms to the July 2020 Aspire CSPA.

July 2020 Aspire Common Stock Purchase Agreement

On July 21, 2020, we entered into the July 2020 Aspire CSPA, 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 $30.0 million of shares of our common stock at our request from time to time during the 30-month term of the agreement. Upon execution of the July 2020 Aspire CSPA, we agreed to sell to Aspire Capital 555,555 shares of our common stock at $9.00 per share for proceeds of $5.0 million. In addition, as consideration for entering into the July 2020 Aspire CSPA, we issued to Aspire Capital 100,000 shares of our common stock as a commitment fee.

Concurrently with entering into the July 2020 Aspire CSPA, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the July 2020 Aspire CSPA. On July 23, 2020, we filed with the SEC a prospectus supplement to our effective shelf Registration Statement on Form S-3 (File No. 333-236583) registering all of the shares of common stock that may be offered to Aspire Capital from time to time under the July 2020 Aspire CSPA.

Under the terms of the July 2020 Aspire CSPA, on any trading day we select, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, or the Purchase Notice, directing Aspire Capital (as principal) to purchase up to 30,000 shares of our common stock per business day, up to an aggregate of $30.0 million of our common stock, at a per share price equal to the lesser of (i) the lowest sale price of our common stock on the purchase date; or (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the ten 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 $0.5 million, unless otherwise mutually agreed. The parties may mutually agree to increase the number of shares of our common stock that may be purchased per trading day pursuant to the terms of the July 2020 Aspire CSPA to up to 200,000 shares.

In addition, on any date on which we submit a Purchase Notice in an amount equal to 30,000 shares, we can also, in our sole discretion, present Aspire Capital with a volume-weighted average price purchase notice, or a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock traded on our principal market on the next trading day, or the VWAP Purchase Date, subject to a maximum number of shares determined by us. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for our common stock traded on our principal market on the VWAP Purchase Date.

Under the terms of the July 2020 Aspire CSPA, the number of shares that may be sold to Aspire Capital is limited to 2,543,364 shares, or the Exchange Cap, which represents 19.99% of our outstanding shares of common stock on July 21, 2020, unless

stockholder approval or an exception pursuant to the rules of our principal market, currently the Nasdaq Capital 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 July 2020 Aspire CSPA is equal to or greater than $5.907, which is the arithmetic average of the five closing sale prices of our common stock immediately preceding the execution of the July 2020 Aspire CSPA. The July 2020 Aspire CSPA provides that we and Aspire Capital shall not effect any sales under the July 2020 Aspire CSPA on any purchase date where the closing sale price of our common stock is less than $0.15.

There are no trading volume requirements or restrictions under the July 2020 Aspire CSPA, and we control the timing and amount of sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we may direct in accordance with the July 2020 Aspire CSPA. 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 July 2020 Aspire CSPA. The July 2020 Aspire CSPA may be terminated by us at any time, at our discretion, without any penalty or additional cost to us. Any proceeds we receive under the July 2020 Aspire CSPA are expected to be used for the advancement of our research and development programs and for general corporate purposes, capital expenditures and working capital.

As of September 30, 2021, we have sold 2,221,040 shares of our common stock at an average price of $8.10 per share under the July 2020 Aspire CSPA for total proceeds of $18.0 million. These amounts, combined with the 100,000 shares issued as part of the commitment fee related to the agreement's execution, resulted in a total of 2,321,040 shares issued to Aspire Capital under the agreement as of September 30, 2021. As of September 30, 2021, there was $12.0 million of remaining availability for sales of common stock under the July 2020 Aspire CSPA.

See "Note 10—Stockholders' Equity (Deficit)" to the accompanying condensed consolidated financial statements for additional information regarding the July 2020 Aspire CSPA.

Paycheck Protection Program

On April 22, 2020, and as subsequently amended, we entered into the Note for an unsecured loan of approximately $1.0 million made to us, or the Loan, under the Paycheck Protection Program, or the PPP. The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and is administered by the United States Small Business Administration, or the SBA. The Loan was made through PNC Bank, National Association. Subject to the terms of the Note, the Loan bore interest at a fixed rate of one percent (1%) per annum. 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 program-eligible expenses. 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. We previously applied for and during the second quarter of 2021 received notification of forgiveness of the entire loan balance, including any accrued interest.

See "Note 9—Paycheck Protection Program" to the accompanying condensed consolidated financial statements for additional information regarding the Loan.

Equity Offerings

June 2021 Public Offering

On June 17, 2021, we entered into an underwriting agreement with Cantor Fitzgerald & Co. relating to the offering, issuance and sale of 3,636,364 shares of common stock. We also granted Cantor Fitzgerald & Co., as underwriter, a 30-day option to purchase up to 545,454 additional shares of common stock, which was not exercised. The June 2021 Public Offering closed on June 21, 2021.

Net proceeds from the June 2021 Public Offering were approximately $37.2 million after deducting underwriting discounts and commissions and offering expenses of approximately $2.8 million.

See "Note 10—Stockholders' Equity (Deficit)" to the accompanying condensed consolidated financial statements for additional information regarding the June 2021 Public 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, or the March 2020 Registered Direct Offering, an aggregate of 1,055,000 shares of our common stock and pre-funded warrants to purchase 805,465 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 55,814 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.

See “Note 10—Stockholders’ Equity (Deficit)” to the accompanying condensed consolidated financial statements for additional information regarding the March 2020 Registered Direct Offering.

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 1,400,000 shares of common stock, pre-funded warrants to purchase 433,333 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 1,833,333 shares of common stock, or, collectively, the March 2020 Public Offering. We also granted H.C. Wainwright, as underwriter, a 30-day option to purchase up to 275,000 additional shares of common stock and/or common warrants to purchase up to an aggregate of 275,000 shares of common stock, which H.C. Wainwright partially exercised on March 2, 2020 to purchase 149,860 shares of common stock and common warrants to purchase 275,000 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 59,496 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 September 30, 2021, 1,855,917 common warrants issued as part of the March 2020 Public Offering have been exercised for an additional $5.6 million of proceeds associated with this offering.

See “Note 10—Stockholders’ Equity (Deficit)” to the accompanying condensed consolidated financial statements for additional information regarding the March 2020 Public Offering.

Research and Development Arrangements

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, we entered into a royalty and milestone payments purchase agreement, or 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, as a treatment for molluscum, and advancing programmatically other activities with respect to SB414, for atopic dermatitis, and SB204, for acne.

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 our own following regulatory approval, as opposed to commercializing through an out-license agreement or other third-party arrangement, we will only be obligated to pay Reedy Creek a low single digits royalty on net sales of the products.

See “Note 6—Research and Development Arrangements” to the accompanying condensed consolidated financial statements for additional information related to the Purchase Agreement.

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, which we used to pursue the development and regulatory approval of SB206, as a treatment for 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 API for our clinical stage product candidates, as a treatment for 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.

See “Note 6—Research and Development Arrangements” to the accompanying condensed consolidated financial statements for additional information related to the Funding Agreement.

Licensing Arrangements

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 $28.8 million from Sato beginning January 2017 through September 30, 2021 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; (iii) $11.2 million of installment payments received following the execution of the Sato Amendment; and (iv) a $4.6 million payment related to a time-based developmental milestone received in the second quarter of 2021. In addition to the upfront payment paid in three installments in 2018 and 2019 that we received from Sato under the terms of the Sato Amendment, 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, of which we received 0.5 billion JPY in the second quarter of 2021.

See “Note 4—Licensing Arrangements” and “Note 5—Revenue Recognition” to the accompanying condensed consolidated financial statements regarding the Amended Sato Agreement.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (16,036)	$ (21,868)
Investing activities	(3,500)	(90)
Financing activities	44,089	50,779
Net increase in cash, cash equivalents and restricted cash	$ 24,553	$ 28,821

Net Cash Used in Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $16.0 million and consisted primarily of a net loss of $21.5 million, with adjustments for non-cash amounts related primarily to (i) depreciation expense of $0.2 million, (ii) impairment of long-lived assets of $0.1 million, (iii) a net favorable adjustment to stock-based compensation of $0.1 million, caused by fair market value adjustments to the Tangible Stockholder Return Plan, (iv) a foreign currency transaction loss of $0.7 million related to fair value adjustments for payments received and to be received under the Amended Sato Agreement, (v) a $1.0 million gain on debt extinguishment related to forgiveness of the PPP loan, and (vi) a $5.4 million

favorable change in cash related to changes in other operating assets and liabilities. The favorable change in cash related to changes in assets and liabilities was primarily due to (i) a $4.4 million decrease in contracts and grants receivable primarily related to receipt of a $4.6 million time-based developmental milestone payment, (ii) a $2.1 million decrease in prepaid insurance, prepaid expenses and other current assets primarily related to the amortization of prepaid service contracts and directors and officers insurance premiums, (iii) a $1.6 million increase in other accrued expenses primarily related to accrued goods and services associated with the planning, design and build-out of our new facility in Durham, North Carolina, (iv) a $0.1 million increase in accrued legal and professional fees, (v) a $0.1 million increase in research and development service obligation liabilities related to the accretion of the liability associated with Ligand, and (vi) a $0.2 million increase in other long-term assets and liabilities. These increases in cash were partially offset by (i) a $2.2 million decrease in deferred revenue associated with our performance under, and revenue recognition of, the Amended Sato Agreement during the nine months ended September 30, 2021, (ii) a $0.7 million decrease in accrued outside research and development services primary related to payments for services related to the SB206 Phase 3 development program, and (iii) a $0.1 million decrease in accrued compensation primarily related to the payment of 2020 performance bonuses in March 2021.

During the nine months ended September 30, 2020, net cash used in operating activities was $21.9 million and consisted primarily of a net loss of $22.7 million, with adjustments for non-cash amounts related primarily to (i) depreciation expense of $1.1 million, (ii) impairment of long-lived assets of $2.4 million, (iii) loss on facility asset group disposition of $0.8 million, (iv) stock-based compensation expense of $0.8 million, (v) fees of $1.7 million related to commitment shares for the June 2020 Aspire CSPA and July 2020 Aspire CSPA, (vi) a loss on disposal of equipment of $0.1 million, and (vii) a $6.1 million net decrease in other operating assets and liabilities. The net decrease in assets and liabilities was primarily due to (i) a $2.2 million decrease in research and development service obligation liabilities related to the amortization of the liability associated with Ligand, (ii) a $3.3 million decrease in deferred revenue associated with our performance under, and revenue recognition of, the Amended Sato Agreement, (iii) $0.3 million decrease in accrued legal and professional fees, and (iv) a $1.4 million decrease in accounts payable. These decreases were partially offset primarily by (i) a $0.7 million decrease in prepaid expenses and other current assets, (ii) a $0.3 million increase in accrued compensation, and (iii) a $0.3 million decrease in contracts and grants receivable. The changes in accounts payable during the nine months ended September 30, 2020 were primarily related to timing of invoice receipts and payments associated with the SB206 Phase 3 development program.

Net Cash Used in Investing Activities

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

During the nine months ended September 30, 2020, the $0.1 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 of $0.4 million, offset by $0.3 million of proceeds from the sale of equipment.

Net Cash Provided by Financing Activities

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

During the nine months ended September 30, 2020, net cash provided by financing activities was $50.8 million and consisted primarily of (i) $5.3 million of proceeds, net of underwriting fees, from closing of our March 2020 Public Offering, (ii) $5.5 million of proceeds from the exercise of common warrants associated with the March 2020 Public Offering, (iii) $7.3 million of proceeds, net of placement agent fees, from our March 2020 Registered Direct Offering, (iv) $1.0 million from the entry into a promissory note for an unsecured loan under the PPP, and (v) $31.9 million of proceeds from the sale of our common stock pursuant to the 2019 Aspire CSPA, the June 2020 Aspire CSPA, and the July 2020 Aspire CSPA. These financing cash inflows

were partially offset by $0.2 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.

Capital Requirements

As of September 30, 2021, we had a total cash and cash equivalents balance of $60.0 million and positive working capital of $48.8 million. 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. As of September 30, 2021, we had an accumulated deficit of $270.7 million.

We will need significant additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates, and our funding needs will largely be determined by our commercialization strategy for SB206, subject to the NDA submission timing and the regulatory approval process and outcome. We are working with Syneos Health to focus on implementing the SB206 prelaunch strategy and commercial preparation, followed by commercial sales of SB206, if approved by the FDA.

Our ability to continue to operate our business, including our ability to advance development programs unrelated to SB206, as well as our ability to progress SB206 for molluscum subsequent to an NDA submission, is dependent upon our ability to access additional sources of capital, including, but not limited to (i) equity or debt financings, including through potential sales using the remaining availability under the July 2020 Aspire CSPA; or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. There can be no assurance that we will be able to obtain new funding on terms acceptable to us, on a timely basis, or at all. Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. We are also exploring the potential for alternative transactions, such as strategic acquisitions or in-licenses, sales or divestitures of some of our assets, or other potential strategic transactions, which could include a sale of the Company. If we were to pursue such a transaction, we may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to us.

Our equity issuances during the year ended December 31, 2020 and the nine months ended September 30, 2021, have resulted in significant dilution to our existing stockholders. Any future additional issuances of equity, or debt that could be convertible into equity, would result in further significant dilution to our existing stockholders.

As of September 30, 2021, we had 18,815,142 shares of common stock outstanding. In addition, as of September 30, 2021, we had reserved 3,066,703 shares of common stock for future issuance related to (i) outstanding warrants to purchase common stock; (ii) outstanding stock options and stock appreciation rights; and (iii) future issuance under the 2016 Incentive Award Plan. Our common stock consists of 200,000,000 authorized shares as of September 30, 2021.

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 new manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204 and SB206 in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies; 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 items described in note “Note 8—Commitments and Contingencies” and the forgiveness of the Loan we received under the PPP as described in “Note 9—Paycheck Protection Program” to the accompanying condensed consolidated financial statements, there were no material changes during the nine months ended September 30, 2021 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; and (iii) 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. 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 nine months ended September 30, 2021, 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 condensed consolidated financial statements.

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.

As of September 30, 2021, our management, with the participation of our principal executive and financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive and financial officers have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level. 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.

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

There have been no 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 three months ended September 30, 2021 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 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 cannot assure you that we will realize the anticipated benefits from our recent reverse stock split.

On May 25, 2021, we effected a one-for-ten Reverse Stock Split of our issued and outstanding shares of our common stock, which we anticipated would result in benefits such as enhancing our ability to raise capital to fund our operations, improving the marketability of our common stock and increasing the appeal of our stock to a broader range of investors. Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, we cannot assure you that the Reverse Stock Split will result in a share price that will attract new investors, including institutional investors, as some investors, analysts and other stock market participants have negative perceptions of reverse stock splits. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve. Also, it is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines further, the percentage decline may be greater than would have occurred in the absence of the Reverse Stock Split.

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

Our stock price has experienced extreme volatility and could vary significantly as a result of many factors. Between January 1, 2021 and November 2, 2021, the last reported sales price of our common stock fluctuated between a high of $25.50 and a low of $6.65. The foregoing stock prices have been adjusted to give effect to the Reverse Stock Split. The market price and trading volume of our common stock may continue to fluctuate from time to time as a result of factors outside of our control. For example, the trading price of our common shares increased significantly in June 2021, which we believe was attributable to general market conditions and recognition of our recently announced top-line results of our B-SIMPLE4 study of SB206 as a treatment for molluscum contagiosum, and has since declined. There is a potential for rapid and substantial decreases in the price of our common stock, including decreases unrelated to our operating performance or prospects, which could result in substantial losses for our existing stockholders.

The continuing effects of the COVID-19 pandemic have had an impact on our business operations and clinical trials and could continue, directly or indirectly, to adversely affect our business, results of operations and financial condition.

As a result of the outbreak of SARS-CoV-2, the virus that causes COVID-19, we may experience disruptions that could impact our supply chain, ongoing and future clinical trials and our work to develop commercialization of SB206. To the extent our suppliers and third party manufacturers are unable to comply with their obligations under our agreements with them or supply chain or other disruptions cause them to be unable to deliver or are delayed in delivering raw materials, API or drug products to us due to COVID-19, our ability to pursue regulatory approval, implement our commercialization efforts for SB206 (if approved) or advance development of our product candidates may become impaired.

COVID-19 continues to evolve and have continuing effects both locally and globally. The extent to which COVID-19, and any variants, may impact our business, including our supply chain, clinical trials and our commercialization efforts for SB206, if approved, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the pandemic.

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

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Amendment to Employment Agreement with Paula Brown Stafford

Effective as of November 9, 2021, we entered into a first amendment, or the Amendment, to the amended and restated employment agreement, effective as of December 17, 2019, with Paula Brown Stafford, our Chairman, Chief Executive Officer and President, or the Employment Agreement, to, among other things, extend the term of the Employment Agreement. As amended, the term of the Employment Agreement will extend to December 31, 2023 and then will automatically extend for successive 1-year periods unless notice is provided by either party prior to the end of the term. The Amendment provides for a grant of 75,000 options to Ms. Stafford in each of 2021 and 2022. The Amendment also provides for the vesting of any then-unvested portion of any outstanding equity awards granted to Ms. Stafford, to give credit for the pro-rated portion of such equity awards for which Ms. Stafford would have qualified based on service through the twelve-month period following the separation date, upon Ms. Stafford's termination without "Cause" or for "Good Reason" not due to a "Change in Control" (each as defined in the Employment Agreement).

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
10.1	First Amendment to Amended and Restated Employment Agreement, dated November 9, 2021, by and between Novan, Inc. and Paula Brown Stafford.	X				
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL Instance document included in Exhibit 101.					

SIGNATURES

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

Novan, Inc.

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

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

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

Date: November 10, 2021

Exhibit 10.1

Execution Copy

FIRST AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This First Amendment to the Amended and Restated Employment Agreement ("Amendment") is effective as of November 9, 2021 (the "Effective Date"), and made and entered into by and among Novan, Inc., a Delaware corporation with its principal place of business in Durham County, North Carolina (the "Company") and Paula Brown Stafford "Executive"). Throughout the remainder of this Agreement, the Company and Executive may be collectively referred to as the "Parties".

WHEREAS, the Company and Executive entered into the Amended and Restated Employment Agreement (the "Employment Agreement"), as of December 17, 2019, under which Executive is currently serving as the Company's President and Chief Executive Officer;

WHEREAS, the Company wishes to extend the term of Executive's Agreement, and provide for additional compensation, including equity compensation, in light of the value of Executive's services to the Company, and Executive wishes to be entitled to such benefits; and

WHEREAS, the Company and Executive wish to amend the Employment Agreement to provide this change.

NOW, THEREFORE, the Company and Executive, intending to be legally bound, and for good and valuable consideration, hereby agree to the following:

1. AMENDMENT TO SECTION 3, COMPENSATION.

   a. Base Salary. Section 3(a) of the Employment Agreement shall be amended by deleting it in its entirety and replacing it with the following:

   "Base Salary. Effective January 1, 2021, Executive shall receive as compensation a base salary at an annual rate of Five Hundred Ninety Eight Thousand Eight Hundred Fifty Dollars ($598,850.00) (the "Base Salary"), less any federal, state and local payroll taxes and other withholdings legally required or properly requested by Executive. Base Salary shall be payable semi-monthly in accordance with the Company's regular payroll practices and procedures. Executive's Base Salary shall be subject to annual review by the Company's Board, and may not be decreased without Executive's consent. Executive shall not receive any additional compensation for service as a director on or as Chairman of the Board of the Company pursuant to her current Board and Chair terms or any subsequent term during the Term."

   b. Stock Appreciation Rights. Section 3(c) of the Employment Agreement shall be amended by deleting the fourth (4th) full sentence and replacing it with the following:

   "The SAR Award will vest over the period ending on December 31, 2021 in equal installments on the last day of each calendar quarter, contingent on Executive's continued

service with the Company, which shall include any uninterrupted service as a director or consultant following termination of employment."

c. Equity Incentive Plans. Section 3(d) of the Employment Agreement shall be amended by adding new Sections 3(d)(i) and 3(d)(ii) as follows:

"Section 3(d)(i):
2021 Option Grant. The Board (or a duly authorized committee thereof) hereby grants Executive 75,000 nonqualified stock options to purchase shares of the Company's Common Stock, with an exercise price to be determined in accordance with the terms of the 2016 Plan (as defined in the Employment Agreement), which options will vest in three (3) installments, with one-half of the options vesting upon the first anniversary of the grant date and one-half of the remaining options vesting on each of the next two annual anniversaries of the grant date, subject to Executive's continuous service with the Company on each such vesting date. Such options will be subject to the terms of the 2016 Plan and the standard stock option award agreement.

Section 3(d)(ii):
2022 Option Grant. Effective on January 3, 2022, the Board (or a duly authorized committee thereof) grants Executive 75,000 nonqualified stock options to purchase shares of the Company's Common Stock, with an exercise price to be determined as of the effective date of such grant in accordance with the terms of the 2016 Plan, subject to Executive remaining employed as of the effective date of such grant. Such options will vest in three (3) installments, with one-half of the options vesting on January 3, 2023, and one-half of the remaining options vesting on January 3, 2024 and January 3, 2025, respectively, subject to Executive's continuous service with the Company on each such vesting date. Such options will be subject to the terms of the 2016 Plan and the standard stock option award agreement."

2. AMENDMENT TO SECTION 4, EMPLOYMENT AT WILL; TERMINATION. Section 4 of the Employment Agreement shall be amended by deleting it in its entirety and replacing it with the following:

"EMPLOYMENT AT WILL; TERMINATION. The initial term of employment under this Agreement (the "Initial Term") shall be for the period beginning on December 17, 2019 and ending on December 31, 2023, unless earlier terminated as provided in this Section 4 and subject to the terms of Section 6. This Agreement shall automatically be extended for successive 1year periods (each, an "Extension Term" and, collectively with the Initial Term, the "Term") unless either party gives notice of nonrenewal to the other no later than 90 days prior to the expiration of the then applicable Term. Subject to Section 6, Executive's employment with the Company is atwill, and either party can terminate the employment relationship and/or this Agreement at any time, for any or no cause or reason, and with or without prior notice."

3. AMENDMENT TO SECTION 6, SEVERANCE PROVISIONS.

a. Section 6(a)(v)(e) shall be amended by deleting it in its entirety.

b. Section 6(b), entitled, Compensation upon Separation without "Cause" or for "Good Reason" Not due to a Change in Control, shall be amended as follows:

i. Section 6(b)(i)(2) shall be deleted and replaced with the following:

"Vesting as of the Separation Date of any then unvested portion of the SAR Award described in Section 3(c) of this Agreement or any then unvested portion of any other equity award from the Company that would have otherwise vested during the twelve (12) month period following the Separation Date (the "Acceleration Period"); provided, however, that if the terms of any unvested equity award provide for quarterly or annual vesting, and a quarterly or annual vesting date occurs after the end of the Acceleration Period, then the acceleration of vesting provided for in this paragraph shall apply such that a percentage of the unvested equity that would otherwise have vested on the first quarterly or annual vesting date occurring after the end of the Acceleration Period will be deemed to be vested as of the Separation Date, with such percentage to be calculated by dividing the number of days between the last applicable vesting date falling within the Acceleration Period and the end of the Acceleration Period by the number of days in the applicable quarterly or annual vesting period; and"

ii. Section 6(b)(ii) shall be deleted in its entirety and the section number shall be reserved.

4. AMENDMENT TO SECTION 9, NOTICES. Section 9 of the Employment Agreement shall be amended by deleting the contact information for the Company, and replacing it with the following:

"If to the Company: Novan, Inc.
4020 Stirrup Creek Drive, suite 110
Durham, NC 27703
(Fax) (919) 237¬9212
Attn: Chair of the Compensation Committee,
Board of Directors"

5. DEFINITIONS. All terms used in this Amendment shall have the same definitions as used in the Employment Agreement, unless otherwise provided herein. All references to the "Employment Agreement" shall include all modifications made by this Amendment, unless provided otherwise.

6. COUNTERPARTS. This Amendment may be executed in counterparts, each of which shall be an original, with the same effect as if the signatures affixed thereto were on the same instrument.

7. EFFECT OF AMENDMENT. This Amendment is effective as of the Effective Date set forth above. Except as specifically amended herein, the Employment Agreement remains in full force and effect.

[Signature Page Follows.]

IN WITNESS WHEREOF, the Parties have entered into this Amendment as of the day and year written below.

NOVAN, INC.

/s/ Robert J. Keegan

Robert J. Keegan
Chairman, Compensation Committee of the Board of Directors

PAULA BROWN STAFFORD

/s/ Paula Brown Stafford

Exhibit 31.1

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

I, Paula Brown Stafford, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

/s/ Paula Brown Stafford

Paula Brown Stafford

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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

I, John M. Gay, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

/s/ John M. Gay

John M. Gay

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 10, 2021

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

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

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

Exhibit 32.2

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 10, 2021

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

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

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