

**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, 2019

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

(State or other jurisdiction of
incorporation or organization)

20-4427682

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

**4105 Hopson Road
Morrisville, North Carolina**

(Address of principal executive offices)

27560

(zip code)

(919) 485-8080

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of November 6, 2019, there were 26,715,356 shares of the registrant's Common Stock outstanding.

Table of Contents

	<u>Page</u>
<u>PART I - FINANCIAL INFORMATION</u>	<u>3</u>
Item 1. <u>Financial Statements</u>	<u>3</u>
<u>Unaudited Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018</u>	<u>3</u>
<u>Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2019 and 2018</u>	<u>4</u>
<u>Unaudited Condensed Consolidated Statements of Stockholders' (Deficit) Equity for the three and nine months ended September 30, 2019 and 2018</u>	<u>5</u>
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018</u>	<u>6</u>
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	<u>7</u>
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>31</u>
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>52</u>
Item 4. <u>Controls and Procedures</u>	<u>52</u>
 <u>PART II - OTHER INFORMATION</u>	 <u>53</u>
Item 1. <u>Legal Proceedings</u>	<u>53</u>
Item 1A. <u>Risk Factors</u>	<u>53</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>53</u>
Item 3. <u>Defaults Upon Senior Securities</u>	<u>53</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>53</u>
Item 5. <u>Other Information</u>	<u>53</u>
Item 6. <u>Exhibits</u>	<u>54</u>
<u>Signatures</u>	<u>55</u>

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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,549	\$ 8,194
Restricted cash	5,651	—
Contracts and grants receivable	216	—
Deferred offering costs	49	49
Prepaid expenses and other current assets	982	1,107
Total current assets	22,447	9,350
Restricted cash	1,345	539
Intangible assets	75	75
Other assets	444	530
Property and equipment, net	10,569	15,868
Right-of-use lease assets	1,837	—
Total assets	\$ 36,717	\$ 26,362
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 2,495	\$ 1,250
Accrued compensation	1,507	1,467
Accrued outside research and development services	1,382	563
Accrued legal and professional fees	168	498
Other accrued expenses	878	871
Deferred revenue, current portion	4,401	4,401
Research and development service obligation liability, current portion	5,651	—
Lease liabilities, current portion	1,156	11
Total current liabilities	17,638	9,061
Deferred revenue, net of current portion	3,725	2,566
Lease liabilities, net of current portion	5,249	10
Warrant liability	10,270	1,240
Research and development service obligation liability, net of current portion	806	—
Research and development funding arrangement liability, related party	25,000	—
Other long-term liabilities	1,634	289
Facility financing obligation	—	7,998
Total liabilities	64,322	21,164
Commitments and contingencies (Note 8)		
Stockholders' (deficit) equity		
Common stock \$0.0001 par value; 200,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 26,524,856 and 26,066,235 shares issued as of September 30, 2019 and December 31, 2018, respectively; 26,515,356 and 26,056,735 shares outstanding as of September 30, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	179,047	177,677
Treasury stock at cost, 9,500 shares as of September 30, 2019 and December 31, 2018	(155)	(155)
Accumulated deficit	(206,500)	(172,327)
Total stockholders' (deficit) equity	(27,605)	5,198
Total liabilities and stockholders' (deficit) equity	\$ 36,717	\$ 26,362

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,	
	2019	2018	2019	2018
License and collaboration revenue	\$ 1,100	\$ 648	\$ 3,301	\$ 1,946
Government research contracts and grants revenue	216	—	216	—
Research and development services revenue	—	—	—	9
Total revenue	1,316	648	3,517	1,955
Operating expenses:				
Research and development	8,598	5,697	19,614	18,208
General and administrative	2,290	3,295	8,595	8,795
Total operating expenses	10,888	8,992	28,209	27,003
Operating loss	(9,572)	(8,344)	(24,692)	(25,048)
Other (expense) income, net:				
Interest income	53	83	149	242
Interest expense	—	(262)	(1)	(785)
Change in fair value of warrant liability	1,160	1,464	(9,030)	5,733
Other income, net	23	28	115	32
Total other (expense) income, net	1,236	1,313	(8,767)	5,222
Net loss and comprehensive loss	\$ (8,336)	\$ (7,031)	\$ (33,459)	\$ (19,826)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.27)	\$ (1.28)	\$ (0.77)
Weighted-average common shares outstanding, basic and diluted	26,189,454	26,046,666	26,108,870	25,707,978

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

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

Nine Months Ended September 30, 2019

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2018	26,056,735	\$ 3	\$ 177,677	\$ (155)	\$ (172,327)	\$ 5,198
Share-based compensation	—	—	168	—	—	168
Exercise of stock options	12,999	—	10	—	—	10
Net loss	—	—	—	—	(7,025)	(7,025)
Adoption of new accounting standards (Note 1)	—	—	—	—	(714)	(714)
Balance as of March 31, 2019	26,069,734	\$ 3	\$ 177,855	\$ (155)	\$ (180,066)	\$ (2,363)
Share-based compensation	—	—	245	—	—	245
Net loss	—	—	—	—	(18,098)	(18,098)
Balance as of June 30, 2019	26,069,734	\$ 3	\$ 178,100	\$ (155)	\$ (198,164)	\$ (20,216)
Share-based compensation	—	—	320	—	—	320
Liability-based awards reclassified to additional paid-in capital	—	—	366	—	—	366
Common stock issued pursuant to common stock purchase agreement	445,622	—	261	—	—	261
Net loss	—	—	—	—	(8,336)	(8,336)
Balance as of September 30, 2019	26,515,356	\$ 3	\$ 179,047	\$ (155)	\$ (206,500)	\$ (27,605)

Nine Months Ended September 30, 2018

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2017	16,005,408	\$ 2	\$ 158,091	\$ (155)	\$ (159,654)	\$ (1,716)
Share-based compensation	—	—	887	—	—	887
Common stock issued through public offering, net of underwriting discounts, warrants, commissions and offering costs (Note 1)	10,000,000	1	17,387	—	—	17,388
Exercise of stock options	33,334	—	37	—	—	37
Net loss	—	—	—	—	(5,217)	(5,217)
Balance as of March 31, 2018	26,038,742	\$ 3	\$ 176,402	\$ (155)	\$ (164,871)	\$ 11,379
Share-based compensation	—	—	546	—	—	546
Exercise of stock options	1,700	—	5	—	—	5
Net loss	—	—	—	—	(7,578)	(7,578)
Balance as of June 30, 2018	26,040,442	\$ 3	\$ 176,953	\$ (155)	\$ (172,449)	\$ 4,352
Share-based compensation	—	—	367	—	—	367
Exercise of stock options	14,167	—	16	—	—	16
Net loss	—	—	—	—	(7,031)	(7,031)
Balance as of September 30, 2018	26,054,609	\$ 3	\$ 177,336	\$ (155)	\$ (179,480)	\$ (2,296)

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,	
	2019	2018
Cash flow from operating activities:		
Net loss	\$ (33,459)	\$ (19,826)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,531	1,234
Share-based compensation	2,444	1,903
Loss on disposal and write-offs of property and equipment	36	93
Change in fair value of warrant liability	9,030	(5,733)
Changes in operating assets and liabilities:		
Contracts and grants receivable	(216)	—
Prepaid expenses and other current assets	125	300
Accounts payable	1,245	(87)
Accrued compensation	40	(479)
Accrued outside research and development services	819	179
Accrued legal and professional fees	(289)	(61)
Other accrued expenses	(17)	(463)
Deferred revenue	1,159	(1,982)
Advanced payment for research and development service obligation	12,000	—
Research and development service obligation liabilities	(5,543)	—
Other long-term assets and liabilities	(326)	46
Net cash used in operating activities	(11,421)	(24,876)
Cash flow from investing activities:		
Purchases of property and equipment	(38)	(869)
Proceeds from the sale of property and equipment	—	41
Net cash used in investing activities	(38)	(828)
Cash flow from financing activities:		
Proceeds from research and development funding arrangement	25,000	—
Proceeds from issuance of common stock, net of underwriting fees and commissions	261	35,625
Payments related to public offering costs	—	(322)
Proceeds from exercise of stock options	10	58
Payments on capital lease obligation	—	(8)
Net cash provided by financing activities	25,271	35,353
Net increase in cash, cash equivalents and restricted cash	13,812	9,649
Cash, cash equivalents and restricted cash as of beginning of period	8,733	3,063
Cash, cash equivalents and restricted cash as of end of period	\$ 22,545	\$ 12,712
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment with accounts payable and accrued expenses	\$ 24	\$ 84
Liability-based awards reclassified to additional paid-in capital	\$ 366	\$ —
Common stock issued for payment of commitment fee	\$ 750	\$ —
Deferred offering costs reclassified to additional paid-in capital	\$ —	\$ 431
Reconciliation to condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 15,549	\$ 12,173
Restricted cash included in current assets	5,651	—
Restricted cash included in noncurrent assets	1,345	539
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	\$ 22,545	\$ 12,712

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

NOVAN, INC.

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

Note 1: Organization and Significant Accounting Policies

Business Description and Basis of Presentation

Novan, Inc. (“Novan” and together with its subsidiaries, the “Company”), is a North Carolina-based clinical development-stage biotechnology company focused on leveraging nitric oxide’s naturally occurring anti-viral, anti-bacterial, anti-fungal and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. Novan was incorporated in January 2006 under the state laws of Delaware. Its wholly-owned subsidiary, Novan Therapeutics, LLC was organized in 2015 under the state laws of North Carolina. On March 14, 2019, the Company completed registration of a wholly-owned Ireland-based subsidiary, Novan Therapeutics, Limited.

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”). The December 31, 2018 year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP. Additionally, the Company’s independent registered public accounting firm report for the December 31, 2018 financial statements included an explanatory paragraph indicating that there is substantial doubt about the Company’s ability to continue as a going concern.

Basis of Consolidation

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

Liquidity and Ability to Continue as a Going Concern

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

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

- The Company has reported a net loss in all fiscal periods since inception and, as of September 30, 2019, the Company had an accumulated deficit of \$206,500.
- As described in Note 6—Research and Development Arrangements, in April 2019 and May 2019 the Company entered into (i) a royalty and milestone payments purchase agreement with a stockholder providing \$25,000 of immediate funding, with an additional \$10,000 contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020; and (ii) a development funding and royalties agreement with a corporate partner providing \$12,000 of immediate funding.
- As described in Note 9—Stockholders’ Equity, in August 2019 the Company entered into a common stock purchase agreement (the ‘Aspire Common Stock Purchase Agreement’) with Aspire Capital Fund, LLC, (“Aspire Capital”) which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25,000 of shares of the Company’s common stock at the Company’s request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement. In consideration for entering into the Aspire Common Stock Purchase Agreement, concurrently with the execution of the Aspire Common Stock Purchase Agreement, the Company issued to Aspire Capital 345,622 shares of the Company’s common stock as a commitment fee. As of September 30, 2019, the Company has sold 100,000 shares of common stock at a price of \$2.61 per share under the Aspire

Common Stock Purchase Agreement. The Company has remaining availability for sales of its common stock under the Aspire Common Stock Purchase Agreement of up to \$24,739 as of September 30, 2019.

- As of September 30, 2019, the Company had a total cash, cash equivalents and restricted cash balance of \$22,545.
- The Company believes that its existing cash, cash equivalents and restricted cash balance and expected contractual payments to be received in connection with previous licensing agreements will (i) provide the Company with adequate liquidity to fund its planned operating needs into the first quarter of 2020, including through expected top-line results of the SB206 Phase 3 clinical trials targeted in the first quarter of 2020, or before; and (ii) into the second quarter of 2020, if paired with the potential \$10,000 funding contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020. This projected cash runway excludes potential sales of common stock under the Aspire Common Stock Purchase Agreement.
- The Company's primary use of cash is to fund its operating expenses, which consist principally of research and development expenditures necessary to advance its product candidates. The Company has evaluated its expected, probable future cash flow needs and has determined that it expects to incur substantial losses in the future as it conducts planned operating activities. As such, the Company has concluded that the prevailing conditions and ongoing liquidity risks it faces raise substantial doubt about its ability to continue as a going concern. The Company will need substantial additional funding to continue its operating activities and make further advancements in its drug development programs beyond those planned in 2019 and the first half of 2020.

The failure of the Company to obtain sufficient funds on acceptable terms, including the inability to utilize the maximum amount available under the Aspire Common Stock Purchase Agreement, or the failure to trigger the \$10,000 contingent payment under the Company's royalty and milestone payments purchase agreement, 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 intends to secure additional capital as needed, including under the Aspire Common Stock Purchase Agreement. Additional capital may potentially include (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings, which could cause dilution.

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 financial statements and notes for the year ended December 31, 2018 set forth in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2019.

Contracts and Grants Receivable

The Company carries its contracts and grants receivable net of an allowance for doubtful accounts. All receivables or portions thereof that are deemed to be uncollectible or that require excessive collection costs are written off to the allowance for doubtful accounts when it is probable that the receivable is unrecoverable. The Company actively reviews and evaluates its contracts and grants receivable, but no allowance for doubtful accounts has been considered necessary as of September 30, 2019. Actual results could differ from the estimates that were used. The Company did not have a contracts and grants receivable balance as of December 31, 2018.

Restricted Cash

Restricted cash as of September 30, 2019 and December 31, 2018 includes \$539 of funds maintained in a separate deposit account to secure a letter of credit for the benefit of the lessor of facility space leased by the Company. Restricted cash as of September 30, 2019 also includes \$6,457 to be used for the development of SB206 for the treatment of molluscum contagiosum, pursuant to the funding agreement with Ligand Pharmaceuticals Incorporated (“Ligand”) described in Note 6—Research and Development Arrangements.

Leases

The Company’s significant accounting policies regarding leases are described in Note 1 of the Notes to the Consolidated Financial Statements included in its Annual Report on Form 10-K for the year ended December 31, 2018. Updates to the Company’s accounting policies, including impacts from the adoption of new accounting standards, are discussed within the section below, “Accounting Pronouncements Adopted”, and within Note 8—Commitments and Contingencies.

Impairment of Long-Lived Assets

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

During the three and nine months ended September 30, 2019 and September 30, 2018, respectively, the Company concluded there were no such events or changes in circumstances requiring review of the carrying amount of the Company’s long-lived assets.

Revenue Recognition

The Company’s revenue includes research revenue earned under contracts and grants with Federal government agencies, which relates to the research and development of its nitric oxide platform.

Government research contracts and grants revenue. Under the terms of the contracts and grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts. Revenues from development and support activities under unconditional government research contracts and grants are recorded in the period in which the related costs are incurred for cost reimbursement grants. Revenue is recognized when earned and expenses are recognized when incurred as research and development expense. Any of the funding sources may, at their discretion, request reimbursement for expenses or return of funds, or both, as a result of noncompliance by the Company with the terms of the grants. No reimbursement of expenses or return of funds has been requested or made since inception of the contracts and grants. Revenue related to conditional government contracts and grants is recognized when the conditions outlined in the government contract or grant have been met. See Note 5—Revenue Recognition for information regarding two government grants the Company received in the third quarter of 2019.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration of common stock equivalents. 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, 2019 and 2018 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,	
	2019	2018
Warrants to purchase common stock associated with January 2018 public offering (Note 10)	10,000,000	10,000,000
Stock options outstanding under the 2008 and 2016 Plans (Note 11)	1,806,502	1,626,488
Stock appreciation rights outstanding under the 2016 Plan (Note 11)	1,000,000	—
Inducement options outstanding (Note 11)	125,500	100,500

Segment and Geographic Information

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

Although all operations are based in the United States, the Company generated revenue from its licensing partner in Japan of \$1,100, or approximately 84% of total revenue, and \$3,301, or approximately 94% of total revenue, during the three and nine months ended September 30, 2019, respectively. The Company generated revenue from its licensing partner in Japan of \$648 and \$1,946 during the three and nine months ended September 30, 2018, respectively, which represented substantially all of the Company's revenue for those periods.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. This guidance revises the accounting related to leases by requiring lessees to recognize a lease liability and a right-of-use asset for all leases. The new lease guidance also simplifies the accounting for sale and leaseback transactions. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, and in March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*. These additional ASUs were issued to provide expanded or clarifying guidance associated with the application of certain principles. Under the guidance, lessees are required to recognize assets and lease liabilities on the balance sheet for most leases including operating leases and provide enhanced disclosures. There are optional practical expedients that a company may elect to apply. The guidance was effective for the Company beginning in its first quarter of 2019.

The Company adopted Topic 842 as of January 1, 2019 using the modified alternative retrospective transition method and initially applied the transition provisions as of January 1, 2019. This transition method allowed the Company to continue to apply the legacy guidance in ASC 840 for periods prior to 2019 and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit as of the date of adoption.

The Company elected the package of transition practical expedients, which, among other things, allowed the Company to keep the historical lease classifications and not have to reassess the lease classification and initial direct costs for any existing or expired leases as of the date of adoption. The Company also made an accounting policy election to apply the short-term lease exception, which allows the Company to exclude leases with an initial term of twelve months or less from the consolidated balance sheets. Lease expense for leases with an initial term of twelve months or less will be recognized over the lease term, similar to the accounting treatment under ASC 840.

As a result of the adoption of Topic 842, the Company derecognized \$10,557 of building assets (property, plant and equipment), and the \$7,998 facility financing obligation associated with the previously existing build-to-suit arrangement related to its sole corporate and manufacturing facility. The Company also capitalized leasehold improvements and ROU assets of \$5,885 and \$1,827, respectively, and recorded lease liabilities for operating leases totaling \$6,786, as of January 1, 2019. The capitalized leasehold improvement assets recorded as part of the adoption of Topic 842 were previously included within the derecognized building asset as part of the previous build-to-suit arrangement. The Company also recognized an increase of \$714 to accumulated deficit related to its de-recognition of its previously recorded build-to-suit arrangement. The impact of the adoption of this guidance is non-cash in nature and did not affect the Company's cash flows. See Note 8—Commitments and Contingencies for additional information related to the adoption of Topic 842.

[Table of Contents](#)

In June 2018 the FASB issued ASU 2018-08 *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. This guidance clarifies and improves the scope and the accounting guidance for contributions received and contributions made, in order to reduce diversity in practice for grants and other similar contracts. For contributions (nonreciprocal transactions), an entity should follow the guidance in ASC 958-605 *Not-for-Profit Entities - Revenue Recognition*, and for exchange (reciprocal) transactions an entity should follow other guidance. This standard is effective for annual reporting periods beginning after June 15, 2018, including interim reporting periods within those annual reporting periods, with early adoption permitted. This ASU was effective for the Company as of January 1, 2019. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements. See Note 5—Revenue Recognition for information related to the adoption of Topic 958.

In June 2018, the FASB issued ASU No. 2018-07 *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This guidance simplifies the accounting for non-employee share-based payment transactions by expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Under the new standard, most of the guidance on stock compensation payments to non-employees would be aligned with the requirements for share-based payments granted to employees. This standard is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within those annual reporting periods, with early adoption permitted. This ASU was effective for the Company as of January 1, 2019. The adoption of this new accounting guidance did not have a material impact on the Company's condensed consolidated financial statements.

Accounting Pronouncements Being Evaluated

In August 2018, the FASB issued ASU No. 2018-13 *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This guidance is intended to improve the effectiveness of disclosure requirements on fair value measurements in Topic 820. The new standard modifies certain disclosure requirements and will be effective for annual reporting periods beginning after December 15, 2019. The Company is currently evaluating the impact of adoption of this ASU and does not expect the adoption of this new standard to have a material impact on its condensed consolidated financial statements.

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

In November 2018, the FASB issued ASU No. 2018-18 *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. Contracts with Customers*. This ASU provided guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact of adoption of this ASU and does not expect the adoption of this new standard to have a material impact on its 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 is an independent, privately held company with a portfolio of operating subsidiaries that are advancing nitric oxide-based therapies using technology that is proprietary and/or in fields where they have exclusive intellectual property rights. The Company does not own any equity interest in KNOW Bio, has no common management or board representation at KNOW Bio, and the contractual arrangements between the two entities do not provide the Company with decision-making authority or power to influence KNOW Bio's drug and medical device development activities.

The Company conducted an initial assessment of KNOW Bio under the variable interest consolidation model pursuant to FASB ASC 810 *Consolidation*, at the time of the Distribution in 2015 and has monitored KNOW Bio during each subsequent reporting period, including two required ASC 810 reassessments performed during 2017. The Company has consistently

determined that KNOW Bio should not be consolidated in its consolidated financial statements. In the fourth quarter of 2018, KNOW Bio and its operating subsidiaries received significant additional equity investments that enable progression of their technology. These events required the Company to conduct another reassessment of variable interest entity characteristics, pursuant to FASB ASC 810-10, *Consolidation*, in which it determined that KNOW Bio should not be consolidated in its consolidated financial statements.

KNOW Bio Technology Agreements

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

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

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the “KNOW Bio Sublicense Agreements” and together with the KNOW Bio License Agreement, the “Original KNOW Bio Agreements”). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the U.S. and foreign patents and patent applications exclusively licensed to the Company from UNC (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, 2019 and 2018.

Amendments to License and Sublicense Agreements with KNOW Bio

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

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

Upon execution of the KNOW Bio Amendments, in exchange for the Oncovirus Field rights, the Company paid a non-refundable upfront payment of \$250. Products the Company develops in the Oncovirus Field based on Nitricil will not be subject to any further milestones, royalties or sublicensing payment obligations to KNOW Bio under the KNOW Bio Amendments. However, if the Company develops products in the Oncovirus Field that incorporate a certain nitric oxide-

releasing composition specified in the KNOW Bio Amendments and (i) are covered by KNOW Bio patents; or (ii) materially use or incorporate know-how of KNOW Bio or the Company related to such composition that was created between December 29, 2015 and December 29, 2018, the Company would be obligated to make certain contingent milestone and royalty payments to KNOW Bio under the KNOW Bio Amendments.

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

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

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

Note 3: Research and Development Licenses

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

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

UNC License Agreement

The Amended, Restated and Consolidated License Agreement dated June 27, 2012, as amended, (the “UNC License Agreement”) provides the Company with an exclusive license to issued patents and pending applications directed to the Company’s library of Nitricil compounds, including patents issued in the U.S., Japan and Australia, with claims intended to cover NVN1000, the NCE for the Company’s current product candidates. The UNC License Agreement requires the Company to pay UNC up to \$425 in regulatory and commercial milestones on a licensed product by licensed product basis and a running royalty percentage in the low single digits on net sales of licensed products. Licensed products include any products being developed by the Company or by its sublicensees.

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

Note 4: Licensing Arrangements

Sato License Agreement

Significant Terms

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

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

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

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

The term of the Amended Sato Agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory (adjusted from the tenth anniversary of the first commercial sale in the license 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 license agreement remain unchanged by the Sato Amendment.

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

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

Note 5: Revenue Recognition

Sato Agreement

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

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

Amended Sato Agreement

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

The Company concluded that the following consideration would be included in the transaction price as they were (i) received prior to September 30, 2019; 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.

[Table of Contents](#)

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

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

	Contract Asset	Contract Liability	Net Deferred Revenue
December 31, 2018	\$ 17,790	\$ 24,757	\$ 6,967
September 30, 2019	\$ 13,330	\$ 21,456	\$ 8,126
	Short-term Deferred Revenue	Long-term Deferred Revenue	Net Deferred Revenue
December 31, 2018	\$ 4,401	\$ 2,566	\$ 6,967
September 30, 2019	\$ 4,401	\$ 3,725	\$ 8,126

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 nine months ended September 30, 2019 was associated with the receipt of the second installment payment of 0.5 billion JPY (approximately \$4,460 USD), and recognition of license and collaboration revenue associated with the Company’s performance during the period (continued amortization of deferred revenue). During the three and nine months ended September 30, 2019, the Company recognized \$1,100 and \$3,301, respectively, in license and collaboration revenue under this agreement. During the three and nine months ended September 30, 2018, the Company recognized \$648 and \$1,946, respectively, in license and collaboration revenue under this agreement.

The Company has concluded that the above consideration is probable of not resulting in a significant revenue reversal and therefore included in the transaction price and is allocated to the single performance obligation. No other variable consideration under the Amended Sato Agreement is probable of not resulting in a significant revenue reversal as of September 30, 2019 and therefore, is currently fully constrained and excluded from the transaction price.

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

Prior to the Sato Amendment, the Company estimated the Sato Agreement development timeline for the SB204 product candidate to be approximately 5 years, starting in February 2017 and completing in the first quarter of 2022. With the Amended Sato Agreement, the Company and Sato are developing both the SB204 and SB206 product candidates for the Japan territory. The parties continue to work collaboratively to reach agreement, but have not yet reached agreement, with respect to the combined SB204 and SB206 development plan for the Japan territory, including a corresponding timeline and estimated duration for the combined development program. The Company’s current estimated timeline remains 7.5 years, starting in February 2017 and completing in the third quarter of 2024. The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. Therefore, if the duration of the combined SB204 and SB206 development program timeline is affected by the establishment or subsequent adjustments to a mutually agreed upon

SB204 and SB206 development plan in the Japan territory, the Company will adjust its estimated performance period for revenue recognition purposes accordingly, as needed.

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

Contract costs—Sato Agreement

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

- The Company entered into an agreement with a third party to assist the Company in exploring the licensing opportunity which led to the execution of the Sato Agreement. The Company is obligated to pay the third party a low-single-digit percentage of all upfront and milestone payments the Company receives from Sato under the Amended Sato Agreement.
- The intellectual property rights granted to Sato under the Sato Agreement include certain intellectual property rights which the Company has licensed from UNC. Under the UNC License Agreement described in Note 3—Research and Development Licenses, the Company is obligated to pay UNC a running royalty percentage in the low single digits on net sales of licensed products, including net sales that may be generated by Sato. Additionally, the Company is obligated to make payments to UNC that represent the portion of the Sato upfront and milestone payments that were estimated to be directly attributable to the UNC intellectual property rights included in the license to Sato.

Performance Obligations under the Sato Agreement

The net amount of existing performance obligations under long-term contracts unsatisfied as of September 30, 2019 was \$8,126. The Company expects to recognize approximately 21% 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 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 from the National Institutes of Health. 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. Upon completion of grant Phase 1 preclinical work, the Company may be eligible to receive further awards for Phase 2 and 3 extensions under this grant. Revenue recognized under this grant was \$26 during the three and nine months ended September 30, 2019.

In September 2019, the Company received a grant from the U.S. Department of Defense's Congressionally Directed Medical Research Programs of approximately \$1,113 as part of its Peer Reviewed Cancer Research Program. The grant will support the development of a non-gel formulation product candidate (WH504) designed to treat high-risk HPV infections that can lead to CIN, with well-characterized physical chemical properties suitable for intravaginal administration. In addition, the grant will support the evaluation of the effect of varying concentrations and treatment durations of berdazimer sodium (NVN1000) against

HPV-18 in human raft cell culture in vitro studies. Revenue recognized under this grant was \$190 during the three and nine months ended September 30, 2019.

Research and Development Services to KNOW Bio

The Company entered into a services agreement with KNOW Bio (the “KNOW Bio Services Agreement”) during 2017 and provided research and development services on a fee-for-service basis. After assessing revenue according to the five-step model of ASC 606, the Company determined that contract research and development services revenue should be recognized in the period in which the services are performed. During the nine months ended September 30, 2018, the Company recognized \$9 in research and development services revenue for services performed under the KNOW Bio Services Agreement. There was no research and development services revenue recognized during the three and nine months ended September 30, 2019 or the three months ended September 30, 2018.

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, which the Company will use primarily to pursue the development, regulatory approval and commercialization (including through out-license agreements and other third party arrangements) activities for SB206, a topical anti-viral gel being developed for the treatment of molluscum contagiosum, and advancing programmatically such activities with respect to SB204, a once-daily, topical monotherapy being developed for the treatment of acne vulgaris, and SB414, a topical cream-based product candidate being developed for the treatment of atopic dermatitis. Reedy Creek will also provide additional funding to the Company of \$10,000 contingent upon the achievement by the Company of SB206 clinical trial success, defined as (i) the achievement, no later than March 31, 2020, of statistically significant rates of complete clearance of lesions for molluscum contagiosum in humans at week 12 in each of the two Phase 3 clinical trials or any other primary endpoint required or accepted by the FDA for the SB206 product; or (ii) equivalent achievement (as agreed upon by the parties).

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

The Company has determined that the Reedy Creek Purchase Agreement is within the scope of ASC 730-20, *Research and Development Arrangements*. The Company concluded that there has not been a substantive and genuine transfer of risk related to the Purchase Agreement as (i) Reedy Creek has the opportunity to recover its investment regardless of the outcome of the research and development programs within the scope of the agreement (prior to commercialization of any in scope assets through potential out-licensing agreements and related potential future milestone payments); and (ii) there is a presumption that the Company is obligated to pay Reedy Creek amounts equal to its investment based on the related party relationship at the time the parties entered into the Purchase Agreement. The Purchase Agreement is a broad funding arrangement, due to (i) the multi-asset, or portfolio approach including three developmental assets that are within the scope of the arrangement; and (ii) Reedy Creek’s approximate 15% ownership of the outstanding shares of common stock of the Company.

As such, the Company has determined that the appropriate accounting treatment under ASC 730-20 is to record the initial proceeds of \$25,000 as cash and cash equivalents, as the Company has the ability to direct the usage of funds, and a long-term liability within its classified balance sheet. The long-term liability will remain until the Company receives future milestones from other potential third parties, as defined within the Purchase Agreement, of which 25% will be contractually owed to Reedy Creek. If potential future milestones are received by the Company, and become partly due to Reedy Creek, the corresponding

partial repayment to Reedy Creek will result in a ratable reduction of the total long-term obligation to repay the initial purchase price.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

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

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

The Company has 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. 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 has concluded that the appropriate accounting treatment under ASC 730-20 is to record the initial proceeds of \$12,000, as restricted cash, as the funds can only be used for the progression of SB206, and a liability on its condensed consolidated balance sheet. The Company will amortize the liability ratably, based on the Ligand funding as a percentage of the total direct costs incurred by the Company related to the progression of the SB206 program. The ratable Ligand funding will be presented within the consolidated statement of operations as an offset to research and development expenses associated with SB206.

For the three and nine months ended September 30, 2019, the Company recorded \$3,350 and \$5,543, respectively, as contra-research and development expense related to the SB206 developmental program, funded by Ligand.

Note 7: Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Computer equipment	\$ 575	\$ 577
Furniture and fixtures	305	312
Laboratory equipment	7,467	7,442
Office equipment	339	400
Building related to facility lease obligation	—	10,557
Leasehold improvements	7,058	1,168
Property and equipment, gross	15,744	20,456
Less: Accumulated depreciation and amortization	(5,175)	(4,588)
Total property and equipment, net	\$ 10,569	\$ 15,868

Depreciation and amortization expense was \$510 and \$1,531 for the three and nine months ended September 30, 2019, respectively, and \$425 and \$1,234 for the three and nine months ended September 30, 2018, respectively.

See Note 1—Organization and Significant Accounting Policies and Note 8—Commitments and Contingencies regarding the adoption of Topic 842, *Leases*, and its impact to property and equipment, net for the nine months ended September 30, 2019.

Note 8: Commitments and Contingencies

Lease Obligations

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

Prior to January 1, 2019, the Company applied the accounting guidance in ASC 840, *Leases*, to its lease agreements. The leases were reviewed for classification as operating or capital leases. For operating leases, rent was recognized on a straight-line basis over the lease period. For capital leases, the Company recorded the leased asset with a corresponding liability and amortized the asset over the lease term. Payments were recorded as reductions to the liability with an appropriate interest charge recorded based on the then-outstanding remaining liability.

The Company considered the nature of the renovations and the Company's involvement during the construction period of previously leased office space to determine if it was considered to be the owner of the construction project during the construction period. If the Company determined that it was the owner of the construction project, it was required to capitalize the fair value of the building as well as the construction costs incurred, including capitalized interest, on its consolidated balance sheet along with a corresponding financing liability ("build-to-suit accounting"). Upon completion of the construction of the facility under a build-to-suit lease, the Company assessed whether the circumstances qualified for sales recognition under the sale-leaseback accounting guidance. If the lease met the sale-leaseback criteria, the Company would remove the asset and related financial obligation from the balance sheet and evaluate the lease for treatment as a capital or operating lease. If upon completion of construction, the project did not meet the sale-leaseback criteria, the leased property was treated as an asset financing for financial reporting purposes. The portion of the facility financing obligation representing the principal that was to be repaid in the following 12 months was classified as a current liability in the condensed consolidated balance sheets, with the remaining portion of the obligation classified as a noncurrent liability.

Beginning January 1, 2019, the Company applies the accounting guidance in ASC 842, *Leases*. As such, the Company assesses all arrangements, that convey the right to control the use of property, plant and equipment, at inception, to determine if it is, or contains, a lease based on the unique facts and circumstances present in that arrangement. For those leases identified, the Company determines the lease classification, recognition, and measurement at the lease commencement date. For arrangements that contain a lease the Company: (i) identifies lease and non-lease components; (ii) determines the consideration in the contract; (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease Right of Use ("ROU") assets and corresponding lease liabilities. Lease liabilities are recorded based on the present value of lease payments over the expected lease term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents; (ii) remaining unamortized initial direct costs and lease incentives; and (iii) any impairments of the ROU asset. The interest rate implicit in the Company's lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. The weighted average discount rate utilized on the Company's operating lease liabilities as of September 30, 2019 was 9.85%. The weighted average remaining lease term for the Company's operating leases as of September 30, 2019 was 6.75 years.

Primary Facility Lease

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

Prior to January 1, 2019, the Company applied the accounting guidance in ASC 840. Based on that guidance, the facility was accounted for as an asset financing, with the building asset and related facility financing obligation remaining on the Company's balance sheet. The building asset was being depreciated over a 25 year period and the facility financing obligation was amortized so that the net carrying value of the building asset and the facility financing obligation were to be equivalent at the end of the initial term of the lease agreement. Monthly rental payments were allocated between principal and interest expense associated with the facility financing obligation, as well as grounds rent expense of \$8 per month.

The Company had recorded an asset related to the building and construction costs within property and equipment of \$10,557 as of December 31, 2018. The non-current facility lease obligation on the Company's condensed consolidated balance sheet was \$7,998 as of December 31, 2018. During the three and nine months ended September 30, 2018, the Company recognized

[Table of Contents](#)

interest expense related to the primary facility lease of \$261 and \$783, respectively, and there was \$41 of accrued interest included in other accrued expenses as of December 31, 2018.

The Company adopted Topic 842 as of January 1, 2019 using the modified retrospective transition method and initially applied the transition provisions as of January 1, 2019. This transition method allowed the Company to continue to apply the legacy guidance in ASC 840 for periods prior to 2019 and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit as of the date of adoption.

The Company elected the package of transition practical expedients, which, among other things, allowed the Company to keep the historical lease classifications and not have to reassess the lease classification for any existing leases as of the date of adoption. The Company also made an accounting policy election to apply the short-term lease exception, which allows the Company to exclude leases with an initial term of twelve months or less from the consolidated balance sheets.

As a result of the adoption of Topic 842, the Company derecognized \$10,557 of building asset (property, plant and equipment), and \$7,998 of facility financing obligation associated with previously existing build-to-suit arrangement related to its sole corporate and manufacturing facility. The Company also capitalized leasehold improvements and ROU assets of \$5,885 and \$1,827, respectively, and recorded lease liabilities for operating leases totaling \$6,786, as of January 1, 2019. The capitalized leasehold improvement assets recorded as part of the adoption of Topic 842 were previously included within the derecognized building asset as part of the previous build-to-suit arrangement. The Company also recognized an increase of \$714 to accumulated deficit related to its de-recognition of its previously recorded build-to-suit arrangement.

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

Rent expense, including both short-term and variable lease components associated with the primary facility lease, was \$225 and \$655 for the three and nine months ended September 30, 2019, respectively, and \$89 and \$220 for the three and nine months ended September 30, 2018, respectively.

The Company's supplemental non-cash disclosure for its ROU assets obtained in exchange for lease liabilities was \$1,827 for the nine months ended September 30, 2019.

At January 1, 2019, maturities of operating lease liabilities over each of the next five years and thereafter were as follows:

	Operating Leases
2019	\$ 1,170
2020	1,205
2021	1,241
2022	1,278
2023	1,317
Thereafter	3,467
Total minimum lease payments	\$ 9,678
Less imputed interest	(2,871)
Total lease liability	\$ 6,807

Primary Facility Sublease

In July 2018, the Company and a third-party tenant entered into a sublease of approximately 6,400 square feet of office space at the Company's headquarters. The sublease has a three-year, non-cancellable term and provides for monthly rental income to the Company of approximately \$12 per month through July 2021. The Company has classified the sublease as an operating lease pursuant to classification criteria in ASC 842 and is recognizing the rental income on a straight-line basis over the lease term. In October 2019, the Company executed a termination agreement with the subtenant for this sublease, with an effective date of December 31, 2019.

Contingencies

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

The Company has entered into, and expects to continue to enter into, contracts in the normal course of business with various third parties who support its clinical trials, preclinical research studies and other services related to its development activities. The scope of the services under these agreements can generally be modified at any time, and these agreements can generally be terminated by either party after a period of notice and receipt of written notice. There have been no material contract terminations as of September 30, 2019.

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.

Legal Proceedings

In prior filings, the Company reported that it was subject to putative stockholder class action lawsuits that were filed in November 2017 in the United States District Court for the Middle District of North Carolina against the Company and certain of its current and former directors and officers, which were consolidated under the case name *In re Novan, Inc. Securities Litigation*. The consolidated amended complaint filed by the designated lead plaintiff asserted claims for violation of Sections 11 and 15 of the Securities Act of 1933 and Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, in connection with statements related to the Company’s Phase 3 clinical trials of SB204. On June 14, 2018, the Company filed a motion to dismiss the consolidated amended complaint. On November 30, 2018, a federal magistrate judge entered an order recommending that the district court grant the Company’s motion. The plaintiff filed objections to this recommendation and the Company filed a response. On January 28, 2019, the district court adopted the magistrate judge’s recommendation, dismissed the action with prejudice and entered judgment in favor of the Company and against the plaintiff. The plaintiff did not appeal this dismissal and judgment. As such, the Company has concluded that this matter is closed.

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

Compensatory Obligations

In conjunction with the departures of three former Company officers in 2019 and 2018, the Company entered into separation and general release agreements that included separation benefits consistent with the Company’s obligations under their previously existing employment agreements for “separation from service” for “good reason.” The Company recognized related severance expense of \$878 and \$332, during the nine months ended September 30, 2019 and 2018, respectively. The remaining accrued severance obligation in respect of the three former officers was \$228 as of September 30, 2019, which is included in accrued compensation in the accompanying condensed consolidated balance sheet. The Company also recognized non-cash stock compensation expense of \$0 and \$212 during the nine months ended September 30, 2019 and 2018, respectively, related to the accelerated vesting of the former officers’ stock options. There was no severance expense or non-cash stock compensation expense in relation to these departures during the three months ended September 30, 2019 and 2018.

In November 2018, the Company realigned its overall employee headcount to reduce certain fixed costs. As of September 30, 2019, severance costs of \$48 were accrued in the accompanying consolidated balance sheet related to this realignment.

See Note 11—Share-Based Compensation regarding the contingent award of Stock Appreciation Rights granted in August 2018.

See Note 12—Tangible Stockholder Return Plan regarding the Tangible Stockholder Return Plan adopted in August 2018.

Note 9: Stockholders' Equity

Capital Structure

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

Aspire Common Stock Purchase Agreement

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

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

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

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

The Aspire Common Stock Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Aspire Common Stock Purchase Agreement on any purchase date where the closing sale price of the Company's common stock is less than \$0.25. There are no trading volume requirements or restrictions under the Aspire Common Stock Purchase Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the Aspire Common Stock Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financing transactions, rights of first refusal, participation rights, penalties or liquidated damages in the Aspire Common Stock Purchase Agreement. The Aspire Common Stock Purchase Agreement may be terminated by the Company at any time, at its discretion, without any penalty or additional cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the Aspire Common Stock Purchase Agreement. Any proceeds the Company receives under the Aspire Common Stock Purchase Agreement are expected to be used for working capital and general corporate purposes.

The Aspire Common Stock Purchase Agreement provides that the number of shares that may be sold pursuant to the Aspire Common Stock Purchase Agreement will be limited to 5,211,339 shares (the "Exchange Cap"), which represents 19.99% of the Company's

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

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

As of September 30, 2019, the Company has sold 100,000 shares of common stock at a price of \$2.61 per share under the Aspire Common Stock Purchase Agreement. The Company has remaining availability for sales of its common stock under the Aspire Common Stock Purchase Agreement of up to \$24,739 as of September 30, 2019.

January 2018 Offering

On January 9, 2018, the Company completed a public offering of its common stock and warrants pursuant to the Company's effective shelf registration statement (the "January 2018 Offering"). The Company sold an aggregate of 10,000,000 shares of common stock and warrants to purchase up to 10,000,000 shares of the Company's common stock at a public offering price of \$3.80 per share of common stock and accompanying warrant. The warrant exercise price is \$4.66 per share and will expire four years from the date of issuance. Net proceeds from the offering were approximately \$35,194 after deducting underwriting discounts and commissions and offering expenses of approximately \$2,806.

The Company incurred costs directly related to (i) the shelf registration statement filing totaling \$110; and (ii) the January 2018 Offering completed in January 2018 totaling \$370, all of which were initially capitalized and included in deferred offering costs. A pro-rata portion of the shelf registration offering costs and all of the January 2018 Offering costs were reclassified to additional paid-in capital upon completion of the January 2018 Offering.

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, 2019 and December 31, 2018. There were 26,515,356 and 26,056,735 shares of voting common stock outstanding as of September 30, 2019 and December 31, 2018, respectively.

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

	September 30, 2019	December 31, 2018
Outstanding stock options (Note 11)	1,932,002	1,671,666
Warrants to purchase common stock issued in January 2018 Offering (Note 10)	10,000,000	10,000,000
Outstanding stock appreciation rights (Note 11)	1,000,000	—
For possible future issuance under 2016 Stock Plan (Note 11)	280,208	699,376
	<u>13,212,210</u>	<u>12,371,042</u>

Preferred Stock

The Company's amended and restated certificate of incorporation provides the Company's board of directors with the authority to issue \$0.0001 par value preferred stock from time to time in one or more series by adopting a resolution and filing a certificate of designations. Voting powers, designations, preferences, dividend rights, conversion rights and liquidation preferences shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and no shares outstanding as of September 30, 2019 and December 31, 2018.

Note 10: Warrants

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period, pursuant to the fair value measurements policy described below. This determination requires significant judgments to be made.

For warrants that are issued or modified and there is a deemed possibility that the Company may have to settle them in cash, the Company records the fair value of the warrants at the initial measurement date, or date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the consolidated statements of operations and comprehensive loss.

The Company has categorized its financial instruments, based on the priority of the inputs used to value the investments, into a three-level fair value hierarchy. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). If the inputs used to measure the investments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the investment. The fair value of warrants falls within Level 3 of the hierarchy as there is currently no active trading market.

On January 9, 2018, the Company sold an aggregate of 10,000,000 shares of common stock and issued warrants to purchase up to 10,000,000 shares of common stock at a public offering price of \$3.80 per share of common stock and accompanying warrant. Pursuant to the warrant agreement and form of warrant dated January 9, 2018 (the "Warrant Agreement"), the warrant exercise price is \$4.66 per share and the warrants will expire four years from the date of issuance.

The Warrant Agreement includes a provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 4.99% (or an amount up to 9.99% if the holder so elects) of the Company's common stock. The Warrant Agreement also provides that the aforementioned exercise limitation provision is not applicable to any warrant holder that beneficially owns 10.0% or more of the Company's outstanding common stock immediately following the closing of the January 2018 Offering and the issuance of the accompanying warrants.

If, at any time the warrants are outstanding, any fundamental transaction occurs, as described in the Warrant Agreement and generally including any consolidation or merger whereby another entity acquires more than 50% of the Company's outstanding common stock, or the sale of all or substantially all of its assets, the successor entity must assume in writing all of the obligations to the warrant holders. Additionally, in the event of a fundamental transaction, the Warrant Agreement provides that each warrant holder will have the right to require the Company, or its successor, to repurchase the warrants for an amount of cash equal to the Black-Scholes value of the remaining unexercised portion of the warrants. Further, the Warrant Agreement states that the volatility input used to derive such Black-Scholes value is the greater of the Company's historical volatility or 100%. Due to the provision that the warrant holder has the option to receive a cash settlement, equal to the Black-Scholes fair value of the remaining unexercised portion of the warrant, in the event that there is a fundamental transaction, the Company has classified the warrants as liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

[Table of Contents](#)

There were no exercises of warrants during the three and nine months ended September 30, 2019 and 2018. The following table presents the Company's warrant liability measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018:

	September 30, 2019			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 10,270	\$ 10,270
Total liabilities at fair value	\$ —	\$ —	\$ 10,270	\$ 10,270

	December 31, 2018			Total
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 1,240	\$ 1,240
Total liabilities at fair value	\$ —	\$ —	\$ 1,240	\$ 1,240

The fair value of the common stock warrants is estimated using a valuation model that approximates a Monte Carlo simulation model, which takes into consideration the probability of a fundamental transaction occurring during the contractual term of the warrants. This valuation model, which includes inputs classified as Level 3 in the fair value hierarchy, estimated a fair value of \$1.03 and \$0.12 per common stock warrant as of September 30, 2019 and December 31, 2018, respectively. The inputs to the valuation model that approximates a Monte Carlo simulation model are presented below.

	September 30, 2019	December 31, 2018
Estimated dividend yield	—	—
Expected volatility	95.36%-100%	77.74%-100%
Risk-free interest rate	1.61%	2.46%
Expected term (years)	2.28	3.02
Fair value per share of common stock underlying the warrant	\$ 2.58	\$ 0.83
Warrant exercise price	\$ 4.66	\$ 4.66

Due to the Company's limited historical stock price data, the Company estimates stock price volatility based on the actual historical volatility of a group of comparable publicly traded companies observed over a historical period equal to the expected life of the warrant.

The decrease in fair value of the warrants of \$1,160 and increase in fair value of the warrants of \$9,030 for the three and nine months ended September 30, 2019, respectively, as well as the decrease in fair value of the warrants of \$1,464 and \$5,733 for the three and nine months ended September 30, 2018, respectively, are included as components of other income and expense in the Company's condensed consolidated statements of operations and comprehensive loss. The change in the warrant liability and the corresponding unrealized loss/gain recognized during the three and nine months ended September 30, 2019 and 2018, respectively, is primarily due to the fluctuations in the market price of the Company's underlying common stock from the date of issuance to September 30, 2019, in addition to fluctuations in the other valuation model inputs.

The following table summarizes the change in the fair value of the warrant liability, which is valued using significant unobservable Level 3 inputs, for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Beginning Balance	\$ 11,430	\$ 13,537	\$ 1,240	\$ —
Issuance	—	—	—	17,806
Revaluations Included In Earnings	(1,160)	(1,464)	9,030	(5,733)
Exercises	—	—	—	—
Expirations	—	—	—	—
Ending Balance	\$ 10,270	\$ 12,073	\$ 10,270	\$ 12,073

Note 11: Share-Based Compensation

2016 Stock Plan

During the nine months ended September 30, 2019, 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 August 16, 2018, the board of directors approved an amendment to the 2016 Plan (“the 2016 Plan Amendment”), subject to stockholder approval, to increase the number of shares reserved under the 2016 Plan by 1,000,000 and to increase the award limit on the maximum aggregate number of shares of the Company’s common stock that may be granted to any one person during any calendar year from 250,000 to 1,000,000 shares of the Company’s common stock. On July 31, 2019, at the Company’s 2019 Annual Meeting of Stockholders, stockholders approved the 2016 Plan Amendment. All other material terms of the 2016 Plan otherwise remain unchanged.

Stock Appreciation Rights

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

The SARs entitle Mr. Martin to a payment (in cash, shares of common stock or a combination of both) equal to the fair market value of one share of the Company’s common stock on the date of exercise less the exercise price of \$3.80 per share. The SARs will vest in full on February 1, 2020. The SARs will be deemed automatically exercised and settled as of February 1, 2020, provided Mr. Martin remains continuously employed with the Company through such date unless vesting is otherwise expressly accelerated pursuant to the SAR Agreement.

Due to the contingent nature of the SAR grant, prior to stockholder approval on July 31, 2019, these share-based payment awards were classified as liabilities and the amount of compensation cost recognized was based on the fair value of those liabilities. The corresponding obligation was recorded within other long-term liabilities on the Company’s condensed consolidated balance sheet at the estimated fair value on the date of issuance and was re-valued each subsequent reporting period with adjustments to the fair value recognized as share-based compensation expense in the condensed consolidated statements of operations.

Subsequent to stockholder approval, the SARs were no longer considered to be granted on a contingent basis. As the Company has the sole discretion to settle any awards with cash, common stock or a combination of both, as of July 31, 2019, the SARs were reclassified from liability to equity-based awards at fair value and reclassified to additional paid-in capital. The fair value of the SARs was estimated using the Black-Scholes option pricing model on the July 31, 2019 remeasurement date. The reclassification from other long-term liabilities to additional paid-in capital in the condensed consolidated balance sheet was \$366 as of July 31, 2019.

[Table of Contents](#)

During the three months ended September 30, 2019, the Company recorded a reduction to employee share-based compensation expense, including fair value adjustments related to the SAR, of \$3. During the nine months ended September 30, 2019, the Company recorded employee share-based compensation expense of \$413 related to the SAR. During the three and nine months ended September 30, 2018, the Company recorded employee share-based compensation expense related to the SARs of \$65.

Inducement Grants

During the nine months ended September 30, 2019 and 2018, the Company awarded nonstatutory stock options to purchase shares of common stock to newly-hired employees, as inducements material to the individuals' entering into employment with the Company within the meaning of Nasdaq Listing Rule 5635(c)(4) (the "Inducement Grants"). On May 31, 2018, the Company awarded 100,500 Inducement Grants with an exercise price of \$3.15 per share, and on September 6, 2019, the Company awarded 25,000 Inducement Grants with an exercise price of \$2.62 per share. The Inducement Grants were awarded outside of the Company's 2016 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), but have terms and conditions generally consistent with the Company's 2016 Plan and vest over three years, subject to the employee's continued service as an employee or consultant through the vesting period.

Stock Compensation Expense

During the three and nine months ended September 30, 2019, the Company recorded employee share-based compensation expense of \$690 and \$2,444, respectively. During the three and nine months ended September 30, 2018, the Company recorded employee share-based compensation expense of \$470 and \$1,903, respectively. Total share-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 376	\$ 204	\$ 957	\$ 907
General and administrative	314	266	1,487	996
	<u>\$ 690</u>	<u>\$ 470</u>	<u>\$ 2,444</u>	<u>\$ 1,903</u>

Stock option activity for the nine months ended September 30, 2019 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, 2018	1,671,666	\$ 5.42		
Options granted	658,030	2.36		
Options forfeited	(384,695)	7.26		
Options exercised	(12,999)	0.76		
Options outstanding as of September 30, 2019	<u>1,932,002</u>	<u>\$ 4.05</u>	<u>8.24</u>	<u>\$ 211</u>

As of September 30, 2019, there were a total of 1,932,002 stock options outstanding, including 125,500 inducement grants. In addition, there were 280,208 shares available for future issuance under the 2016 Plan as of September 30, 2019.

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 is tiered, with two separate tranches, each of which has a distinct share price target (measured as the average publicly traded share price of the Company's common stock on the Nasdaq stock exchange for a 30 consecutive trading day period) that will, if achieved, trigger a distinct fixed bonus pool. The share price target for the first tranche and related bonus pool are \$11.17 per share and \$25,000, respectively. The share price target for the second tranche and related bonus pool

are \$25.45 per share and \$50,000, respectively. The compensation committee has discretion to distribute the bonus pool related to each tranche among eligible participants by establishing individual minimum bonus amounts before, as well as by distributing the remainder of the applicable pool after, the achievement of each tranche specific share price target. Otherwise, if the Company does not achieve one or both related share price targets, as defined, no portion of the bonus pools will be paid.

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

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

For purposes of determining whether a share price target has been met, the share price targets will be adjusted in the event of any stock splits, cash dividends, stock dividends, combinations, reorganizations, reclassifications or similar events. In the event of a change in control, as defined in the Performance Plan, during the term of the Performance Plan, a performance bonus pool will be generated based on pro-rata progress toward achievement of the applicable share price target through the date of the change in control.

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

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

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

During the three and nine months ended September 30, 2019, the Company recorded employee share-based compensation expense related to the Performance Plan of \$429 and \$1,353, respectively. During the three and nine months ended September 30, 2018, the Company recorded employee share-based compensation expense related to the Performance Plan of \$38.

Note 13: Related Party Transactions

Members of the Company's board of directors held 1,002,776 and 782,083 shares of the Company's common stock as of September 30, 2019 and December 31, 2018, respectively.

In June 2017, G. Kelly Martin was appointed as the Company's Interim Chief Executive Officer before being named as the Company's Chief Executive Officer in April 2018. Mr. Martin continues to serve as a member of the Company's board of directors and previously served as chief executive officer of Malin Corporation plc until October 1, 2017. Malin Corporation plc is the parent company of Malin Life Sciences Holdings Limited ("Malin"), which beneficially owns approximately 10% of the Company's outstanding common stock.

Two of the Company's directors during 2018 were also affiliated with Malin. Sean Murphy, who resigned from the Company's board in September 2018, was an executive officer and a director of Malin, and an executive vice president of Malin Corporation plc. In addition, Robert A. Ingram, the Company's executive chairman of the board, was also a director of Malin Corporation plc until July 2018.

Cilatus BioPharma

During the three and nine months ended September 30, 2019, the Company incurred costs of \$78 and \$250, respectively, in relation to a development and manufacturing consulting agreement with Cilatus BioPharma AG ("Cilatus Agreement"), which is majority-owned by Malin Corporation plc. During the three and nine months ended September 30, 2018, the Company incurred costs of \$121 and \$491, respectively, under the Cilatus Agreement. These costs are expensed as incurred and are classified as research and development expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. Estimated fees remaining under the current statements of work are approximately \$93, and are expected to be incurred throughout the remainder of 2019.

Health Decisions

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

Reedy Creek

Reedy Creek beneficially owns approximately 15% of the Company's outstanding common stock and approximately 3.9 million warrants, all of which was acquired during the Company's public offering of common stock and accompanying warrants in January 2018. Accordingly, Reedy Creek is a related party of the Company. The purchase agreement with Reedy Creek, described in Note 6—Research and Development Arrangements, was evaluated and approved pursuant to the Company's existing related party transactions policy.

Note 14: Subsequent Events

Sato Payment

On November 7, 2019, the Company received the final installment payment related to the Amended Sato Agreement of 0.5 billion JPY (approximately \$4,554 USD).

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, 2018 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 27, 2019.

In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. These statements are often identified by the use of words such as “believe,” “contemplate,” “continue,” “due,” “goal,” “objective,” “plan,” “seek,” “target,” “expect,” “believe,” “anticipate,” “intend,” “may,” “will,” “would,” “could,” “should,” “potential,” “predict,” “project,” or “estimate,” and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Except as may be required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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

- We will need substantial additional funding and as of September 30, 2019, we had an accumulated deficit of \$206.5 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 eventual commercialization efforts.*
- We have entered into and rely on, and may enter into and rely on other, strategic relationships for the further development and commercialization of our product candidates and if we are unable to enter into such relationships on favorable terms or at all, or if such relationships are unsuccessful, if disputes arise between us and our strategic partners or if we fail to trigger contingent payments under such strategic relationships, we may be unable to realize the potential economic benefit of those product candidates.*
- Ongoing or future product development activities and preclinical studies may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of our product candidates.*
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.*
- Delay or termination of planned clinical trials for our product candidates could result in unplanned expenses or significantly adversely impact our remaining developmental activities and potential commercial prospects with respect to, and ability to generate potential revenues from, such product candidates.*
- We may not be able to achieve the objectives described in the section entitled “Overview—Key Product Candidate Development Updates” and “Overview—Business Updates” below. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for any of our product candidates, or regulatory approval of our product candidates.*
- The regulatory approval processes of the Food and Drug Administration, or FDA, are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.*
- We specialize solely in developing nitric oxide-based therapeutics to treat a range of diseases with significant unmet needs, and if we do not successfully achieve regulatory approval for any of our product candidates or successfully commercialize them, we may not be able to continue as a business.*
- The issuance of shares upon exercise of our outstanding warrants and options or sales under the Common Stock Purchase Agreement with Aspire Capital Fund, LLC may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.*

[Table of Contents](#)

- *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, 2018 financial statements included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern.*
- *We rely on third parties to conduct some of our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.*
- *We currently manufacture clinical trial materials internally and we intend to utilize third parties, including Orion Corporation, or Orion, to manufacture components of our clinical trial materials and, potentially, commercial supplies of any approved product candidates. If we do not have sufficient quantities of clinical trial materials at acceptable quality levels and within established timelines, it could adversely impact our development and potential future commercialization of any of our product candidates or result in our breaching our obligations to others.*
- *Unexpected delays in our ability to manufacture our NVN1000 active pharmaceutical ingredient, or API, or the associated drug product in a deliverable form, in our facility or at a third party manufacturer for support of our development and/or commercialization activities could adversely affect our development and commercialization timelines and result in increased costs of our development programs.*
- *We intend to rely on third parties to manufacture raw materials, including our NVN1000 API, and drug product components utilized in clinical trial materials for us and parties with which we contract. Failure to transfer technology and processes to third parties, including our NVN1000 API contract manufacturer and Orion, effectively or failure of those third parties to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities, to provide us with sufficient quantities of raw materials, including API, and drug product components or to provide such raw materials or drug product components at acceptable quality levels or prices could adversely impact our development and potential future commercialization of any of our product candidates or result in our breaching our obligations to others.*
- *Our product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.*
- *Our product candidates, if approved, will face significant competition, and our failure to effectively compete may prevent us from achieving significant market penetration.*
- *If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.*
- *If we are unable to establish sales, marketing and distribution capabilities for our product candidates or any future product candidate that receives regulatory approval, either through a commercial partner or internally, we may not be successful in commercializing and generating potential revenues from those product candidates, if approved.*
- *Changes to our leadership team or operational resources could prove disruptive to our operations and have adverse consequences for our business and operating results.*
- *We recently broadened the focus of our product development strategy, and there can be no guarantee that these areas of our platform will be successful or the most profitable.*

For a further discussion of risks that could cause or contribute to differences between actual results and those implied by forward-looking statements, see the “Risk Factors” section of the Annual Report on Form 10-K filed with the SEC on March 27, 2019.

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

Overview

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

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

We are advancing strategic development programs in the field of dermatology, while also further expanding the platform into women's health and gastroenterological, or GI, therapeutic areas. We have clinical-stage dermatology drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208) and anti-inflammatory (SB414) mechanisms of action. We have recently introduced SB207 as a possible product candidate for additional anti-viral programs. We are also conducting preclinical work on NCEs and formulations for the treatment of human papilloma virus, or HPV, related illnesses in the women's health field (WH504 and WH602) and inflammatory diseases in the GI field. Further advancement of these development activities is dependent upon our ability to access additional capital. Additional capital may potentially include (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings, which could cause dilution. We are actively pursuing capital sourcing pathways through ongoing discussions around our late-stage assets and the broader dermatology platform.

As of September 30, 2019, we had a total cash, cash equivalents and restricted cash balance of \$22.5 million and positive working capital of \$4.8 million. As described below in "Business Updates", in late April 2019 and early May 2019 we entered into (i) a royalty and milestone payments purchase agreement with a stockholder providing \$25.0 million of immediate funding, with an additional \$10.0 million contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020; and (ii) a development funding and royalties agreement with a corporate partner providing \$12.0 million of immediate funding.

As also described below, in August 2019 we entered into a common stock purchase agreement, or the Aspire Common Stock Purchase Agreement, with an institutional investor, Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock at our request from time to time during the 30-month term of the agreement.

We believe that our existing cash, cash equivalents and restricted cash balance and a contractual payment received in the fourth quarter of 2019 in connection with a previous licensing agreement will (i) provide us with adequate liquidity to fund our planned operating needs into the first quarter of 2020, including through expected top-line results of the SB206 Phase 3 clinical trials targeted in the first quarter of 2020, or before; and (ii) into the second quarter of 2020, if paired with the potential \$10.0 million funding contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020. This projected cash runway excludes potential sales of common stock under the Aspire Common Stock Purchase Agreement, described below. As of September 30, 2019, up to \$24.7 million remains available to us for sales of common stock under the Aspire Common Stock Purchase Agreement.

We expect that we will continue to incur substantial expenses as we continue clinical trials and preclinical studies for, and research and development of, our product candidates and maintain, expand and protect our intellectual property portfolio. We will need additional funding to continue our operating activities and make further advancements in our drug development programs. Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

Our near-term programmatic focus remains on our molluscum contagiosum (SB206) and atopic dermatitis (SB414) programs.

We conducted and completed our SB206 Phase 2 trial for the treatment of molluscum contagiosum in December 2018 and in early March 2019, completed an end-of Phase 2 meeting with the FDA and received written minutes. During the second quarter of 2019, we commenced the Phase 3 pivotal development program for the treatment of molluscum contagiosum. Patient recruitment for the Phase 3 trials was completed in August 2019 and top line results are targeted no later than early in the first quarter of 2020.

[Table of Contents](#)

We have completed two complementary Phase 1b clinical trials with SB414 in patients with psoriasis and atopic dermatitis. During the second quarter of 2019, we initiated non-clinical studies with SB414 for atopic dermatitis to support a Phase 2 program launch, with clinical startup procedures initiating in the fourth quarter of 2019. We currently plan to enroll our first patient in this Phase 2 program in the first quarter of 2020, and expect top line results in the fourth quarter of 2020.

Key Product Candidate Development Updates

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

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

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

With the full results from this Phase 2 trial made available, we held an end-of-Phase 2 (Type B) meeting with the FDA in early March 2019. Based on this meeting and the written minutes received, we commenced the Phase 3 development program for molluscum, primarily comprised of two pivotal clinical trials, in the second quarter of 2019 with SB206 12% once-daily as the active treatment arm. The Phase 3 pivotal trials consist of two multi-center, randomized, double-blind, vehicle-controlled studies to evaluate the efficacy and safety of SB206 12% once-daily in approximately 680 patients (2:1 active:vehicle randomization), ages 6 months and above, with molluscum. Patients will be treated once-daily with SB206 12% or Vehicle Gel once daily for a minimum of 4 weeks and up to 12 weeks to all treatable lesions (baseline and new). There will be visits at Screening/Baseline, Week 2, Week 4, Week 8, Week 12 and safety follow-up at Week 24. The primary endpoint is the proportion of patients achieving complete clearance of all molluscum lesions at Week 12. Both Phase 3 pivotal trials began dosing patients in June 2019 and we completed patient recruitment in August 2019. We target top line results no later than early in the first quarter of 2020.

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

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

Atopic Dermatitis

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

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

[Table of Contents](#)

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 initiated non-clinical studies in the second quarter of 2019 to support the Phase 2 program launch, with clinical startup procedures initiating in the fourth quarter of 2019. We currently plan to enroll our first patient in this Phase 2 program in the first quarter of 2020, and expect top line results in the fourth quarter of 2020. We expect that we will need to obtain additional financing, including potential utilization of the Aspire Common Stock Purchase Agreement, or strategic partnering in order to complete the Phase 2 clinical program.

Psoriasis

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

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

SB204, for the Treatment of Acne Vulgaris

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

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

Business Updates

Expansion of Nitric Oxide Platform

In October 2019, we submitted a request for a pre-IND meeting with the FDA for a new anti-viral product candidate, SB207. We anticipate that the meeting will be held in December 2019. We have identified targeted viral opportunities of high unmet need where we believe our nitric oxide releasing technology could provide clinical benefit to patients. The SB207 product incorporates our existing drug substance, berdazimer sodium (NVN1000), with a new formulation specifically engineered for a number of anti-viral programs, including external genital warts.

Advancement in Women's Health

In August 2019, we received a Phase 1 Federal grant of approximately \$0.2 million from the National Institutes of Health. The funds are to be used to advance formulation development of a nitric oxide-containing intravaginal gel (WH602) designed to

[Table of Contents](#)

treat high-risk HPV infections that can lead to cervical intraepithelial neoplasia, or 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 our clinical and in vitro studies. Upon completion of grant Phase 1 preclinical work, we may be eligible to receive further awards that would focus on the completion of IND-enabling toxicology and pharmacology studies and other preclinical activity with respect to WH602.

In September 2019, we received a Federal grant from the U.S. Department of Defense's, or DoD, Congressionally Directed Medical Research Programs, or CDMRP, of approximately \$1.1 million as part of its Peer Reviewed Cancer Research Program. The grant will support the development of a non-gel formulation product candidate (WH504) designed to treat high-risk HPV infections that can lead to CIN, with well-characterized physical chemical properties suitable for intravaginal administration. In addition, the grant will support the evaluation of the effect of varying concentrations and treatment durations of berdazimer sodium (NVN1000) against HPV-18 in human raft cell culture in vitro studies. This targeted research aims to create a disease-altering treatment that could be used upon detection and the early signs of high-risk HPV infection to intervene before progression to cervical cancer.

These product candidates currently in development together represent the core of our Women's Health business unit. This unit will continue to be supported through a collaboration with Health Decisions, Inc., or Health Decisions.

Purchase Agreement and Registration Rights Agreement with Aspire Capital

On August 30, 2019, we entered into the Aspire Common Stock Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock at our request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement. Concurrently with entering into the Aspire Common Stock Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreement, 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, or the Securities Act, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Aspire Common Stock Purchase Agreement. On September 16, 2019, we filed with the Securities and Exchange Commission, or the SEC, a prospectus to our effective Registration Statement on Form S-1 (File No. 333-233632) registering 7,032,630 shares of common stock that have been and may be offered to Aspire Capital from time to time under the Aspire Common Stock Purchase Agreement.

There are no trading volume requirements or restrictions under the Aspire Common Stock Purchase Agreement, and we will 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 Aspire Common Stock Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financing transactions, rights of first refusal, participation rights, penalties or liquidated damages in the Aspire Common Stock Purchase Agreement. In consideration for entering into the Aspire Common Stock Purchase Agreement, concurrently with the execution of the Aspire Common Stock Purchase Agreement, we issued to Aspire Capital 345,622 shares of our common stock, or the Commitment Shares. The Aspire Common Stock Purchase Agreement may be terminated by us any time, at our discretion, without any penalty or additional cost to us. Any proceeds we receive under the Aspire Common Stock Purchase Agreement are expected to be used for working capital and general corporate purposes.

As of September 30, 2019, we have sold 100,000 shares of common stock at a price of \$2.61 per share under the Aspire Common Stock Purchase Agreement, and up to \$24.7 million remain available to us for sales of common stock under the Aspire Common Stock Purchase Agreement. Please refer to "Liquidity and Capital Resources" for further discussion of the Aspire Common Stock Purchase Agreement and the Registration Rights Agreement.

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 Investments LLC, or Reedy Creek, pursuant to which Reedy Creek provided us funding in an initial amount of \$25.0 million, which we will use primarily to pursue the development, regulatory approval and commercialization (including through out-license agreements and other third party arrangements) activities for SB206, for the treatment of molluscum, and advancing programmatically other activities with respect to SB414, for atopic dermatitis, and SB204, for acne. Reedy Creek will also provide \$10.0 million of additional funding contingent upon our achievement of SB206 clinical trial success, defined as (i) the achievement, no later than March 31, 2020, of statistically significant rates of complete clearance of lesions for molluscum contagiosum in humans at week 12 in each of the two Phase 3 clinical trials or any other primary endpoint required or accepted by the FDA for the SB206 product; or (ii) equivalent achievement (as agreed upon by the parties). Pursuant to the

[Table of Contents](#)

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 SB204, SB206 and SB414 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 such 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 SB204, SB206 or SB414 on our own following regulatory approval, as opposed to commercializing through an out-license agreement or other third party arrangement, we will be obligated to pay Reedy Creek a low single digit royalty on net sales of such products.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

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

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

Drug Substance and Drug Product Agreements

On October 15, 2018, we established a strategic alliance with Orion, a Finnish full-scale pharmaceutical company with broad experience in 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 intend for Orion to be able to manufacture the drug product, or the finished dosage form of the gel, in accordance with our established manufacturing processes, in compliance with applicable regulatory guidelines, as appropriate for clinical trials and alongside our current internal manufacturing capabilities. The expansion of this agreement enables the manufacture of multiple assets for clinical trial materials and, potentially, commercial quantities. Importantly, this alliance is being aligned to support major global markets in which we and our partners pursue regulatory approvals for our product candidates and complements our present internal capability.

In June 2019, we executed a master contract manufacturing agreement with a full-scale active pharmaceutical ingredient (API) manufacturer. The agreement establishes an operating and business relationship for this manufacturer to become the primary external supplier of our proprietary berdazimer sodium (NVN1000) drug substance. Also incorporated in the agreement is the process and analytical method transfer necessary to advance the production of our berdazimer sodium (NVN1000) drug substance for future clinical trials and importantly, upon approval of any of our drug product candidates, for commercial purposes on a global basis.

Our relationships with the aforementioned third party manufacturers are integral to our operating strategy which includes an increased utilization of and reliance upon third party vendors and strategic partners for the performance of activities, processes and services that (i) do not result in the generation of significant new intellectual property; and (ii) can leverage existing robust infrastructure, systems, and facilities as well as associated subject matter expertise. Our strategic objective is to reduce our own internal resources, facilities, and infrastructure of capabilities that have historically performed such activities, processes and services. While we will incur certain discrete costs as we transition to this new operating strategy, we believe it will ultimately provide operating efficiencies and allow us to direct a greater portion of our capital towards the generation of new technologies and intellectual property.

[Table of Contents](#)

Addition of Gastrointestinal Disease as a Therapeutic Focus

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

Corporate Updates

Organizational Alignment with Current Strategy

In September 2019, we hired and appointed Michelle Patterson as Vice President of Project Management. She will manage the delivery of key product portfolio milestones by integrating work activity across our business functions including regulatory, pre-clinical, clinical, manufacturing and our chemistry, manufacturing and controls, or CMC, processes. Ms. Patterson will lead the cross-functional coordination and orchestration of integrated project plans for the SB206 NDA submission, should results from the Phase 3 clinical program in mollusum be positive. Ms. Patterson reports to Paula Brown Stafford, President and Chief Operating Officer.

Stock Appreciation Rights

As described in Note 11—Share-Based Compensation, on August 8, 2018, we entered into an employment agreement with G. Kelly Martin, or the Employment Agreement. The Employment Agreement provided for 1,000,000 stock appreciation rights, or SARs, granted on a contingent basis that would have been considered irrevocably forfeited and voided in full if we failed to obtain stockholder approval for an amendment to the 2016 Incentive Award Plan, or the 2016 Plan. If such approval had not been obtained, we would have been required to pay Mr. Martin the cash equivalent of the value of the SARs.

On July 31, 2019, at our 2019 Annual Meeting of Stockholders, our stockholders approved a proposal to amend the 2016 Plan, to (i) increase the number of shares of our common stock reserved for issuance under the 2016 Plan by 1,000,000 shares; and (ii) increase the limit on the number of awards that may be granted to any one person in any year. As such, with stockholder approval of the amendment to the 2016 Plan, the SARs detailed within the Employment Agreement have been awarded to Mr. Martin and are no longer considered granted on a contingent basis.

Financial Overview

Since our inception in 2006, we have devoted substantially all of our efforts to developing our nitric oxide platform technology and resulting product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We conduct these activities in a single operating segment. We have not generated any revenue from product sales and, to date, have funded our operations through a variety of sources described in further detail within the "Liquidity and Capital Resources" section below. From inception through September 30, 2019, we have raised total equity and debt proceeds of \$184.3 million to fund our operations. In addition, through September 30, 2019, we have also generated additional liquidity and capital through other sources including (i) governmental research contracts and grants totaling \$11.8 million, excluding two grants to us from Federal agencies in the third quarter of 2019 for which funds have not yet been received; (ii) our licensing and supply arrangements with Sato Pharmaceutical Co., Ltd., or Sato, totaling \$19.7 million, excluding a payment received in the fourth quarter of 2019, described below; and (iii) \$37.0 million in proceeds from two funding transactions during the second quarter of 2019, also described below.

The approximately \$19.7 million we have received from Sato from January 2017 through September 30, 2019 under our amended license agreement includes a \$10.8 million upfront payment received following the execution of the agreement in January 2017, a \$2.2 million payment related to the initiation of a Phase 1 trial in Japan in the third quarter of 2018, and \$6.7 million of installment payments received following the October 2018 amendment to our amended license agreement with Sato. The remaining installment payment of \$4.6 million (or 0.5 billion JPY) was payable on September 13, 2019 and received during the fourth quarter of 2019.

As noted above, in April 2019 and May 2019, respectively, we entered into the Purchase Agreement with Reedy Creek, which provided \$25.0 million of immediate funding, with an additional \$10.0 million contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020, and the Funding Agreement with Ligand, which provided \$12.0 million of immediate funding.

[Table of Contents](#)

As also noted above, in August 2019, we entered into the Aspire Common Stock Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock at our request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement. As of September 30, 2019, up to \$24.7 million remain available to us for sales of common stock under the Aspire Common Stock Purchase Agreement.

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

We have never generated revenue from product sales and have incurred net losses in each year since inception. As of September 30, 2019, we had an accumulated deficit of \$206.5 million. We incurred net losses of \$8.3 million and \$33.5 million during the three and nine months ended September 30, 2019, respectively, and \$7.0 million and \$19.8 million during the three and nine months ended September 30, 2018, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities. We do not expect to generate revenue from product sales unless and until we obtain regulatory approval from the FDA for our clinical-stage product candidates. If we obtain regulatory approval for any of our product candidates, we and/or our commercial partners would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

We expect that we will continue to incur substantial expenses as we continue clinical trials and preclinical studies for, and research and development of, our product candidates and maintain, expand and protect our intellectual property portfolio. We will need substantial additional funding to support our planned and future operating activities. Adequate future funding may not be available to us on acceptable terms, or at all. The current market value of our common stock may negatively impact funding options and the acceptability of funding terms. Additionally, future advancement of our product candidates may occur after the formation of additional partnering, collaborations, licensing, grants or other strategic relationships. Our failure to enter into such additional relationships, the termination or failure of our current strategic relationships, including a failure to receive any contingent payments under such strategic relationships, or our failure to obtain sufficient additional funds on acceptable terms as and when needed, including the inability to utilize the maximum amount available under the Aspire Common Stock Purchase Agreement, could cause us to alter or reduce our planned operating activities, including but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents or to dissolve and liquidate our assets or seek protection under bankruptcy laws. Such actions could delay development timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. As further discussed in our condensed consolidated financial statements and related footnotes included in this Quarterly Report on Form 10-Q, these matters raise substantial doubt about our ability to continue as a going concern.

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

Components of our Results of Operations

Revenue

License and collaboration revenue consists of the amortization of certain fixed and variable consideration under the Sato license agreement that was entered into during the first quarter of 2017, as amended in October 2018, or the Amended Sato Agreement, that (i) has been received to date in the form of upfront and milestone payments; or (ii) are future, non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events. This consideration is being recognized on a straight-line basis over the estimated performance period of approximately 7.5 years, from February 2017 through the third quarter of 2024. The material terms of the Amended Sato Agreement and related revenue recognition are described within Note 4—Licensing Arrangements, and Note 5—Revenue Recognition to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Government Contracts and Grants Revenue

Government research contracts and grant revenue relates to the research and development of our nitric oxide platform for preclinical advancement of NCEs and formulations related to potential treatments for illnesses in the women’s health field. Revenue related to conditional government contracts and grants is recognized when the conditions outlined in the government contract or grant have been met. Revenues from development and support activities under unconditional government research contracts and grants are recorded in the period in which the related costs are incurred for cost reimbursement grants.

Research and Development Expenses

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

- external research and development expenses incurred under agreements with contract research organizations, 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, and to develop and manufacture such drug substance and drug product, with external contract manufacturing organizations;
- legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- salaries and related costs, including share-based compensation, for personnel in our research and development functions; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, utilities, equipment and other supplies.

From inception through September 30, 2019, we have incurred approximately \$156.5 million in research and development expenses to develop, expand or otherwise improve our nitric oxide platform and resulting product candidates, as well as costs incurred to generate research and development services revenue. This amount is net of \$3.4 million and \$5.5 million of contra-research and development expense recorded for the three and nine months ended September 30, 2019 representing amortization of the liability related to the \$12.0 million of funding received from Ligand to pursue the development and regulatory approval of SB206. For additional information about the Funding Agreement with Ligand, please see Note 6—Research and Development Arrangements of the accompanying condensed consolidated financial statements.

The table below sets forth our external research and development expenses incurred for current product candidates and unallocated internal research and development expenses for the three and nine months ended September 30, 2019 and 2018.

All research and development salaries and related personnel costs, manufacturing capability and campaign costs, costs to establish drug substance and drug product manufacturing capabilities at third-party CMOs and facility and infrastructure expenses are included in unallocated internal research and development expenses.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
External:				
SB204	\$ 19	\$ 151	\$ 194	\$ 1,060
SB206	3,440 (1)	1,998	5,968 (1)	4,037
SB208	—	—	7	—
SB414	720	47	1,055	1,658
Unallocated internal research and development expenses	4,419	3,501	12,390	11,453
Total research and development expenses	\$ 8,598	\$ 5,697	\$ 19,614	\$ 18,208

(1) Amount shown net of \$3.4 million and \$5.5 million of contra-research and development expense recorded for the three and nine months ended September 30, 2019, respectively, related to the Funding Agreement with Ligand described in Note 6—Research and Development Arrangements.

[Table of Contents](#)

We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on our current clinical programs and our future pipeline development. During the three and nine months ended September 30, 2019, our major clinical development activities were primarily associated with our SB206 molluscum program, where we completed our Phase 2 clinical program activities, held an end-of-Phase 2 meeting with the FDA, and commenced the Phase 3 development program for molluscum including two pivotal clinical trials.

We expect to incur substantial research and development expenses in the future as we develop our clinical product candidates and for other existing or future product candidates. In particular, with our existing capital resources, we expect to continue to incur substantial external development service provider fees and other research and development costs during the remainder of 2019 as we: (i) conduct SB206 molluscum Phase 3 program activities; (ii) conduct certain preclinical studies and prepare to initiate a Phase 2 clinical trial in the SB414 atopic dermatitis program; (iii) continue to progress drug product manufacturing capability transfer activities to Orion; (iv) conduct expected API manufacturing capability transfer activities to our external third party CMO; and (v) conduct other platform technology research and development, including developing NCEs, formulations and delivery devices in the dermatology, GI and women's health fields.

We may decide to revise our plans or the related timing, depending on information we learn through our research and development activities, our ability to access additional capital, our ability to enter into strategic arrangements and our financial priorities.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current product candidates or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See the "Risk Factors" section in our Annual Report on Form 10-K filed with the SEC on March 27, 2019, for a discussion of the risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

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

We expect to continue to incur substantial general and administrative expenses during the remainder of 2019 in support of our product development 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. However, we have experienced, and expect to continue to experience, a decrease in litigation defense fees during 2019 as we concluded that the putative stockholder class action lawsuits, as described in the section entitled Note 8—Commitments and Contingencies—Legal Proceedings to the unaudited interim financial statements in this Quarterly Report on Form 10-Q, are substantially complete.

Other Income (Expense), net

Other income (expense), net consists primarily of (i) fair value adjustments to our warrant liability; (ii) interest income earned on cash and cash equivalents; and (iii) other miscellaneous income and expenses. We expect continued fluctuations in the fair value of the warrant liability, based primarily on fluctuations in the market value of our common stock.

Results of Operations**Comparison of Three Months Ended September 30, 2019 and 2018**

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

	Three Months Ended September 30,			
	2019	2018	\$ Change	% Change
	(in thousands, except percentages)			
License and collaboration revenue	\$ 1,100	\$ 648	\$ 452	70 %
Government research contracts and grants revenue	216	—	216	100 %
Total revenue	1,316	648	668	103 %
Operating expenses:				
Research and development	8,598	5,697	2,901	51 %
General and administrative	2,290	3,295	(1,005)	(31)%
Total operating expenses	10,888	8,992	1,896	21 %
Operating loss	(9,572)	(8,344)	(1,228)	15 %
Other (expense) income, net:				
Interest income	53	83	(30)	(36)%
Interest expense	—	(262)	262	(100)%
Change in fair value of warrant liability	1,160	1,464	(304)	(21)%
Other income, net	23	28	(5)	(18)%
Total other (expense) income, net	1,236	1,313	(77)	(6)%
Net loss and comprehensive loss	\$ (8,336)	\$ (7,031)	\$ (1,305)	19 %

Revenue

License and collaboration revenue of \$1.1 million and \$0.6 million for the three months ended September 30, 2019 and 2018, respectively, was associated with our performance during the period and the related amortization of the non-refundable upfront and expected milestone payments under the Amended Sato Agreement.

Government research contracts and grants revenue of \$0.2 million for the three months ended September 30, 2019 primarily includes \$0.2 million of revenue recognized related to the \$1.1 million grant we received in September 2019 from the DoD's CDMRP as part of its Peer Reviewed Cancer Research Program. For additional information regarding the Company's government research contracts and grants revenue, see Note 5—Revenue Recognition to the accompanying condensed consolidated financial statements.

Research and development expenses

Research and development expenses were \$8.6 million for the three months ended September 30, 2019, compared to \$5.7 million for the three months ended September 30, 2018. The net increase of \$2.9 million was primarily related to (i) a net \$1.4 million increase in the SB206 program, (ii) a \$0.9 million increase in unallocated internal research and development expenses, (iii) a \$0.7 million increase in our SB414 program due to the continued conduct of non-clinical studies during the third quarter of 2019, partially offset by (iv) a \$0.1 million decrease in our SB204 program due to the completion of certain chemistry, manufacturing, and control activities that took place during the comparative period.

In the SB206 program, we experienced a \$4.8 million increase in gross costs incurred due to the continued conduct of two Phase 3 pivotal trials and the initiation of other Phase 3 development activities, including ancillary supporting trials and studies, for the molluscum indication in the third quarter of 2019. This increase was partially offset by \$3.4 million of contra-research and development expense representing the amortization of the liability related to the Funding Agreement with Ligand, which contributes to the clinical development and regulatory approval of SB206 for the treatment of molluscum.

The \$0.9 million increase in unallocated internal research and development expenses was primarily driven by costs associated with our increased utilization of third party manufacturers and other strategic partners during the current reporting period. Specifically, we experienced (i) a \$0.9 million increase in service and support costs associated with our manufacturing technology transfers and process engineering projects ongoing with our contract API manufacturer and Orion, our contract drug product manufacturer, (ii) a \$0.2 million increase in development service fees associated with pre-clinical development of new drug formulations and NCEs for use in the fields of women's health and GI and (iii) a \$0.1 million increase in allocated rental

[Table of Contents](#)

expense following the January 1, 2019 adoption of FASB Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, which was reported as interest expense in previous reporting periods prior to adoption of Topic 842.

These unallocated research and development expense increases were partially offset by (i) a \$0.1 million decrease in other research and development service provider fees incurred during the comparative period that did not recur in 2019 and (ii) a \$0.2 million decrease in research and development personnel-related costs. The decrease in personnel-related costs is comprised of (i) a \$0.4 million decrease in recurring salary and benefit expenses due to reductions in research and development personnel between the comparative periods, partially offset by (ii) a net \$0.2 million increase in non-cash performance-based compensation expense associated with the change in the fair value of the liability related to our Tangible Stockholder Return Plan, or the Performance Plan, which was established in the third quarter of 2018. The Performance Plan liability valuation increased during the third quarter of 2019 due to appreciation in our common stock's market price, which is a key input to the Performance Plan's valuation model.

General and administrative expenses

General and administrative expenses were \$2.3 million for the three months ended September 30, 2019, compared to \$3.3 million for the three months ended September 30, 2018. The decrease of approximately \$1.0 million, or 31%, was primarily due to a \$0.7 million decrease in general and administrative personnel and related costs and a \$0.3 million reduction in legal fees related to litigation defense fees for the putative stockholder class action lawsuits incurred the third quarter of 2018 that did not recur in the third quarter of 2019.

The \$0.7 million decrease in general and administrative personnel and related costs is primarily due to (i) a one-time signing bonus of \$0.6 million in accordance with the employment agreement with our chief executive officer executed in the third quarter of 2018, (ii) decrease in salary and benefits costs of \$0.2 million, and (iii) reduced non-cash stock compensation expense of \$0.1 million. These decreases were partially offset by a \$0.2 million increase in non-cash compensation expense associated with the change in the fair value of our Performance Plan liability.

Other (expense) income, net

Other (expense) income, net was \$1.2 million income for the three months ended September 30, 2019, compared to \$1.3 million income for the three months ended September 30, 2018. The net income decrease of approximately \$0.1 million was primarily due to the change in fair value of the warrant liability of \$0.3 million, partially offset by a \$0.3 million decrease in interest expense associated with our Morrisville, North Carolina facility lease. The decrease in interest expense is due to the adoption of Topic 842 on January 1, 2019, whereby we no longer report a portion of our lease costs as interest expense as of the adoption date.

Comparison of Nine Months Ended September 30, 2019 and 2018

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

	Nine Months Ended September 30,			
	2019	2018	\$ Change	% Change
(in thousands, except percentages)				
License and collaboration revenue	\$ 3,301	\$ 1,946	\$ 1,355	70 %
Government research contracts and grants revenue	216	—	216	100 %
Research and development services revenue	—	9	(9)	(100)%
Total revenue	3,517	1,955	1,562	80 %
Operating expenses:				
Research and development	19,614	18,208	1,406	8 %
General and administrative	8,595	8,795	(200)	(2)%
Total operating expenses	28,209	27,003	1,206	4 %
Operating loss	(24,692)	(25,048)	356	(1)%
Other income (expense), net:				
Interest income	149	242	(93)	(38)%
Interest expense	(1)	(785)	784	(100)%
Change in fair value of warrant liability	(9,030)	5,733	(14,763)	(258)%
Other income, net	115	32	83	259 %
Total other (expense) income, net	(8,767)	5,222	(13,989)	(268)%
Net loss	\$ (33,459)	\$ (19,826)	\$ (13,633)	69 %

[Table of Contents](#)

Revenue

License and collaboration revenue of \$3.3 million and \$1.9 million for the nine months ended September 30, 2019 and 2018, respectively, was associated with our performance during the period and the related amortization of the non-refundable upfront and expected milestone payments under the Amended Sato Agreement.

Government research contracts and grants revenue of \$0.2 million for the nine months ended September 30, 2019 primarily includes \$0.2 million of revenue recognized related to the \$1.1 million grant we received in September 2019 from the DoD's CDMRP as part of its Peer Reviewed Cancer Research Program. For additional information regarding the Company's government research contracts and grants revenue, see Note 5—Revenue Recognition to the accompanying condensed consolidated financial statements.

Research and development expenses

Research and development expenses were \$19.6 million for the nine months ended September 30, 2019, compared to \$18.2 million for the nine months ended September 30, 2018. The net increase of \$1.4 million, or 8%, was primarily related to (i) a \$1.9 million net increase in the SB206 program and (ii) a \$0.9 million increase in unallocated internal research and development expenses, partially offset by (iii) decreases in our SB414 and SB204 development programs totaling \$1.5 million due to the completion of certain clinical trials during the comparative period.

In the SB206 program, we experienced a \$7.4 million increase in gross costs incurred due to the initiation and conduct of two Phase 3 pivotal trials and the initiation of other Phase 3 development activities, including ancillary supporting trials and studies, for the mollusum indication in the 2019 reporting period. This increase was partially offset by \$5.5 million of contra-research and development expense representing the amortization of the liability related to the Funding Agreement with Ligand, which contributes to the clinical development and regulatory approval of SB206 for the treatment of mollusum.

The \$0.9 million increase in unallocated internal research and development expenses was primarily driven by costs associated with our increased utilization of third party manufacturers and other strategic partners during the current reporting period. Specifically, we experienced (i) a \$1.1 million increase in service and support costs associated with our manufacturing technology transfers and process engineering projects ongoing with our contract API manufacturer and Orion, our contract drug product manufacturer, (ii) a \$0.2 million net increase in development service fees associated with pre-clinical development of new drug formulations and NCEs for use in the fields of women's health and GI and (iii) a \$0.3 million increase in allocated rental expense following the January 1, 2019 adoption of FASB Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, which was reported as interest expense in previous reporting periods prior to adoption of Topic 842.

These unallocated research and development expense increases were partially offset by (i) a \$0.1 million decrease in other research and development service provider fees incurred during the comparative period that did not recur in 2019 and (ii) a \$0.6 million decrease in research and development personnel-related costs. The net decrease in personnel-related costs is comprised of (i) a \$1.0 million decrease in recurring salary and benefit expenses due to reductions in research and development personnel between the comparative periods, partially offset by (ii) a \$0.4 million discrete severance expense charge in the first quarter of 2019 associated with the departure of our former chief scientific officer. Non-cash performance-based compensation expense was consistent between the two periods, but included (i) a \$0.6 million increase associated with the change in the fair value of the liability related to our Performance Plan established in the third quarter of 2018, offset by (ii) a \$0.6 million decrease in stock option related compensation expense. The Performance Plan liability valuation increased during the 2019 reporting period due to appreciation in our common stock's market price, which is a key input to the Performance Plan's valuation model. The decrease in non-cash stock option related compensation expense is associated with (i) the forfeiture of stock options previously held by former officers and employees who departed the Company prior to or during the first nine months of 2019; and (ii) expense associated with the annual grant of stock option awards to all employees during the first nine months of 2018, which did not recur in the first nine months of 2019 after the establishment of the Performance Plan in the third quarter of 2018.

General and administrative expenses

General and administrative expenses were \$8.6 million for the nine months ended September 30, 2019, compared to \$8.8 million for the nine months ended September 30, 2018. The decrease of approximately \$0.2 million, or 2%, was primarily due to (i) a one-time signing bonus of \$0.6 million incurred during the comparative 2018 period in conjunction with the execution of the employment agreement with our chief executive officer, (ii) a \$0.5 million decrease in professional services, business development and other administrative costs necessary to support our operations as a public company, partially offset by (iii) a net \$0.5 million increase in non-cash stock compensation expense, (iv) a \$0.2 million net increase in severance charges and other personnel-related costs and (v) a \$0.2 million increase in facility costs.

[Table of Contents](#)

The \$0.5 million net increase in non-cash stock compensation expense is primarily due to (i) a \$0.7 million increase associated with the change in the value of our Performance Plan liability, and (ii) a \$0.2 million net decrease in stock option related expense.

The \$0.2 million net increase in severance charges and other one-time compensatory payments is comprised of (i) a \$0.5 million discrete charge in the first quarter of 2019 primarily related to severance and one-time payments associated with the departure of our former chief business officer in January 2019, which was partially offset by (ii) a \$0.3 million discrete severance charge in the first quarter of 2018 associated with the departure of our former chief commercial officer in January 2018.

Other (expense) income, net

Other (expense) income, net was \$8.8 million expense for the nine months ended September 30, 2019, compared to \$5.2 million income for the nine months ended September 30, 2018. The other expense increase of approximately \$14.0 million was primarily due to the change in fair value of the warrant liability of \$14.8 million, partially offset by a decrease in interest expense of \$0.8 million associated with our Morrisville, North Carolina facility lease. The warrant liability valuation increased during the nine months ended September 30, 2019 primarily due to appreciation in our common stock's market price, which is a key input to the warrant liability valuation model. The decrease in interest expense is due to the adoption of Topic 842 on January 1, 2019, whereby we no longer report a portion of our lease costs as interest expense as of the adoption date.

Liquidity and Capital Resources

As of September 30, 2019, we had a total cash, cash equivalents and restricted cash balance of \$22.5 million and positive working capital of \$4.8 million.

Since our inception through September 30, 2019, we have financed our operations primarily with \$184.3 million in net proceeds from the issuance and sale of equity securities and convertible debt securities, including \$35.2 million in net proceeds from the sale of common stock and accompanying warrants in the January 2018 Offering, \$44.6 million in net proceeds from the sale of common stock in our 2016 initial public offering and \$0.3 million in proceeds from the sale of common stock under the Aspire Common Stock Purchase Agreement. In addition, through September 30, 2019, we have also generated additional liquidity and capital through other sources including (i) governmental research contracts and grants totaling \$11.8 million, excluding two grants to us from Federal agencies in the third quarter of 2019 for which funds have not yet been received; (ii) our licensing and supply arrangements with Sato Pharmaceutical Co., Ltd., or Sato, totaling \$19.7 million, excluding a payment received in the fourth quarter of 2019, described below; and (iii) \$37.0 million in proceeds from two funding transactions during the second quarter of 2019, also described below.

In the first quarter of 2017, we received an upfront payment of approximately \$10.8 million following the execution of the Sato Agreement for the exclusive right to develop, use and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris. In addition, we received a milestone payment of approximately \$2.2 million in the fourth quarter of 2018, related to the initiation of a Phase 1 trial in Japan in the third quarter of 2018. Under the terms of the Sato Amendment which expanded the Sato Agreement to include SB206, we also received a payment of \$2.2 million (or 0.25 billion JPY) in October 2018 and a payment of \$4.5 million (or 0.5 billion JPY) in March 2019, representing the first and second installments of an upfront payment of 1.25 billion JPY. The remaining installment payment of \$4.6 million (or 0.5 billion JPY) was payable on September 13, 2019 and received during the fourth quarter of 2019.

As described below, in late April 2019 and early May 2019, respectively, we entered into (i) the Purchase Agreement with Reedy Creek, which provided \$25.0 million of immediate funding, with an additional \$10.0 million contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020; and (ii) the Funding Agreement with Ligand, which provided \$12.0 million of immediate funding.

As also described below, in August 2019, we entered into the Aspire Common Stock Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock at our request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement.

We believe that our existing cash, cash equivalents and restricted cash balance and a contractual payment received in the fourth quarter of 2019 in connection with the Sato Amendment will (i) provide us with adequate liquidity to fund our planned operating needs into the first quarter of 2020, including through expected top-line results of the SB206 Phase 3 clinical trials targeted in the first quarter of 2020, or before; and (ii) into the second quarter of 2020, if paired with the potential \$10.0 million funding contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020. This projected cash runway excludes potential sales of common stock under the Aspire Common Stock Purchase Agreement.

[Table of Contents](#)

As of September 30, 2019, up to \$24.7 million remains available to us for sales of common stock under the Aspire Common Stock Purchase Agreement.

We believe the remaining capacity under the Aspire Common Stock Purchase Agreement provides us additional flexibility and discretion to fund specific platform development initiatives and other operating expenses, dependent on the advancement of the Company's strategic operating and funding objectives. Our ability to continue to operate our business, including our ability to advance our development programs, is dependent upon our ability to access additional sources of capital, including, but not limited to (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings, which could cause dilution. We may revise our development and operating activities or their timing depending on the availability of additional funding, partnership opportunities and our financial priorities. Our assumptions and plans may change and could impact the magnitude and/or timing of development and operating expenses and therefore our cash runway, including the potential usage of the Aspire Common Stock Purchase Agreement.

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization by a strategic partner or by ourselves. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin any commercialization activities. We are subject to all of the risks inherent in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Although we (i) secured additional capital in April 2019 with the Reedy Creek Purchase Agreement and in May 2019 with the Funding Agreement with Ligand; and (ii) have remaining availability for sales of common stock under the Aspire Common Stock Purchase Agreement of up to \$24.7 million as of September 30, 2019, we have concluded that the prevailing conditions and ongoing liquidity risks we face raise substantial doubt about our ability to continue as a going concern. We need substantial additional funding to continue our operating activities and make further advancements in our drug development programs beyond those planned in 2019 and the first half of 2020.

As we continue to endeavor to raise additional capital, there can be no assurance that we will be able to obtain new funding on terms acceptable to us, on a timely basis, or at all. A failure to obtain sufficient funds on acceptable terms when needed, including the inability to utilize the maximum amount available under the Aspire Common Stock Purchase Agreement, could cause us to alter or reduce our planned operating activities to conserve our cash and cash equivalents, including but not limited to delaying planned activities directly related to or in support of product candidate development. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and have a material adverse effect on our results of operations, financial condition and market valuation. As of September 30, 2019, we had an accumulated deficit of \$206.5 million and there is substantial doubt about our ability to continue as a going concern.

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

Aspire Common Stock Purchase Agreement

On August 30, 2019, we entered into the Aspire Common Stock Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock at our request from time to time during the 30-month term of the Aspire Common Stock Purchase Agreement.

Under the Aspire Common Stock Purchase Agreement, 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 100,000 shares of our common stock per business day, up to an aggregate of \$25.0 million of our common stock, at a per share price, or the Purchase 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 (3) lowest closing sale prices for our 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 \$0.5 million. In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount equal to 100,000 shares and our stock price is not less than \$0.25 per share, 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 its principal market on the next trading day, or the VWAP Purchase Date, as determined by us. Under the terms of the Aspire Common Stock

[Table of Contents](#)

Purchase Agreement, the number of shares that may be sold to Aspire Capital is limited to 5,211,339 shares, or the Exchange Cap, which represents 19.99% of our outstanding shares of common stock on August 30, 2019, unless stockholder approval or an exception pursuant to the rules of the Nasdaq Global Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Aspire Common Stock Purchase Agreement is equal to or greater than \$2.17, or the Minimum Price, which was the closing sale price of our common stock immediately preceding the execution of the Aspire Common Stock Purchase Agreement.

There are no trading volume requirements or restrictions under the Aspire Common Stock Purchase Agreement, and we will 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 directed by the Company in accordance with the Aspire Common Stock Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financing transactions, rights of first refusal, participation rights, penalties or liquidated damages in the Aspire Common Stock Purchase Agreement. In consideration for entering into the Aspire Common Stock Purchase Agreement, concurrently with the execution of the Aspire Common Stock Purchase Agreement, we issued to Aspire Capital 345,622 shares of our common stock, or the Commitment Shares. The Aspire Common Stock Purchase Agreement may be terminated by us any time, at our discretion, without any penalty or additional cost to us. Any proceeds we receive under the Aspire Common Stock Purchase Agreement are expected to be used for working capital and general corporate purposes. As of September 30, 2019, we have sold 100,000 shares of common stock at a price of \$2.61 per share under the Aspire Common Stock Purchase Agreement, and we have up to \$24.7 million available for sales of common stock under the Aspire Common Stock Purchase Agreement.

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, we entered into the Purchase Agreement with Reedy Creek, pursuant to which Reedy Creek provided us funding in an initial amount of \$25.0 million, which we will use primarily to pursue the development, regulatory approval and commercialization (including through out-license agreements and other third party arrangements) activities for SB206, for the treatment of molluscum, and advancing programmatically other activities with respect to SB414, for atopic dermatitis, and SB204, for acne. Reedy Creek will also provide \$10 million of additional funding contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020. Pursuant to the Purchase Agreement, we will pay Reedy Creek ongoing quarterly payments, calculated based on an applicable percentage per product of any upfront fees, milestone payments, royalty payments or equivalent payments received by us pursuant to any out-license agreement for the products in the United States, Mexico or Canada, net of any upfront fees, milestone payments, royalty payments or equivalent payments paid by us to third parties pursuant to any agreements under which we have in-licensed intellectual property with respect to the products.

The applicable percentage used for determining the ongoing quarterly payments, applied to amounts received directly by us pursuant to any out-license agreement for each product, ranges from 10% for SB206 to 20% for SB414 and SB204. However, the agreement provides that the applicable percentage for each product will be 25% for fees or milestone payments received by us (but not royalty payments received by us) until Reedy Creek has received payments under the Purchase Agreement equal to the total funding amount provided by Reedy Creek under the Purchase Agreement. If we decide to commercialize any product on its own following regulatory approval, as opposed to commercializing through an out-license agreement or other third party arrangement, we will be obligated to pay Reedy Creek a low single digits royalty on net sales of the products.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

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

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

Expansion of Partnership with Sato in Japanese Territory

On October 5, 2018, we and Sato entered into the second amendment to the initial license agreement dated January 12, 2017, or the Sato Amendment. The initial license agreement had focused on the development and commercialization of SB204 for the treatment of acne vulgaris in Japan. The Sato Amendment also provides Sato with the exclusive rights to develop and commercialize SB206 and related dosage forms for the treatment of viral skin infections, including but not limited to

[Table of Contents](#)

mollusum contagiosum and external genital warts, in Japan. Under the terms of the Sato Amendment, we will receive an upfront payment from Sato totaling 1.25 billion JPY (approximately \$11.1 million USD) to be paid in three installments over a 12 months period. We received the first installment of 0.25 billion JPY (approximately \$2.2 million USD) in October 2018 and the second installment of 0.5 billion JPY (approximately \$4.5 million USD) in March 2019. The third installment of 0.5 billion JPY (approximately \$4.6 million USD) became payable in September 2019 and was received during the fourth quarter of 2019. The Sato Amendment also provides for an aggregate of 1.0 billion JPY in additional non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events.

Primary Facility Lease Financing

Our approximately 51,000 square foot leased facility in Morrisville, North Carolina serves as our corporate headquarters and sole research, development and manufacturing facility. We entered into the ten-year, non-cancellable lease agreement in 2016, currently have approximately six years, nine months remaining under the lease term and currently have approximately \$8.8 million in remaining minimum lease payments.

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

In July 2018, the Company and a third-party tenant entered into a sublease of approximately 6,400 square feet of office space, or approximately 12% of total facility square footage, at our Morrisville, North Carolina headquarters. In October 2019, we executed a termination agreement with the subtenant for this sublease, with an effective date of December 31, 2019.

We assess the carrying value of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. As of September 30, 2019, we concluded there were no such events or changes in circumstances requiring review of the carrying amount of the Company's long-lived assets.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (11,421)	\$ (24,876)
Investing activities	(38)	(828)
Financing activities	25,271	35,353
Net increase in cash, cash equivalents and restricted cash	\$ 13,812	\$ 9,649

Net Cash Used in Operating Activities

During the nine months ended September 30, 2019, net cash used in operating activities was \$11.4 million and consisted primarily of a net loss of \$33.5 million, with adjustments for non-cash amounts related primarily to an increase in fair value of warrant liability of \$9.0 million, depreciation expense of \$1.5 million, share-based compensation expense of \$2.4 million, and a \$9.0 million net favorable change in other operating assets and liabilities. The favorable change in assets and liabilities was primarily due to a \$12.0 million increase related to the advanced payment for the research and development service obligation associated with the Funding Agreement with Ligand, offset by a \$5.5 million decrease in research and development service obligation liabilities related to the amortization of the liability associated with Ligand, a \$1.2 million increase in deferred revenue following the receipt of an additional upfront installment payment under the Amended Sato Agreement during the first quarter of 2019, a \$1.2 million increase in accounts payable and a \$0.8 million increase in accrued outside research and development services. The increase in accounts payable and accruals was primarily related to the Phase 3 development program for mollusum. These favorable changes were partially offset by changes in other operating assets and liabilities totaling \$0.7 million, including an increase in contracts and grants receivable and a decrease in accrued legal and professional fees.

During the nine months ended September 30, 2018, net cash used in operating activities was \$24.9 million and consisted primarily of a net loss of \$19.8 million, with adjustments for non-cash amounts related primarily to depreciation expense of

[Table of Contents](#)

\$1.2 million, share-based compensation expense for both equity-based and liability-based awards of \$1.9 million, decrease in fair value of warrant liability of \$5.7 million and a \$2.5 million net decrease in other operating assets and liabilities. The net decrease in assets and liabilities was primarily due to a \$0.5 million decrease in accrued compensation following the payment of annual employee bonuses in the first quarter of 2018, a \$0.5 million decrease in other accrued expenses following the payment of various accrued expenses during the period, including \$0.2 million in travel costs paid to Malin Life Sciences Holdings Limited, or Malin, in the first quarter of 2018 related to certain strategic and tactical initiatives and activities performed by Malin employees that did not recur in 2019, and a \$2.0 million decrease in deferred revenue associated with the continued recognition of licensing revenues from the Sato Agreement during 2018. These decreases were partially offset by a favorable change in prepaid expenses and other current assets and accounts payable of \$0.2 million.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2019, net cash used in investing activities was minimal and consisted of purchases of laboratory and manufacturing equipment.

During the nine months ended September 30, 2018, net cash used in investing activities was \$0.8 million, which related primarily to purchases of laboratory equipment and leasehold improvements at our facility in Morrisville, North Carolina.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was \$25.3 million and consisted of \$25.0 million of funding received pursuant to the Purchase Agreement with Reedy Creek and \$0.3 million of proceeds from the sale of our common stock pursuant to the Aspire Common Stock Purchase Agreement.

During the nine months ended September 30, 2018, net cash provided by financing activities was \$35.4 million, consisting primarily of net proceeds from our offering of common stock and warrants in January 2018, after deducting underwriting discounts and offering expenses.

Capital Requirements

As of September 30, 2019, we had a total cash, cash equivalents and restricted cash balance of \$22.5 million and positive working capital of \$4.8 million. As described above, in late April 2019 and early May 2019, respectively, we entered into (i) the Purchase Agreement with Reedy Creek, which provided \$25.0 million of immediate funding, with an additional \$10.0 million contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020; and (ii) the Funding Agreement with Ligand, which provided \$12.0 million of immediate funding. As also described above, in August 2019 we entered into the Aspire Common Stock Purchase Agreement. As of September 30, 2019, up to \$24.7 million remain available to us for sales of common stock under the Aspire Common Stock Purchase Agreement.

We believe that our currently existing cash, cash equivalents and restricted cash balance and a contractual payment received in the fourth quarter of 2019 in connection with the Sato Amendment will (i) provide us with adequate liquidity to fund our planned operating needs into the first quarter of 2020, including through expected top-line results of the SB206 Phase 3 clinical trials targeted in the first quarter of 2020, or before; and (ii) into the second quarter of 2020, if paired with the potential \$10.0 million funding contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020. This projected cash runway excludes potential sales of common stock under the Aspire Common Stock Purchase Agreement, described above. As of September 30, 2019, up to \$24.7 million remains available to us for sales of common stock under the Aspire Common Stock Purchase Agreement.

We believe the remaining capacity under the Aspire Common Stock Purchase Agreement provides us additional flexibility and discretion to fund specific platform development initiatives and other operating expenses, dependent on the advancement of the Company's strategic operating and funding objectives. Our ability to continue to operate our business, including our ability to advance our development programs, is dependent on upon our ability to access additional sources of capital, including, but not limited to (i) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships; or (ii) equity or debt financings, which could cause dilution. We may revise our development and operating activities or their timing depending on the availability of additional funding, partnership opportunities and our financial priorities. Our assumptions and plans may change and could impact the magnitude and/or timing of development and operating expenses and therefore our cash runway, including the potential usage of the Aspire Common Stock Purchase Agreement. We continue to explore other potential non-dilutive business development activities around the developmental and commercial rights to the clinical-stage assets in our platform, including various geographic and indication-specific opportunities.

[Table of Contents](#)

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate revenue from product sales unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization by a strategic partner or by ourselves. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin any commercialization activities. We are subject to all of the risks inherent in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Although we (i) secured additional capital in April 2019 with the Reedy Creek Purchase Agreement and in May 2019 with the Funding Agreement with Ligand; and (ii) have remaining availability for sales of our common stock under the Aspire Common Stock Purchase Agreement of up to \$24.7 million as of September 30, 2019, we have concluded that the prevailing conditions and ongoing liquidity risks we face raise substantial doubt about our ability to continue as a going concern. We need substantial additional funding to continue our operating activities and make further advancements in our drug development programs beyond those planned in 2019 and the first half of 2020.

As we continue to attempt to raise additional capital, there can be no assurance that we will be able to obtain it on terms acceptable to us, on a timely basis, or at all. A failure to obtain sufficient funds on acceptable terms when needed, including the inability to utilize the maximum amount available under the Aspire Common Stock Purchase Agreement, could cause us to alter or reduce our planned operating activities to conserve our cash and cash equivalents, including but not limited to delaying planned activities directly related to or in support of product candidate development. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and have a material adverse effect on our results of operations, financial condition and market valuation. As of September 30, 2019, we had an accumulated deficit of \$206.5 million and there is substantial doubt about our ability to continue as a going concern.

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

- the initiation, progress, timing, costs, results, and evaluation of results of trials for our clinical-stage product candidates, including trials conducted by us or potential future partners;
- the progress, timing, costs and results of development and preclinical study activities relating to other potential applications of our nitric oxide platform;
- the number and characteristics of product candidates that we pursue;
- our ability to enter into strategic relationships to support the continued development of certain product candidates and the success of those arrangements;
- our success in optimizing the size and capability of our current manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204 and SB206 in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- whether we are able to obtain the contingent \$10.0 million payout under the Purchase Agreement with Reedy Creek contingent upon achieving successful top-line results of the SB206 Phase 3 clinical trials no later than March 31, 2020;
- any commercialization efforts, including by us or potential future partners, and related preparatory activities related to potential product sales, marketing, manufacturing and distribution;
- 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;

[Table of Contents](#)

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies; and
- subject to receipt of marketing approval, revenue received from commercial sales or out licensing of our product candidates.

Contractual Obligations and Contingent Liabilities

Except for compensatory obligations described in Note 8—Commitments and Contingencies to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there were no material changes during the nine months ended September 30, 2019 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 on Form 10-K filed with the SEC on March 27, 2019.

Off-Balance Sheet Arrangements

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

Jumpstart Our Business Startups Act of 2012 (JOBS Act)

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

Critical Accounting Policies and Use of Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. Our significant accounting policies are more fully described in Note 1—Organization and Significant Accounting Policies to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and in Note 1—Organization and Significant Accounting Policies to our audited consolidated financial statements contained in our Annual Report on Form 10-K filed with the SEC on March 27, 2019. During the nine months ended September 30, 2019, there were no material changes to our critical accounting policies, except as presented below:

Leases

Effective January 1, 2019, we adopted ASU No. 2016-02, *Leases (Topic 842)* using the modified retrospective transition method and established our lease accounting policy pursuant to this new standard. We initially applied the transition provisions at January 1, 2019, which allowed us to continue to apply the legacy guidance in ASC 840 for periods prior to 2019. Our policy, and related significant judgments and estimates used to recognize right-of-use assets and lease liabilities under our policy, is described in Note 1—Organization and Significant Accounting Policies and Note 8—Commitments and Contingencies to the condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

Recently issued accounting pronouncements that we have adopted or are currently evaluating are described in detail within Note 1—Organization and Significant Accounting Policies to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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

Our management, with the participation of our principal executive and financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019, the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based upon such evaluation, our principal executive and financial officers have concluded that our disclosure controls and procedures were effective as of such date at the reasonable assurance level.

(b) Changes in Internal Controls Over Financial Reporting

There have not been any changes in our internal controls over financial reporting during our fiscal quarter ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors.

There have been no material changes to the risk factors disclosed in the Annual Report on Form 10-K filed with the SEC on March 27, 2019, the Quarterly Report on Form 10-Q filed with the SEC on May 15, 2019, or the Quarterly Report on Form 10-Q filed with the SEC on August 13, 2019.

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

Unregistered Sales of Equity Securities

Pursuant to the Nasdaq inducement grant exception, during the quarter ended September 30, 2019, we issued options to purchase an aggregate of 25,000 shares of common stock to a newly-hired employee at an exercise price of \$2.62 per share. The shares underlying these option awards will be registered on a Form S-8 registration statement prior to the first vesting event applicable to such award.

During the quarter ended September 30, 2019, we sold an aggregate of 100,000 shares of common stock to Aspire Capital under the Aspire Common Stock Purchase Agreement, generating aggregate proceeds of \$0.3 million. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(a)(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(a)(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. Such shares are registered for re-sale by Aspire Capital on our Registration Statement on Form S-1 (File No. 333-233632) registering 7,032,630 shares of common stock that have been or may be offered to Aspire Capital from time to time under the Aspire Common Stock Purchase Agreement.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

[Table of Contents](#)

Item 6. Exhibits

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

EXHIBIT NO.	DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
			FORM	File No.	Exhibit	Filing Date
4.1	Registration Rights Agreement, dated August 30, 2019, between Novan, Inc. and Aspire Capital Fund, LLC.		8-K	001-37880	4.1	September 5, 2019
10.1	Novan, Inc. 2016 Incentive Award Plan, as amended and restated		8-K	001-37880	10.1	August 6, 2019
10.2	Common Stock Purchase Agreement, dated August 30, 2019, between Novan, Inc. and Aspire Capital Fund, LLC.		8-K	001-37880	10.1	September 5, 2019
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	XBRL Instance Document.	X				
101.SCH	XBRL Taxonomy Extension Schema Document.	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	XBRL Taxonomy Extension Definition Document.	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X				

SIGNATURES

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

Novan, Inc.

By: /s/ G. Kelly Martin
G. Kelly Martin
Chief Executive Officer
(Principal Executive Officer)

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

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

Date: November 12, 2019

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

I, G. Kelly Martin, 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 12, 2019

/s/ G. Kelly Martin

G. Kelly Martin

Chief Executive Officer

(Principal Executive Officer)

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

I, John M. Gay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Novan, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2019

/s/ John M. Gay

John M. Gay

Vice President, Finance and Corporate Controller

(Principal Financial Officer)

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

I, G. Kelly Martin, 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, 2019 (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 12, 2019

/s/ G. Kelly Martin

G. Kelly Martin

Chief Executive Officer

(Principal Executive Officer)

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

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

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

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

- (1) the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2019 (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 12, 2019

/s/ John M. Gay

John M. Gay

Vice President, Finance and Corporate Controller

(Principal Financial Officer)

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

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