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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2017

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

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**Novan, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**4105 Hopson Road**  
**Morrisville, North Carolina**  
(Address of principal executive offices)

**20-4427682**  
(I.R.S. Employer  
Identification No.)

**27560**  
(zip code)

**(919) 485-8080**

(Registrant's telephone number, including area code)

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 type="checkbox"/> (Do not check if a smaller reporting company)	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 August 10, 2017, there were 15,984,091 shares of the registrant's Common Stock outstanding.

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,067	\$ 34,611
Prepaid expenses and other current assets	629	958
Total current assets	<u>19,696</u>	<u>35,569</u>
Restricted cash	539	539
Intangible assets	75	75
Other assets	213	—
Property and equipment, net	<u>16,938</u>	<u>16,290</u>
Total assets	<u>\$ 37,461</u>	<u>\$ 52,473</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,351	\$ 3,130
Accrued compensation	2,007	2,305
Accrued outside research and development services	1,822	5,737
Accrued legal and professional fees	440	382
Other accrued expenses	1,950	1,813
Deferred revenue, current portion	2,406	—
Capital lease obligation, current portion	<u>10</u>	<u>10</u>
Total current liabilities	9,986	13,377
Deferred revenue, net of current portion	7,709	—
Capital lease obligation, net of current portion	27	32
Facility financing obligation	<u>7,998</u>	<u>7,998</u>
Total liabilities	<u>25,720</u>	<u>21,407</u>
Commitments and contingencies (Notes 2, 3 and 5)		
Stockholders' equity		
Preferred stock \$0.0001 par value; 10,000,000 shares designated as of June 30, 2017 and December 31, 2016; 0 shares issued and outstanding as of June 30, 2017 and December 31, 2016	—	—
Common stock \$0.0001 par value; 200,000,000 shares authorized as of June 30, 2017 and December 31, 2016; 15,991,091 and 15,949,492 shares issued as of June 30, 2017 and December 31, 2016; 15,981,591 and 15,939,992 shares outstanding as of June 30, 2017 and December 31, 2016	2	2
Additional paid-in-capital	156,421	154,252
Treasury stock at cost, 9,500 shares as of June 30, 2017 and December 31, 2016	(155)	(155)
Accumulated deficit	<u>(144,527)</u>	<u>(123,033)</u>
Total stockholders' equity	11,741	31,066
Total liabilities and stockholders' equity	<u>\$ 37,461</u>	<u>\$ 52,473</u>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
License and collaboration revenue	\$ 601	\$ —	\$ 701	\$ —
Research and development services revenue	68	—	68	—
Total revenue	<u>669</u>	<u>—</u>	<u>769</u>	<u>—</u>
Operating expenses:				
Research and development	6,962	14,468	13,908	\$ 22,373
General and administrative	3,361	3,467	7,892	6,834
Total operating expenses	<u>10,323</u>	<u>17,935</u>	<u>21,800</u>	<u>29,207</u>
Operating loss	<u>(9,654)</u>	<u>(17,935)</u>	<u>(21,031)</u>	<u>(29,207)</u>
Other (expense) income, net	(233)	31	(463)	43
Net loss and comprehensive loss	<u>\$ (9,887)</u>	<u>\$ (17,904)</u>	<u>\$ (21,494)</u>	<u>\$ (29,164)</u>
Net loss per share, basic and diluted	<u>\$ (0.62)</u>	<u>\$ (7.31)</u>	<u>\$ (1.35)</u>	<u>\$ (11.92)</u>
Weighted-average common shares outstanding, basic and diluted	<u>15,975,108</u>	<u>2,448,747</u>	<u>15,971,515</u>	<u>2,447,067</u>

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

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

	Six Months Ended June 30,	
	2017	2016
Cash flow from operating activities:		
Net loss	\$ (21,494)	\$ (29,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	639	388
Share-based compensation	2,135	534
Gain on disposal of property and equipment	(3)	(2)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	329	39
Accounts payable	(1,638)	(289)
Accrued compensation	(298)	439
Accrued outside research and development services	(3,915)	5,133
Accrued legal and professional fees	58	(98)
Accrued expenses	(145)	977
Deferred revenue	10,115	—
Other	(213)	(18)
Net cash used in continuing operating activities	(14,430)	(22,061)
Net cash used in discontinued operating activities	—	(257)
Net cash used in operating activities	(14,430)	(22,318)
Cash flow from investing activities:		
Purchases of property and equipment	(1,143)	(2,333)
Purchase of intangible asset	—	(75)
Cash restricted to secure letter of credit	—	(1)
Net cash used in investing activities	(1,143)	(2,409)
Cash flow from financing activities:		
Payments related to public offering costs	—	(1,183)
Proceeds from exercise of stock options	34	34
Purchase of treasury stock	—	(155)
Payments on capital lease obligation	(5)	(3)
Payments on facility lease obligation	—	(52)
Net cash provided by (used in) financing activities	29	(1,359)
Net decrease in cash and cash equivalents	(15,544)	(26,086)
Cash and cash equivalents as of beginning of period	34,611	45,688
Cash and cash equivalents as of end of period	\$ 19,067	\$ 19,602
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of equipment with accounts payable and accrued expenses	\$ 561	\$ 334
Non-cash addition to facility financing obligation	\$ —	\$ 5,191
Non-cash addition to deferred offering costs	\$ —	\$ 839

*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 subsidiary, the “Company”) is a North Carolina-based pharmaceutical company focused on the development and commercialization of nitric oxide-based therapies in dermatology. Novan was incorporated in January 2006 under the state laws of Delaware and its wholly owned subsidiary, Novan Therapeutics, LLC, was organized in 2015 under the state laws of North Carolina.

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 year-end condensed balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP.

***Basis of Consolidation***

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

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. Beginning in the fourth quarter of 2015, KNOW Bio’s financial results for periods prior to the Distribution were reflected in the Company’s consolidated financial statements, retrospectively, as discontinued operations. During the six months ended June 30, 2016, the Company made payments of accounts payable associated with the discontinued operations that were not assumed by KNOW Bio as part of the Distribution. These payments are classified as discontinued operating activities in the accompanying condensed consolidated statement of cash flows for the six months ended June 30, 2016.

The Company does not own an equity interest in KNOW Bio, but does have variable interests in KNOW Bio through the following contractual arrangements:

- At the time of the Distribution, the Company entered into exclusive sublicense agreements with KNOW Bio, as described in Note 3—Collaboration Arrangements. The Company’s potential obligation to pay future milestones or royalties to UNC and other licensors in the event of KNOW Bio non-performance under the sublicense arrangements creates a variable interest.
- The Company entered into a master development services and clinical supply agreement with KNOW Bio in April 2017 (the “KNOW Bio Services Agreement”) and a related statement of work in May 2017 (the “KNOW Bio SOW #1). Under KNOW Bio SOW #1, the Company is providing certain development services to KNOW Bio’s respiratory drug development subsidiary. Pursuant to applicable guidance in FASB ASC 810-10, *Consolidation*, a service provider arrangement such as KNOW Bio SOW #1 is deemed a variable interest when a reporting entity has another previously existing variable interest in a legal entity, such as the Company’s sublicense arrangements with KNOW Bio, as described above.

KNOW Bio is advancing work in non-dermatologic nitric oxide therapies through its portfolio of operating subsidiary companies. The Company determined that KNOW Bio is currently a variable interest entity based on a reassessment of variable interest entity characteristics, pursuant to FASB ASC 810-10, *Consolidation*, performed by the Company during the second quarter of 2017. The reassessment was required because certain triggering events, including the execution of KNOW Bio SOW #1, occurred during the second quarter of 2017.

The Company has concluded that it is not the primary beneficiary of KNOW Bio and, therefore, does not consolidate KNOW Bio in its condensed consolidated financial statements herein. This conclusion is based on the fact that the Company has no significant power or decision-making authority over KNOW Bio’s drug and medical device development activities, which are the activities most significantly impacting KNOW Bio’s economic performance. Under KNOW Bio SOW #1, the Company is providing certain development services to KNOW Bio on commercial terms. In exchange for these services, KNOW Bio pays service fees for actual time and materials incurred by the Company on a cost-plus basis.

NOVAN, INC.

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

As of June 30, 2017, the Company has no exposure to loss as a result of its involvement with KNOW Bio. The Company's sublicense arrangement with KNOW Bio does expose the Company to potential future risk of loss, whereby the Company is obligated to pay future milestones or royalties to UNC or other licensors in the event of KNOW Bio non-performance under the sublicense arrangement; however, if KNOW Bio failed to pay these obligations, KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. See Note 2—Research and Development Agreements for detailed information regarding potential future milestone and royalty payments due to UNC and other licensors. The contractual terms of KNOW Bio SOW #1, including upfront payment requirements, cost-plus pricing and timely payment terms mitigate the current or potential future risk of loss to the Company for services performed under KNOW Bio SOW #1.

***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 June 30, 2017, the Company had an accumulated deficit of \$144,527.
- 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. The Company expects that the amount of cash and cash equivalents on hand as of June 30, 2017 will not be sufficient to fund all planned operating activities within one year from the date that these financial statements are issued.

The Company has concluded that these conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date that these financial statements are issued. To mitigate these conditions, the Company needs and intends to raise additional funds through equity or debt financings or generate revenues or other payments from collaborative or licensing partners prior to the commercialization of the Company's product candidates. There can be no assurance that the Company will be able to obtain additional equity or debt financing or generate revenues or other payments from collaborative or licensing partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could cause the Company to alter or reduce its planned operating activities, including but not limited to delaying planned product candidate development activities, to conserve its cash and cash equivalents. Such actions could delay development timelines and have a material adverse effect on the Company's results of operations, financial condition and market valuation. Additionally, there is no assurance that the Company can achieve its development milestones or that its intellectual property rights will not be challenged.

***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.

NOVAN, INC.

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

***Unaudited Interim Condensed Consolidated Financial Statements***

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP 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 set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2017.

***Leases***

The Company leases office space and certain equipment under non-cancelable lease agreements. The leases are reviewed for classification as operating or capital leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, the Company records the leased asset with a corresponding liability and amortizes the asset over the lease term. Payments are recorded as reductions to the liability with an appropriate interest charge recorded based on the then-outstanding remaining liability.

The Company considers the nature of the renovations and the Company's involvement during the construction period of newly leased office space to determine if it is considered to be the owner of the construction project during the construction period. If the Company determines that it is the owner of the construction project, it is 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 assesses whether the circumstances qualify for sales recognition under the sale-leaseback accounting guidance. If the lease meets the sale-leaseback criteria, the Company will 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 does not meet the sale-leaseback criteria, the leased property will be treated as an asset financing for financial reporting purposes. The portion of the facility financing obligation representing the principal that will be repaid in the next 12 months will be classified as a current liability in the consolidated balance sheets, with the remaining portion of the obligation classified as a noncurrent liability. See Note 5—Commitments and Contingencies for further discussion of the Company's application of this guidance related to the Company's primary facility lease.

***Research and Development Expense Accruals***

The Company is required to estimate its expenses resulting from its obligations under contracts with clinical research organizations, clinical site agreements, vendors, and consultants in connection with conducting clinical trials and preclinical development. The financial terms of these contracts are subject to negotiations which vary from contract to contract, and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate development and clinical trial expenses in its financial statements by matching those expenses with the period in which the services and efforts are expended.

For clinical trials, the Company accounts for these expenses according to the progress of the trial as measured by actual hours expended by contract research organization (CRO) personnel, investigator performance or completion of specific tasks, patient progression, or timing of various aspects of the trial. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company utilizes judgment and experience to estimate its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in increases or decreases in research and development expenses in future periods when the actual results become known.

For preclinical development services performed by outside service providers, the Company determines accrual estimates through financial models, taking into account development progress data received from outside service providers and discussions with applicable Company and service provider personnel.

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

***Revenue Recognition—Licensing Arrangements***

The Company entered into a licensing arrangement in the first quarter of 2017, and may enter into additional licensing arrangements in the future, in exchange for non-refundable upfront payments and potential future milestone and royalty payments. Such arrangements include multiple elements, including the sale of licenses and the provision of services. For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has “stand-alone value” to the licensee. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. When an arrangement is accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue recognized. Management exercises significant judgment in the determination of (i) whether a deliverable has stand-alone value, (ii) whether the deliverable is considered to be a separate unit of accounting and (iii) the estimation of the relative fair value of each deliverable in the arrangement.

The Company recognizes a milestone payment when earned if it is substantive and the Company has no ongoing performance obligations related to the milestone. A milestone payment is considered substantive if it: (i) is commensurate with either the Company’s performance to achieve the milestone or the enhanced value of the delivered item as a result of a specific outcome from the performance to achieve the milestone; (ii) relates solely to past performance; and (iii) is reasonable relative to all of the deliverables and payment terms, including consideration of other potential milestones, within the arrangement.

Amounts received prior to satisfying all revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. See Note 3—Collaboration Arrangements for further information and accounting considerations related to licensing arrangements revenue recognition.

***Revenue Recognition—Research and Development Services***

The Company recently entered into an arrangement to provide research and development services on a fee-for-service basis and may enter into additional arrangements in the future. Under such arrangements, revenue is recognized when all of the following conditions are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) fees are fixed or determinable, and (iv) collection of fees is reasonably assured. The Company’s contract research and development services revenue is recognized in the period in which the services are performed.

During the three and six months ended June 30, 2017, the Company recognized \$68 in research and development services revenue for services performed under KNOW Bio SOW #1 and had current deferred revenue related to these services of \$3 as of June 30, 2017.

***Share-Based Compensation***

*Employees.* The Company applies the fair value method of accounting for share-based compensation, which requires all such compensation to employees, including the grant of employee stock options, to be recognized in the statement of operations based on its fair value at the measurement date (generally the grant date). The expense associated with share-based compensation is recognized on a straight-line basis over the service period of each award. Share-based awards granted to non-employee directors as compensation for serving on the Company’s Board of Directors are accounted for in the same manner as employee share-based compensation awards.

*Non-employees.* For share-based compensation granted to non-employees, other than non-employee directors, the measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

The fair value of each option grant is estimated using a Black-Scholes option-pricing model on the grant date using expected volatility, risk-free interest rate, expected life of options and fair value per share assumptions. Due to limited historical data, the Company estimates stock price volatility based on the actual volatility of comparable publicly traded companies over the expected life of the option. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, financial leverage, size and risk profile.

NOVAN, INC.

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

The Company does not have sufficient history of exercise of stock options to estimate the expected term of employee stock options and thus continues to calculate expected life based on the mid-point between the vesting date and the contractual term, which is in accordance with the simplified method. The expected term for share-based compensation granted to non-employees is the contractual life. The risk-free rate is based on the U.S. Treasury yield curve during the expected life of the option.

**Income Taxes**

The Company did not record a federal or state income tax benefit for the three and six months ended June 30, 2017 and 2016 due to its conclusion that a full valuation allowance is required against the Company's deferred tax assets.

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

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

The Company's policy for recording interest and penalties is to record them as a component of general and administrative expenses. As of June 30, 2017 and December 31, 2016, the Company accrued no interest and penalties related to uncertain tax positions.

Tax years that remain subject to examination by federal and state tax jurisdictions date back to the year ended December 31, 2008. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years are under examination.

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

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its net operating loss carryforwards created during the tax periods prior to the change in ownership. The Company has not determined whether ownership changes exceeding this threshold, including the Company's initial public offering ("IPO"), have occurred. If a change in equity ownership has occurred which exceeds the Section 382 threshold, a portion of the Company's net operating loss carryforwards may be limited.

**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 for 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 antidilutive 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 six months ended June 30, 2017 and 2016 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. Subsequent to the completion of the IPO in September 2016, the convertible preferred stock securities are no longer potentially dilutive, because upon completion of the IPO, all outstanding shares of the convertible preferred stock were converted into shares of common stock at their conversion prices.

	June 30,	
	2017	2016
Convertible preferred stock	—	8,776,269
Stock options outstanding	1,105,251	612,066

NOVAN, INC.

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

***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.

Although all operations are based in the United States, the Company generated revenue of \$701, or 91% of total revenue, from its licensing partner in Japan during the six months ended June 30, 2017. Revenues are attributed to countries based on the location of the partner or customer.

***Recently Issued Accounting Standards***

*Accounting Pronouncements Adopted*

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The FASB issued ASU 2016-09 to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences. This ASU is effective for annual and interim periods beginning after December 15, 2016, with early adoption permitted. This standard was effective for the Company as of January 1, 2017. The adoption of this standard did not have a material impact on its consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-17, *Consolidation (Topic 810): Interests Held through Related Parties That Are under Common Control*, which amends the consolidation guidance on how a reporting entity that is a single decision maker of a variable interest entity should treat indirect interests in the entity held through related parties that are under common control. This guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. This ASU was effective for the Company as of January 1, 2017. Adoption of this standard did not have a material impact on its consolidated financial statements.

*Accounting Pronouncements Being Evaluated*

In May 2014, the FASB and the International Accounting Standards Board issued a converged standard on the recognition of revenue from contracts with customers. The converged standard has been codified within Topic 606, *Revenue from Contracts with Customers* of the FASB Accounting Standard Codification (ASC). The objective of the new standard is to establish a single comprehensive revenue recognition model that is designed to create greater comparability of financial statements across industries and jurisdictions. Under the new standard, companies will recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will require expanded disclosures on revenue recognition and changes in assets and liabilities that result from contracts with customers. In July 2015, the FASB delayed the effective date of the new standard by one year. Early adoption as of January 1, 2017 is permitted. In March, April and May of 2016, the FASB issued additional ASUs to amend Topic 606 and to provide expanded or clarifying guidance associated with the application of certain principles within the revenue recognition model, including the areas of principle and agent, identification of performance obligations, licensing and other improvements and practical expedients.

The Company intends to adopt the Topic 606 guidance on January 1, 2018. The Company is currently evaluating the impact that Topic 606 will have on reported revenues in 2017 and in future periods associated with the Sato Agreement (Note 3—Collaboration Arrangements) and the KNOW Bio Services Agreement and related KNOW Bio SOW #1. The Company is also evaluating the impact that the adoption of Topic 606 will have on its recognition of costs related to obtaining contracts. The standard permits the use of either the full retrospective or modified retrospective transition method and the Company has not yet selected which transition method it will apply.

In February 2016, the FASB issued 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. This ASU is effective for annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

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In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The FASB issued ASU 2016-09 to improve U.S. GAAP by providing guidance on the cash flow statement classification of eight specific areas where there is existing diversity in practice. The FASB expects that the guidance in this ASU will reduce the current and potential future diversity in practice in such areas. This ASU is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company plans to adopt this standard on January 1, 2018 and is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, to improve U.S. GAAP by providing guidance on how to classify and present changes in restricted cash or restricted cash equivalents occurring due to transfers between cash, cash equivalents and restricted cash. This ASU is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company plans to adopt this standard on January 1, 2018 and is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which clarifies the definition of a business to provide additional guidance with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This ASU is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company plans to adopt this standard on January 1, 2018 and is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, to clarify and reduce diversity in practice and cost and complexity of applying guidance for modifications in Topic 718. Specifically, this ASU further defines which changes to terms or conditions of share-based awards require application of modification accounting in Topic 718. This ASU is effective for annual periods beginning after December 15, 2017, including interim periods within those periods, with early adoption permitted. The Company plans to adopt this standard on January 1, 2018 and is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

**Note 2: 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 the University of North Carolina at Chapel Hill ("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, and KIPAX AB. 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 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 new chemical entity ("NCE") for the Company's product candidates. The UNC 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, KNOW Bio and Sato Pharmaceutical Co., Ltd. ("Sato"), as described further in Note 3—Collaboration Arrangements. Additionally, as described in Note 3—Collaboration Arrangements, the Company made a payment to UNC in February 2017 representing the portion of the upfront payment under the license agreement entered into with Sato that was estimated to be directly attributable to the UNC intellectual property rights included in the license to Sato.

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Unless earlier terminated, the UNC 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 3: Collaboration Arrangements**

***KNOW Bio Technology Agreement***

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 granted to KNOW Bio exclusive licenses, with the right to sublicense, to certain U.S. and foreign patents and patent applications controlled by the Company as of December 29, 2015. The Company also granted to KNOW Bio a non-exclusive license, with the right to sublicense, to any patents and patent applications that may become controlled by the Company during the three years immediately following the agreement's effective date related to nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing and other nitric oxide-based therapeutics.

*Sublicense of UNC and other third party intellectual property to KNOW Bio.* The Company also 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 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, KNOW Bio is subject to the terms and conditions under the UNC License Agreement, including milestone and diligence payment obligations. However, the Company is obligated to pay UNC any future milestones or royalties in the event of KNOW Bio non-performance under the sublicense arrangement. In such an event, KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. There were no milestone or royalty payments required during the three and six months ended June 30, 2017 and 2016.

***Sato License Agreement***

***Significant Terms***

On January 12, 2017, the Company entered into a license agreement, and related amendment, with Sato, relating to SB204, its drug candidate for the treatment of acne vulgaris in Japan (the "Sato Agreement"). Pursuant to the Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable right and license under certain of the Company's intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 in certain topical dosage forms for the treatment of acne vulgaris, and to make the finished form of such products. The rights granted to Sato do not include the right to manufacture the active pharmaceutical ingredient of SB204, which the Company, or its designated contract manufacturer, will retain the rights to supply to Sato. The Company, or its designated contract manufacturer, will also supply finished product to Sato for use in the development of SB204 in the licensed territory. During a specified time period, Sato has an exclusive option to negotiate the terms under which its license would be expanded to include certain additional territories within Asia, subject to Sato's payment of a specified option exercise fee. Under the terms of the Sato Agreement, the Company also has exclusive rights to certain intellectual property that may be developed by Sato in the future, which the Company could choose to use for its own development and commercialization of SB204 outside of Japan.

In exchange for the licenses granted to Sato under the Sato Agreement, Sato agreed to pay the Company an upfront payment, as well as additional milestone payments upon achievement of various future development, regulatory and commercial milestones. Pursuant to the terms of the Sato Agreement, Sato was required to pay the Company an upfront payment of 1.25 billion Japanese Yen ("JPY"), which the Company received in January 2017 in the amount of \$10,813 when converted to U.S. Dollars. Sato is also required to pay the Company an aggregate of 2.75 billion JPY upon the achievement of various development and regulatory milestones. Under the Sato Agreement, Sato also agreed to pay the Company up to an aggregate of 0.9 billion JPY in milestone payments upon the achievement of various commercial milestones. Sato must also pay the Company a royalty equal to a mid-single digit percentage of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

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The term of the Sato Agreement and the period during which Sato must pay royalties under the Sato Agreement expires, on a licensed product-by-licensed product basis, on the tenth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory. The term of the Sato Agreement may be renewed by mutual written agreement of the parties for additional two year periods following expiration of the initial term.

The Company, by itself or through its designated third party contract manufacturer, is obligated pursuant to the Sato Agreement to supply Sato with all quantities of licensed products required by Sato to develop the licensed products in the licensed field in the licensed territory. As part of the Sato Agreement, the Company and Sato have also agreed to negotiate a commercial supply agreement pursuant to which the Company, by itself or through its designated third party contract manufacturer, would be the exclusive supplier to Sato of the active pharmaceutical ingredient of licensed products for the manufacture of licensed products in the licensed territory.

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 in the U.S, (ii) sharing all future scientific information the Company may obtain during the term of the Sato Agreement pertaining to SB204, (iii) performing certain additional pre-clinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of \$1,000 and (iv) participating in a joint committee that oversees, reviews and approves Sato's development and commercialization activities under the Sato Agreement. Additionally, the Company has granted Sato the option to use the Company's trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to the Company's approval of such use.

The Sato Agreement may be terminated by (i) Sato without cause upon 120 days' advance written notice to the Company, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) force majeure, (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency and (v) the Company immediately upon written notice if Sato challenges the validity, patentability, or enforceability of any of the Company's patents or patent applications licensed to Sato under the Sato Agreement. In the event of a termination, no portion of the upfront fee received from Sato in January 2017 is refundable.

*Accounting Considerations and Revenue Recognition*

The Company has identified the following four performance deliverables 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 grant of an optional right to use the Company's trademark. The Sato Agreement also contains an obligation to manufacture and supply all quantities of the active pharmaceutical ingredient contained in the licensed product manufactured by Sato for commercial sale in Japan. The Company concluded this commercial supply obligation was a contingent deliverable because SB204 is not yet a commercially approved product and is currently subject to additional clinical studies prior to commercial approval in Japan. The Company considered the provisions of the multiple-elements arrangement guidance and determined that none of the deliverables have standalone value because Sato's ability to utilize the value of the licensed intellectual property rights is limited absent the delivery of the other elements of the arrangement. In particular, the Company has maintained control of the methods and expertise necessary to manufacture and supply the active pharmaceutical ingredient in the licensed product, which limits the utility and causes an interdependency of the remaining elements on the delivery of quantities of licensed product required for development activities in Japan. As a result, all deliverables have been combined into a single unit of accounting.

The Company evaluated the timing of delivery for each of the deliverables and concluded that its obligation to participate on the joint committee during Sato's development process would be the last delivered element under the arrangement and therefore would be the basis for revenue recognition for the combined unit of accounting. The Company began to participate on the joint committee in March 2017 and estimates that its participation will continue through the third quarter of 2021. This time period is the Company's estimated performance period. The total upfront consideration under this agreement is being recognized as license and collaboration revenue on a straight-line basis over the estimated performance period. As described in Note 1—Organization and Significant Accounting Policies, the Company intends to adopt FASB ASC Topic 606, *Revenue from Contracts with Customers*, guidance on January 1, 2018, and is currently evaluating the impact that Topic 606 will have on reported revenues in 2017 and in future periods.

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The Company determined that the future contingent payments meet the definition of a milestone. The development and regulatory milestones are not considered to be substantive because they do not relate solely to past performance. Accordingly, revenue for the achievement of development milestones will be recognized over the performance period, assuming collectability is reasonably assured. The revenue for the achievement of regulatory milestones will be recognized over the ten year commercial term of the Sato Agreement. As of June 30, 2017, no amounts have been recognized as license and collaboration revenue for any of these potential future milestones and all the contingent payments remained eligible for achievement as of June 30, 2017.

During the three and six months ended June 30, 2017, the Company recognized \$601 and \$701, respectively, in license and collaboration revenue under this agreement. The deferred revenue balance pertaining to the Sato Agreement as of June 30, 2017 was \$10,112, including \$2,403 and \$7,709 in current and non-current deferred revenue, respectively.

*Contract Acquisition Costs*

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 Company's license agreement with UNC described in Note 2—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 made a payment to UNC in February 2017 representing the portion of the Sato upfront payment that was estimated to be directly attributable to the UNC intellectual property rights included in the license to Sato.

The Company also 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 paid a fee of \$216 to the third party upon execution of the Sato Agreement and is obligated to pay the third party a low-single-digit percentage of any future milestone payments the Company may receive from Sato under the Sato Agreement.

The fees associated with payments made to UNC and the third party have been capitalized as an other asset, including current and noncurrent portions, in the accompanying balance sheet and are being amortized as general and administrative expense on a straight-line basis over the same estimated period used to recognize revenue on the upfront payment received from Sato.

**Note 4: Property and Equipment, Net**

Property and equipment consisted of the following:

	June 30, 2017	December 31, 2016
Computer equipment	\$ 517	\$ 500
Furniture and fixtures	524	504
Laboratory equipment	6,856	5,723
Office equipment	166	106
Building related to facility lease obligation	10,557	10,557
Leasehold improvements	1,359	1,338
	<u>19,979</u>	<u>18,728</u>
Less: Accumulated depreciation and amortization	(3,041)	(2,438)
	<u>\$ 16,938</u>	<u>\$ 16,290</u>

Depreciation and amortization expense was \$340 and \$639 for the three and six months ended June 30, 2017, respectively, and \$201 and \$388 for the three and six months ended June 30, 2016.

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**Note 5: Commitments and Contingencies**

***Lease Obligations***

*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 initial term of the lease agreement extends through June 30, 2026. The Company has an option to extend the lease agreement by five years upon completion of the initial lease term. Current contractual base rent payments are \$93 per month, subject to a three percent increase annually over the term of the lease agreement.

As a result of the nature of and the involvement in the renovations during the construction period of the leased space, the Company was the “deemed owner,” for accounting purposes only, of the construction project and was required to capitalize the fair value of the building as well as the construction costs incurred by either the landlord or the Company on its condensed consolidated balance sheets pursuant to FASB ASC 840, *Leases*, and the accounting policy described in Note 1—Organization and Significant Accounting Policies. The Company determined that the facility was substantially complete as of December 31, 2016 because the Company began to utilize the facility for all intended purposes, including primary research, development and drug compound manufacturing operations, in addition to administrative and corporate headquarters activities. Following the determination that the facility was substantially complete, the Company assessed the facility for sale-leaseback criteria qualification, which could result in a de-recognition of the building asset and the related financing obligation. The Company concluded that the facility did not meet the sale-leaseback criteria due to the Company’s continuing involvement in the leased facility. As a result, the facility is being 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 is being depreciated over a 25 year period and the facility financing obligation is being amortized so that the net carrying value of the building asset and the facility financing obligation are equivalent at the end of the initial term of the lease agreement. Monthly rental payments will be allocated between principal and interest expense associated with the facility financing obligation, as well as grounds rent expense of \$8 per month.

The Company has recorded an asset related to the building and construction costs within property and equipment of \$10,557 as of June 30, 2017. The non-current facility lease obligation on the Company’s condensed consolidated balance sheet is \$7,998 as of June 30, 2017 and December 31, 2016. During the three and six months ended June 30, 2017, the Company recognized interest expense of \$261 and \$522, respectively, including \$21 of accrued interest included in other accrued expenses as of June 30, 2017.

*Operating Leases*

The Company leased a facility under a non-cancelable operating lease that expired in April 2017. Rent expense for operating leases totaled \$93 and \$251 for the three and six months ended June 30, 2017, respectively, and \$124 and \$209 for the three and six months ended June 30, 2016, respectively.

***Contingencies***

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not subject to any current pending legal matters or 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 June 30, 2017.

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***Indemnification***

In the ordinary course of business, the Company has entered into contractual arrangements under which it has agreed to provide indemnification of varying scope and terms to business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of the Company's breach of such agreements and out of intellectual property infringement claims made by third parties. In these circumstances, payment may be conditional on the other party making a claim pursuant to the procedures specified in the particular contract.

The Company's obligations under these agreements may be limited in terms of time or amount, and in some instances, the Company may have recourse against third parties for certain payments. The terms of such obligations vary.

It is not possible to make a reasonable estimate of the maximum potential amount of future payments under these or similar agreements due to the conditional nature of the Company's obligations and the unique facts and circumstances involved in each particular agreement. No material indemnification liabilities were identified or accrued in the accompanying financial statements.

***Compensatory Obligations***

In conjunction with the departures of Richard Peterson, former Chief Financial Officer, in March 2017 and M. Joyce Rico, M.D., former Chief Medical Officer, in May 2017, the Company entered into separation and general release agreements with both individuals that included separation benefits consistent with the Company's obligations under their previously existing employment agreements for "separation from service" for "good reason." Each former officer's separation agreement provided for (i) cash severance payments equal to 12 months of base salary, which will be paid over 12 months commencing with the first payroll period following the departure date; (ii) accelerated vesting of any options to purchase the Company's common stock held by the former officers that would have vested during calendar year 2017 but for their departure; and (iii) the continuation of certain medical, dental and life insurance benefits for 18 months (subject to reduction or discontinuation of benefits if the individual becomes covered by the plans of a subsequent employer). The resulting combined severance expense recognized in the three and six months ended June 30, 2017 totaled approximately \$397 and \$793, respectively. The remaining accrued severance obligation in respect of the two former officers was \$640 as of June 30, 2017, which is included in accrued compensation in the accompanying condensed consolidated balance sheet. The Company also recognized approximately \$124 and \$374 in stock compensation expense during the three and six months ended June 30, 2017, respectively, related to the accelerated vesting of the former officers' stock options.

In June 2017, the Company reduced its overall employee workforce to reduce operating expenditures and preserve cash on hand. Employee severance costs associated with this action were \$224, which were expensed during the second quarter of 2017. The remaining accrued severance obligation was \$105 as of June 30, 2017.

**Note 6: Stockholders' Equity**

***Capital Structure***

*Authorized Shares.* In conjunction with the completion of the IPO 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.

***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 June 30, 2017 and December 31, 2016.

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**Common Stock**

*Authorized, Issued and Outstanding Common Shares*

The Company's common stock has a par value of \$0.0001 per share and consists of 200,000,000 authorized shares as of June 30, 2017 and December 31, 2016. There were 15,981,591 and 15,939,992 shares of voting common stock outstanding as of June 30, 2017 and December 31, 2016, respectively. The following table summarizes common stock share activity for the six months ended June 30, 2017:

	<u>Common Stock</u>
Balance as of December 31, 2016	15,939,992
Exercise of stock options	41,599
Balance as of June 30, 2017	<u>15,981,591</u>

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

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Outstanding stock options	1,105,251	825,130
For possible future issuance under 2016 Stock Plan (Note 7)	1,348,470	615,207
	<u>2,453,721</u>	<u>1,440,337</u>

**Note 7: Stock Option Plan**

*2008 Stock Plan*

During 2008, the Company adopted the 2008 Stock Plan (the "2008 Plan"). As amended, a total of 1,416,666 shares of common stock were reserved for issuance under the 2008 Plan. Eligible plan participants included employees, directors, and consultants. The 2008 Plan permitted the granting of incentive stock options, nonqualified stock options, and other stock-based awards. As further described below, as of September 20, 2016, no additional awards will be granted under the 2008 Plan.

*2016 Stock Plan*

Effective September 20, 2016 (the "Effective Date"), the Company adopted the 2016 Incentive Award Plan (the "2016 Plan"). The 2016 Plan is the successor to the 2008 Plan. As of the Effective Date, no additional awards will be granted under the 2008 Plan, but all stock awards granted under the 2008 Plan prior to the Effective Date will remain subject to the terms of the 2008 Plan. Any shares associated with stock awards previously granted under the 2008 Plan that are forfeited subsequent to the Effective Date of the 2016 Plan are not eligible for future issuance under the 2016 Plan. All awards granted on and after the Effective Date will be subject to the terms of the 2016 Plan. The 2016 Plan provides for the grant of the following awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. Eligible plan participants include employees, directors, and consultants. An aggregate of 833,333 shares of the Company's common stock were initially available for issuance under awards granted pursuant to the 2016 Plan, which shares may be authorized but unissued shares, treasury shares, or shares purchased in the open market.

On June 5, 2017, the Company's stockholders approved an amendment to the 2016 Plan to increase the aggregate number of shares of common stock that may be issued pursuant to awards under the 2016 Plan by an additional 1,200,000 shares. All other material terms of the 2016 Plan otherwise remained unchanged. As of June 30, 2017, there were 1,348,470 shares available for future issuance under the 2016 Plan.

Under both the 2008 Plan and the 2016 Plan, options to purchase the Company's common stock may be granted at a price no less than the fair value of a common stock share on the date of grant. The fair value shall be the closing sales price for a share as quoted on any established securities exchange for such grant date or the last preceding date for which such quotation exists. Vesting terms of options issued are determined by the board of directors or compensation committee of the board. The Company's stock options vest based on terms in the stock option agreements and have a maximum term of ten years.

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*Stock Compensation Expense*

During the three and six months ended June 30, 2017, the Company recorded employee share-based compensation expense of \$883 and \$2,135, respectively. During the three and six months ended June 30, 2016, the Company recorded employee share-based compensation expense of \$307 and \$534, respectively. Total share-based compensation expense included in the condensed consolidated statements of operations is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	\$ 430	\$ 92	\$ 826	\$ 179
General and administrative	453	215	1,309	355
	<u>\$ 883</u>	<u>\$ 307</u>	<u>\$ 2,135</u>	<u>\$ 534</u>

Stock option activity for the six months ended June 30, 2017 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, 2016	825,130	\$ 11.27		
Options granted	535,738	5.40		
Options forfeited	(214,018)	11.09		
Options exercised	(41,599)	0.82		
Options outstanding as of June 30, 2017	<u>1,105,251</u>	\$ 8.43	8.54	\$ 401

**Note 8: Related Party Transactions**

Members of the Company's board of directors held 1,561,916 shares of the Company's common stock as of June 30, 2017 and December 31, 2016, respectively.

In June 2017, Kelly Martin, Chief Executive Officer of Malin Corporation, PLC, a greater than 10% shareholder of the Company, assumed the role of the Company's Chief Executive Officer on an interim basis. Mr. Martin also continues to serve as a member of the Company's board of directors. Mr. Martin has not received any additional compensation for his service in this role during the three and six months ended June 30, 2017. Mr. Martin is continuing to be compensated pursuant to the Company's non-employee director compensation policy.

## 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, 2016 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 20, 2017.*

*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 "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "potential," "predict," "project," "estimate," or "continue" 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:*

- 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 commercial prospects with respect to, and ability to generate revenues from, such 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 dermatology therapeutics, 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.*
- We will need substantial additional funding and as of June 30, 2017, we had an accumulated deficit of \$144.5 million. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs.*
- 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, 2016 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 rely on third parties to manufacture clinical drug supplies for us and parties with which we contract, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Failure of those third parties to obtain approval of the FDA or comparable regulatory authorities, to provide us with sufficient quantities of drug product or to provide sufficient quantities of drug product at acceptable quality levels or prices could adversely impact our 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 any other Nitricil NCEs, in our facility, for support of our development activities could adversely affect our development and commercialization timelines and result in increased costs of our development programs.*
- 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.*
- Even if we obtain marketing approval for any product candidates, the products may become subject to unfavorable third-party coverage or reimbursement policies.*

- *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.*
- *Changes to our leadership team could prove disruptive to our operations and have adverse consequences for our business and operating results.*

*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.*

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 pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using our nitric oxide platform. 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 first-in-class 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 topical formulation science, both of which we use to tune our product candidates for specific indications. We believe that our ability to conveniently deploy nitric oxide on demand in topical formulations allows us the potential to significantly improve patient outcomes in a variety of skin diseases. We have advanced programs with four product candidates for dermatological conditions with significant unmet medical need, including development programs with anti-acne (SB204), anti-viral (SB206), anti-inflammatory (SB414), and anti-fungal (SB208) applications.

### Key Drug Development Updates

We recently made adjustments to focus our near-term drug development strategy on the advancement of our SB206 anti-viral drug candidate for the treatment of external genital warts and molluscum based on positive Phase 2 results and our recent positive interactions with the FDA. We also plan to conduct two Phase 1b trials of our SB414 drug candidate for the treatment of psoriasis and atopic dermatitis based upon promising clinical and preclinical data demonstrating mechanistic evidence of nitric oxide's potential in the treatment of such diseases.

Below is a summary of selected key developments related to our drug candidates during or subsequent to the second quarter of 2017 and certain upcoming milestones.

- **SB204 for the Treatment of Acne Vulgaris**—We recently completed our 40-week long term safety trial in eligible patients with acne who had previously completed 12 weeks of treatment in the related Phase 3 pivotal trials of SB204. No significant adverse events were observed with over 400 patients followed for six months and over 200 patients followed for one year. The FDA has granted a pre-NDA meeting to be held in the third quarter of 2017. We intend to seek clinical and regulatory clarity around the SB204 program during this meeting and, afterwards, we will determine the appropriate path forward for the SB204 program.
- **SB206, a Topical Anti-viral Treatment for Viral Skin Infections**—We completed an end-of-Phase 2 meeting with the FDA in the second quarter of 2017 and we believe we are in a position to proceed to Phase 3 development for the treatment of external genital and perianal warts caused by human papilloma virus. We target initiating Phase 3 pivotal trials in the first half of 2018, along with related open label long term safety testing to evaluate recurrence rates and multiple courses of treatment.

Also at the end-of-Phase 2 meeting, we had a constructive discussion with the FDA regarding expansion of the SB206 program into the treatment of molluscum contagiosum, a contagious skin infection caused by the *molluscipoxvirus*. Molluscum affects approximately six million people in the U.S. annually, mostly children. There is no FDA-approved treatment for molluscum and practitioners often prescribe products approved for the treatment of external genital warts to patients with molluscum. Our in-licensed sodium nitrite/citric acid topical treatment that generates nitric oxide when applied to the skin demonstrated a clinically meaningful (48%) complete clearance rate of baseline molluscum lesions compared to a 29% rate with placebo group after 12 weeks of treatment. This observational learning, combined with our SB206 program knowledge, provides a logical pathway for SB206 development in the molluscum indication. We target initiating a Phase 2 clinical trial utilizing SB206 for the treatment of molluscum in the first quarter of 2018.

- **SB414, a Topical Cream for the Treatment of Inflammatory Skin Diseases**—We presented data at the annual Society for Investigative Dermatology meeting in the second quarter of 2017 that demonstrated mechanistic evidence of nitric oxide's potential when administered as a locally-applied, topical cream formulation for the treatment of inflammatory skin diseases. Specifically, we observed in preclinical models that SB414 significantly ( $p < 0.05$ ) reduced composite psoriasis scores, which consist of erythema and plaque scores, and reduced pro-inflammatory cytokines, including IL-17, in a psoriasis mouse model. Additionally, in two in vivo models that assess critical components of atopic dermatitis disease pathology, SB414 displayed potent anti-staphylococcal activity and dose-dependent inhibition of inflammation comparable to betamethasone, a mid-potency corticosteroid used to treat patients with atopic dermatitis, or eczema. We have conducted toxicology studies for SB414 in support of the submission of an investigational new drug application, or IND, to the FDA with a planned filing in the third quarter of 2017.

We target initiating two Phase 1b trials, one in patients with psoriasis and one in patients with atopic dermatitis, before the end of 2017. These trials will allow us to assess (i) systemic exposure through pharmacokinetic evaluations, (ii) key biomarkers of inflammation, and (iii) safety and cutaneous tolerability.

We need and intend to access additional capital through equity or debt financing or collaborative, licensing or other non-dilutive sources of capital. Further advancement of our development programs, as described above, is dependent upon our ability to access this capital and our financial priorities.

### ***Corporate Updates—Organizational Structure***

We repositioned our organizational structure to align with the aforementioned drug development strategy. In doing so, position changes occurred at the board and executive management team levels, as described below. We also reduced our employee workforce by approximately 20% in June 2017 to reduce near-term operating costs and preserve cash on our balance sheet.

#### *Board of Directors*

- In June 2017, Robert Ingram, the Chairman of our board of directors, assumed the role of non-employee Executive Chairman of the board of directors. Also in June 2017, Kent Geer assumed the role of Lead Independent Director in addition to his current role as Chairman of the audit committee.

#### *Executive Management Team*

- In June 2017, Nathan Stasko, formerly President and Chief Executive Officer, began his new role of President and Chief Scientific Officer, in which he is responsible for helping us deepen the understanding of the possibilities of nitric oxide and its potential therapeutic applications across patient needs.
- Also in June 2017, Kelly Martin, one of our directors, assumed the role of our Chief Executive Officer on an interim basis, in which he is responsible for positioning us in a manner that allows the science to further mature and develop on an accelerated timeline. Additionally, he is focused on extending the business runway and broadening the therapeutic applications of the underlying drug technology platform. Mr. Martin continues to serve as a director on our board but, effective with this transition, stepped down from his previous role as a member of the board's compensation committee.
- In May 2017, M. Joyce Rico, M.D., our former Chief Medical Officer, departed the Company. We entered into a separation and general release agreement with Dr. Rico that included separation benefits. Associated costs and obligations are described in "Note 5—Commitments and Contingencies" to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and in the "Results of Operations" and "Liquidity and Capital Resources" sections below.
- In August 2017, we extended our employment arrangement with William L. Hodges, Interim Chief Financial Officer, through November 15, 2017.

### ***Corporate Updates—Other***

- In June 2017, our stockholders approved an amendment to our 2016 Incentive Award Plan (the "Plan") to increase the number of shares that may be issued under the Plan by 1,200,000 shares.

### **Financial Overview**

Since our inception, 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 June 30, 2017, we have raised total equity and debt proceeds of \$148.7 million to fund our operations. We have incurred net losses in each year since inception and, as of June 30, 2017, we had an accumulated deficit of \$144.5 million. We incurred net losses of \$21.5 million and \$29.2 million in the six months ended June 30, 2017 and 2016, 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, there will be significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

In addition, 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. As a result, we will need substantial additional funding to support our future operating activities. Adequate future funding may not be available to us on acceptable terms, or at all. The top-line results from our parallel pivotal SB204 Phase 3 trials, coupled with the recent decline in

the market value of our common stock, may negatively impact our available funding options and the acceptability of funding terms. Our failure to obtain sufficient funds on acceptable terms as and when needed could cause us to alter or reduce our planned operating activities, including but not limited to delaying or discontinuing planned product candidate development activities, to conserve our cash and cash equivalents. 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.

## **Components of Our Results of Operations**

### ***Revenue***

Licensing and collaboration revenue consists of the amortization of a non-refundable \$10.8 million upfront payment received under the license agreement we entered into during the first quarter of 2017 with Sato Pharmaceuticals, Ltd. (“Sato”). The material terms of the Sato Agreement and related revenue recognition are described within “Note 3—Collaboration Arrangements” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. The \$10.8 million upfront consideration under this agreement is being recognized on a straight-line basis over the estimated performance period, which is currently March 2017 through the third quarter of 2021.

Research and development services revenue is associated with the master development services and clinical supply agreement and related statement of work, or KNOW Bio SOW #1, we entered into with KNOW Bio, LLC, or KNOW Bio, during the second quarter of 2017. Under KNOW Bio SOW #1, we are providing certain development services to KNOW Bio in exchange for service fees expected to total approximately \$0.3 million. We recognized approximately \$0.1 million of services revenue during the three months ended June 30, 2017 and expect to perform the remaining services and recognize the remaining revenue by the end of 2017. We may also provide clinical stage manufacturing services to KNOW Bio under future statements of work. We do not expect the fees received under KNOW Bio SOW #1 to significantly increase the period over which our cash and cash equivalents can fund our operating expenses.

We intend to adopt FASB ASC Topic 606, *Revenue from Contracts with Customers*, guidance on January 1, 2018, and we are currently evaluating the impact that Topic 606 will have on reported revenues in 2017 and in future periods, including revenues associated with the Sato Agreement and KNOW Bio SOW #1. Additional information about our adoption of Topic 606 is included in “Note 1—Organization and Significant Accounting Policies” to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

### ***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, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- costs to acquire, develop and manufacture supplies for clinical trials and preclinical studies, including fees paid to contract manufacturing organizations, or CMOs;
- legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- salaries and related costs, including stock-based compensation and travel expenses, 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 June 30, 2017, we have incurred approximately \$102.6 million in research and development expenses to develop, expand or otherwise improve our nitric oxide platform and resulting product candidates. 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 six months ended June 30, 2017 and 2016. All research and development salaries and related personnel costs, as well as certain manufacturing costs and facilities expenses are included in unallocated internal research and development expenses.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands)		(in thousands)	
External:				
SB204	\$ 2,333	\$ 11,011	\$ 5,565	\$ 15,701
SB206	24	802	(291)	1,784
SB208	183	498	389	642
SB414	750	120	1,325	294
Other programs	50	83	50	183
Unallocated internal research and development expenses	3,622	1,954	6,870	3,769
Total research and development expenses	<u>\$ 6,962</u>	<u>\$ 14,468</u>	<u>\$ 13,908</u>	<u>\$ 22,373</u>

We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on our clinical programs and on our future pipeline development. Major clinical and preclinical development activities conducted during the three and six months ended June 30, 2017 and 2016 are summarized as follows:

- For SB204, we commenced parallel pivotal Phase 3 clinical trials in the first quarter of 2016 and completed the trials and reported top-line results in the first quarter of 2017. Other related supporting clinical and nonclinical studies are being conducted, including the 40-week long-term safety trial of patients selected from our parallel pivotal trials.
- For SB206, we completed a Phase 2 clinical trial for the treatment of external genital warts and announced top-line results in the fourth quarter of 2016. The SB206 program expense credit of \$0.3 million in the six months ended June 30, 2017 relates primarily to a \$0.4 million favorable change in our accrued Phase 2 trial cost estimate recognized in the first quarter of 2017 as we obtained final trial activity data and reached an agreement on final trial costs with the clinical research organization that conducted the trial.
- For SB208, we initiated a Phase 2 clinical development program in July 2016 and announced top-line results in April 2017.
- For SB414, we continued to conduct and complete preclinical development activities in support of the submission of an IND to the FDA. In the second quarter of 2017, we also began start-up activities associated with Phase 1b trials we intend to initiate by the end of 2017.

We expect to continue to incur substantial research and development expenses in the future as we develop our clinical product candidates. In particular, we expect to continue to incur substantial research and development expenses, including both external development service provider fees as well as internal personnel and other research and development costs, through the remainder of 2017 associated with the development plan summarized in the “Overview—Key Drug Development Updates” section above. We may decide to revise our plans or the related timing, depending on our ability to access additional capital and our financial priorities. Although we expect external research and development expenses associated with the previously described 2017 clinical development activities to be substantial, we expect such expenses to be lower in 2017 than external research and development expenses incurred in 2016.

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 20, 2017, for a discussion of the risks and uncertainties associated with our research and development projects.

#### **General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation and travel expenses for personnel in our executive, finance, commercial, 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, and professional services fees for auditing, tax and general legal services.

We expect to continue to incur substantial general and administrative expenses in 2017 as we conduct our product development operating activities and support our operations in a public company environment, including significant expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors' and officers' liability insurance premiums and investor relations activities.

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

Other (expense) income, net consists primarily of (i) lease interest expense on our primary facility lease financing obligation, (ii) interest income earned on cash and cash equivalents and (iii) other miscellaneous expenses. We expect to continue to incur interest expense on our primary facility lease financing obligation during 2017 and throughout the remainder of the initial lease term that expires in 2026.

### **Results of Operations**

#### **Comparison of Three Months Ended June 30, 2017 and 2016**

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

	Three Months Ended June 30,		\$ Change	% Change
	2017	2016		
	(in thousands, except percentages)			
License and collaboration revenue	\$ 601	\$ —	\$ 601	*
Research and development services revenue	68	—	68	*
Total revenue	669	—	669	*
Operating expenses:				
Research and development	6,962	14,468	(7,506)	(52)%
General and administrative	3,361	3,467	(106)	(3)%
Total operating expenses	10,323	17,935	(7,612)	(42)%
Operating loss	(9,654)	(17,935)	8,281	46%
Other (expense) income, net	(233)	31	(264)	*
Net loss	\$ (9,887)	\$ (17,904)	\$ 8,017	45%

\* Not Meaningful

#### **Revenue**

License and collaboration revenue of \$0.6 million for the three months ended June 30, 2017 is related to the amortization of a non-refundable upfront payment received under the Sato Agreement, which was executed in January 2017. Research and development services revenue of \$0.1 million for the three months ended June 30, 2017 is associated with development services we performed under the master development services and clinical supply agreement and related statement of work entered into with KNOW Bio during the second quarter of 2017.

#### **Research and development expenses**

Research and development expenses were \$7.0 million for the three months ended June 30, 2017 compared to \$14.5 million for the three months ended June 30, 2016. The decrease of \$7.5 million was primarily due to the recent completion of certain clinical trials in our active development programs, including the two parallel Phase 3 pivotal trials in the SB204 program in the first quarter of 2017, which resulted in a decrease of \$8.7 million, the Phase 2 clinical trial for SB206 in the fourth quarter of 2016, which resulted in a decrease of \$0.8 million and the Phase 2 clinical trial for SB208 program, which resulted in a decrease of \$0.3 million. These program cost decreases were partially offset by a \$0.6 million increase in SB414 program costs as we conducted (i) preclinical studies in preparation for an IND submission and (ii) clinical start-up activities to support the planned initiation of Phase 1b trials by the end of 2017.

In addition, other unallocated internal research and development expenses increased by \$1.7 million due to a \$1.0 million increase in research and development personnel costs and a \$0.7 million increase in facility and manufacturing costs. The \$1.0 million increase in personnel costs is primarily comprised of \$0.8 million in severance costs associated with the reduction in workforce and the departure of our former Chief Medical Officer, including \$0.6 million in cash severance costs and \$0.2 million of non-cash stock compensation expense associated with the accelerated vesting of option awards. The remaining increase in personnel costs is due to an increase of \$0.2 million in non-cash stock compensation expense associated with recent awards granted to our research and development personnel. The \$0.7 million increase in facility and manufacturing costs is primarily due to operating in our current headquarters and manufacturing facility in Morrisville, North Carolina during 2017, which we began to occupy in October 2016.

### General and administrative expenses

General and administrative expenses were \$3.4 million for the three months ended June 30, 2017, compared to \$3.5 million for the three months ended June 30, 2016. The decrease of approximately \$0.1 million was primarily due to decreases of \$0.7 million in market research and related costs and \$0.2 million in general corporate costs. These decreases were partially offset by an increase of \$0.8 million in professional services, insurance, board compensation and other administrative costs necessary to support our operations as a public company.

### Other (expense) income, net

Other (expense) income, net was (\$0.2) million for the three months ended June 30, 2017, compared to approximately \$31,000 for the three months ended June 30, 2016. The net expense increase of approximately \$0.2 million was primarily due to the recognition of approximately \$0.3 million of lease interest expense on our primary facility lease financing obligation beginning in the first quarter of 2017, following the completion of the facility's build-out phase in December 2016. This interest expense incurred during the three months ended June 30, 2017 was partially offset by less than \$0.1 million of interest income earned on cash and cash equivalents.

### Comparison of Six Months Ended June 30, 2017 and 2016

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

	Six Months Ended June 30,		\$ Change	% Change
	2017	2016		
	(in thousands, except percentages)			
License and collaboration revenue	\$ 701	\$ —	\$ 701	*
Research and development services revenue	68	—	68	*
Total revenue	769	—	769	*
Operating expenses:				
Research and development	13,908	22,373	(8,465)	(38)%
General and administrative	7,892	6,834	1,058	15%
Total operating expenses	21,800	29,207	(7,407)	(25)%
Operating loss	(21,031)	(29,207)	8,176	28%
Other (expense) income, net	(463)	43	(506)	(1177)%
Net loss	\$ (21,494)	\$ (29,164)	\$ 7,670	26%

\* Not Meaningful

### Revenue

License and collaboration revenue of \$0.7 million for the six months ended June 30, 2017 was related to the amortization of a non-refundable upfront payment received under the Sato Agreement, which was executed in January 2017. Research and development services revenue of \$0.1 million for the six months ended June 30, 2017 is associated with the master development services and clinical supply agreement and related statement of work entered into with KNOW Bio during the second quarter of 2017.

### Research and development expenses

Research and development expenses were \$13.9 million for the six months ended June 30, 2017, compared to \$22.4 million for the six months ended June 30, 2016. The decrease of \$8.5 million was primarily due to the recent completion of certain clinical trials in our active development programs, including the two parallel Phase 3 pivotal trials in the SB204 program, which resulted in a decrease of \$10.1 million, the Phase 2 clinical trial for SB206, which resulted in a decrease of \$2.1 million and the Phase 2 clinical trial for SB208, which resulted in a decrease of \$0.3 million. In addition, other programs decreased by \$0.1 million. These program cost decreases were partially offset by a \$1.0 million increase in SB414 program costs as we conducted (i) preclinical studies in preparation for an IND submission and (ii) clinical start-up activities to support the planned initiation of Phase 1b trials by the end of 2017.

In addition, other unallocated internal research and development expenses increased by \$3.1 million, primarily comprised of a \$2.0 million increase in research and development personnel costs and a \$1.1 million increase in facility and manufacturing costs. The \$2.0 million increase in personnel costs includes \$0.6 million in cash severance costs associated with the reduction in workforce and the departure of our former Chief Medical Officer and a related \$0.2 million in non-cash stock compensation expense associated with the accelerated vesting of option awards. The remaining increase in personnel costs includes an increase in stock compensation expense of \$0.5 million associated with awards recently granted to our research and development personnel and \$0.7 million associated with increased personnel costs to support and administer our active development programs during the comparative periods. The \$1.1 million increase in facilities and manufacturing costs is primarily due to operating in our current headquarters and manufacturing facility in Morrisville, North Carolina during 2017, which we began to occupy in October 2016.

#### *General and administrative expenses*

General and administrative expenses were \$7.9 million for the six months ended June 30, 2017, compared to \$6.8 million for the six months ended June 30, 2016. The increase of approximately \$1.1 million is primarily comprised of \$0.8 million in severance costs associated with the reduction in workforce and the departure of our former Chief Financial Officer, including \$0.5 million of cash severance costs and \$0.3 million in related non-cash stock compensation expense associated with the accelerated vesting of option awards. The remaining increase relates to \$1.5 million in professional services, insurance, board compensation and other administrative costs necessary to support our operations as a public company. These increases were partially offset by a decrease of \$1.2 million in market research and related costs.

#### *Other (expense) income, net*

Other (expense) income, net was (\$0.5) million expense for the six months ended June 30, 2017, compared to approximately \$43,000 income for the six months ended June 30, 2016. The net expense increase of approximately \$0.5 million was primarily due to the recognition of approximately \$0.5 million of interest expense on our primary facility lease financing obligation beginning in the first quarter of 2017, following the completion of the facility's build-out phase in December 2016. This interest expense incurred during the six months ended June 30, 2017 was partially offset by less than \$0.1 million of interest income earned on cash and cash equivalents.

#### **Liquidity and Capital Resources**

Since our inception through June 30, 2017, we have financed our operations primarily with \$148.7 million in net proceeds from the issuance and sale of equity securities and convertible debt securities, including \$44.6 million in net proceeds from the sale of common stock in our 2016 initial public offering, or our IPO. Other historical forms of funding have included payments received from licensing and supply arrangements and government research contracts and grants. We received an upfront payment of approximately \$10.8 million following the execution of the Sato Agreement in the first quarter of 2017 for the exclusive right to develop, use and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris.

As of June 30, 2017, we had \$19.1 million of cash and cash equivalents. 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.

#### *Facility Lease Financing*

Our 51,000 square foot leased facility in Morrisville, North Carolina serves as our corporate headquarters and primary research, development and drug compound manufacturing facility. We have accounted for this lease as a capitalized asset and a corresponding facility financing obligation on our balance sheets. We began recognizing interest expense associated with this financing obligation in the first quarter of 2017, following the completion of the build-out phase in December 2016. See "Note 1—Organization and Significant Accounting Policies" and "Note 5—Commitments and Contingencies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for further discussion of the accounting for this lease.

## Cash Flows

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

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash provided by (used in):		
Continuing operating activities	\$ (14,430)	\$ (22,061)
Continuing investing activities	(1,143)	(2,409)
Continuing financing activities	29	(1,359)
Net decrease in cash and cash equivalents – discontinued operations	—	(257)
Net decrease in cash and cash equivalents	<u>\$ (15,544)</u>	<u>\$ (26,086)</u>

### Net Cash Used in Continuing Operating Activities

During the six months ended June 30, 2017, net cash used in operating activities was \$14.4 million and consisted primarily of a net loss of \$21.5 million, with adjustments for non-cash amounts related primarily to depreciation expense of \$0.6 million, stock-based compensation expense of \$2.1 million, and a \$4.3 million favorable change in assets and liabilities. The favorable net change in assets and liabilities was primarily due to receipt of an upfront payment of \$10.8 million following the execution of the Sato Agreement. This increase was partially offset by decreases in accounts payable and accrued expense balances associated with our outside research and development activities during the period, including a \$3.9 million decrease in accrued outside research and development services. The decrease in payables and accruals for these services was primarily related to the completion of two identically designed Phase 3 pivotal trials in our SB204 program and the Phase 2 clinical trial in our SB206 program. In addition, we had approximately \$0.7 million in accrued severance costs as of June 30, 2017, which we expect to settle through cash disbursements during the second half of 2017 and first half of 2018.

During the six months ended June 30, 2016, net cash used in operating activities was \$22.1 million and consisted primarily of a net loss of \$29.2 million with adjustments for non-cash amounts related primarily to depreciation expense of \$0.4 million, stock-based compensation expense of \$0.5 million and a \$6.2 million change in assets and liabilities. The favorable net change in assets and liabilities was primarily due to a \$5.1 million increase in accrued outside research and development services during the period. The increase in these services was related to our increased development program activities, including the commencement and conduct of our SB204 Phase 3 clinical trials and the conduct of our SB206 Phase 2 clinical trial.

### Net Cash Used in Continuing Investing Activities

During the six months ended June 30, 2017 net cash used in investing activities was \$1.1 million, which related to purchases of property and equipment associated with laboratory equipment and leasehold improvements at our facility in Morrisville, North Carolina.

During the six months ended June 30, 2016, net cash used in investing activities was \$2.4 million, which represented purchases of property and equipment of \$2.3 million and the purchase of intangible assets of \$0.1 million.

### Net Cash Provided by (Used in) Continuing Financing Activities

During the six months ended June 30, 2017 net cash provided by financing activities was \$29,000, consisting primarily of proceeds from the exercise of stock options.

During the six months ended June 30, 2016, net cash used in financing activities was \$1.4 million, consisting primarily of payments related to public offering costs.

### Capital Requirements

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 and commercialize one of our current or future product candidates. 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 to commercialize any approved products. We are subject to all of the risks incident 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.

Our primary use of cash is to fund our operating expenses, which consist principally of research and development expenditures necessary to advance our clinical-stage product candidates. Based upon our current operating plan, we anticipate we have sufficient cash and cash equivalents to operate at least through December 31, 2017. We anticipate that we will need substantial additional funding to continue our operating activities and make further advancements in each of our drug development programs, as summarized in the “Overview—Key Drug Development Updates” section above. Specifically, we anticipate that additional funding will be required to initiate our planned Phase 2 and Phase 3 trials in our SB206 program for the treatment of molluscum contagiosum and external genital warts, respectively. Additional funding will also be required to complete the Phase 1b trials of SB414 product candidate in patients with psoriasis and atopic dermatitis, which we target initiating by the end of 2017. We may decide to revise our activities or the relevant timing depending on the availability of funding, partnership opportunities and our financial priorities. We are currently reviewing various potential financing options to fund our continued and planned operations, including non-dilutive partnership opportunities across our pipeline of product candidates, traditional private and public equity financings, and debt and other structured facilities. We recently implemented cost savings measures and continue to evaluate whether other potential cost savings measures may be necessary. As a result of all these factors, our anticipated expenditure levels may change if we make adjustments to our current operating plan. As of June 30, 2017, we had an accumulated deficit of \$144.5 million and there is substantial doubt about our ability to continue as a going concern if we do not secure adequate additional financing.

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 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 SB204, SB206, SB208 and SB414;
- the progress, timing, costs and results of preclinical studies relating to other potential applications of our nitric oxide platform;
- the number and characteristics of product candidates that we pursue;
- our success in scaling our manufacturing process;
- 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 in Japan;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the 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 outlicensing of our product candidates.

We also expect to incur capital expenditures as we continue to invest in information technology systems and equipment at our corporate headquarters and manufacturing facility in Morrisville, North Carolina.

#### **Contractual Obligations and Contingent Liabilities**

Except for compensatory obligations described in “Note 5—Commitments and Contingencies” to the accompanying condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there were no material changes 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 20, 2017.

#### **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 the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, 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 the end of such five-year period.

## **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 accounting principles generally accepted in the United States, or 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 20, 2017. During the three and six months ended June 30, 2017, there were no material changes to our critical accounting policies, except as presented below.

### *Revenue Recognition—Licensing Arrangements*

We entered into a licensing arrangement in the first quarter of 2017, and may enter into additional licensing arrangements in the future, in exchange for non-refundable upfront payments and potential future milestone and royalty payments. Such arrangements include multiple elements, including the sale of licenses and the provision of services. For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has “stand-alone value” to the licensee. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. When an arrangement is accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue recognized. Management exercises significant judgment in the determination of (i) whether a deliverable has stand-alone value, (ii) whether the deliverable is considered to be a separate unit of accounting and (iii) the estimation of the relative fair value of each deliverable in the arrangement.

We recognize a milestone payment when earned if it is substantive and we have no ongoing performance obligations related to the milestone. A milestone payment is considered substantive if it: (i) is commensurate with either our performance to achieve the milestone or the enhanced value of the delivered item as a result of a specific outcome from the performance to achieve the milestone; (ii) relates solely to past performance; and (iii) is reasonable relative to all of the deliverables and payment terms, including other potential milestone consideration, within the arrangement.

#### *Revenue Recognition—Research and Development Services*

We recently entered into an arrangement to provide research and development services on a fee-for-service basis and may enter into additional arrangements in the future. Under such arrangements, revenue is recognized when all of the following conditions are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) fees are fixed or determinable, and (iv) collection of fees is reasonably assured. Our contract research and development services revenue is recognized in the period in which the services are performed.

#### **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 condensed consolidated financial statements included within this Quarterly Report on Form 10-Q.

#### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our primary exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of less than three months. The primary objectives of our investment activities are the preservation of principal and maintenance of liquidity for the purpose of funding operations and maximizing total return. The related interest income sensitivity is affected by changes in the general level of short-term U.S. interest rates. We place our cash and cash equivalents with high-credit quality financial institutions. Our investment policy prohibits us from holding corporate bonds, auction rate securities, asset-backed securities, municipal obligations, structured investment vehicles, extendable commercial paper or collateralized debt/loan obligations.

As of June 30, 2017, we had cash and cash equivalents of \$19.1 million. We believe that an immediate one percentage point increase or decrease in interest rates would not materially affect the fair value of these cash equivalents. We do not believe that our cash and cash equivalents have significant risk of default or illiquidity and do not expect our operating results or cash flows to be affected significantly by a sudden change in market interest rates. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in fair value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Following the execution of the Sato Agreement in January 2017, we have become exposed to Japanese yen foreign exchange risk because this transaction is denominated in Japanese yen. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made, and all monetary balances are translated to U.S. dollars using the period-end exchange rate. A hypothetical 10% change in the exchange rate between the Japanese yen and the U.S. dollar during any of the periods presented would not have had a significant impact on our results of operations, financial position or financial performance.

#### **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 Interim Chief Executive Officer and our Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Interim Chief Executive Officer and our Interim Chief Financial Officer 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 June 30, 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II— OTHER INFORMATION**

### **Item 1. Legal Proceedings**

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

### **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 20, 2017, except as set forth below.

*Changes to our leadership team could prove disruptive to our operations and have adverse consequences for our business and operating results.*

We are currently conducting a search for a permanent chief executive officer and permanent chief financial officer, and our chief medical officer resigned effective May 5, 2017. Managing transitions in our executive leadership team may divert our existing management team's attention from our core operations, and the recent transitions we have experienced may make it more difficult for us to identify a permanent chief executive officer or permanent chief financial officer or to retain existing employees. If we are unable to timely locate successors for key management positions, it may negatively impact our business. In addition, the recent transitions we have experienced have increased our dependency on the remaining members of the senior executive team and other key employees within the organization. We have incurred costs related to these transitions, including severance payments, and expect to incur recruitment costs related to the hiring of new executives.

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

#### *Unregistered Sales of Equity Securities*

None.

#### *Use of Proceeds from Initial Public Offering*

On September 20, 2016, the SEC declared our Registration Statement on Form S-1 (File No. 333-213276) effective for our initial public offering, which closed on September 26, 2016, pursuant to which we sold an aggregate of 4,715,000 shares of our common stock, including the underwriters option to purchase 615,000 additional shares, at a price to the public of \$11.00 per share for aggregate gross proceeds of \$51.9 million. As a result, we received net proceeds of \$44.6 million (after underwriters' discounts, commissions, and reimbursements totaling \$4.1 million and additional offering related costs of \$3.2 million). The managing underwriter of the offering was Piper Jaffray & Co.

The net proceeds of the IPO have been invested in accordance with our investment policy. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus dated September 20, 2016 and filed with the SEC on September 22, 2016.

***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.**

On August 10, 2017, we and William L. Hodges, our Interim Chief Financial Officer, entered into an amendment, or the Letter Agreement, to the offer letter dated March 21, 2017, as amended, or the Offer Letter. The Letter Agreement provides that Mr. Hodges will continue to serve as our Interim Chief Financial Officer and principal financial and accounting officer through November 15, 2017, or the Extension Period. Pursuant to the Letter Agreement, Mr. Hodges will continue to receive the same monthly base salary during the Extension Period as established in the Offer Letter.

The foregoing description of the Letter Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Letter Agreement, a copy of which is filed as Exhibit 10.5 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

The Offer Letter was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated March 22, 2017.

**Item 6. Exhibits**

See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**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  
Interim Chief Executive Officer  
(Principal Executive Officer)

By: /s/ William Hodges  
William Hodges  
Interim Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: August 11, 2017

**INDEX TO EXHIBITS**

EXHIBIT NO.	DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
			FORM	FILE NO.	EXHIBIT	FILING DATE
10.1	Separation and General Release Agreement, dated May 6, 2017, by and between Novan, Inc. and M. Joyce Rico.		10-Q	001-37880	10.5	May 12, 2017
10.2	First Amendment to Amended and Restated Employment Agreement, dated June 4, 2017, by and between Novan, Inc. and Nathan Stasko.		8-K	001-37880	10.1	June 5, 2017
10.3	Letter Agreement dated June 28, 2017, by and between Novan, Inc. and William L. Hodges.		8-K	001-37880	10.1	June 29, 2017
10.4	Non-Employee Director Compensation Plan	X				
10.5	Letter Agreement dated August 10, 2017, by and between Novan, Inc. and William L. Hodges.	X				
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	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				

## NOVAN, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

## AS AMENDED BY THE BOARD OF DIRECTORS, JUNE 5, 2017

Non-employee members of the board of directors (the “*Board*”) of Novan, Inc. (the “*Company*”) shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Policy (this “*Policy*”). The cash and equity compensation described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a “*Non-Employee Director*”), who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Policy shall become effective on the date (the “*Effective Date*”) of the Company’s initial public offering (the “*IPO*”) and shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors and between any subsidiary of the Company and any of its non-employee directors. No Non-Employee Director shall have any rights hereunder, except with respect to equity awards granted pursuant to the Policy.

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$35,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of \$25,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of \$7,500 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$12,500 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of \$6,250 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of \$5,000 for such service.

(v) Lead Director. A Non-Employee Director serving as Lead Director shall receive an additional annual retainer of \$15,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, such Non-Employee Director shall receive a prorated portion of the retainer(s) otherwise payable to such Non-Employee Director for such calendar quarter pursuant to Section 1(b), with such prorated portion determined by multiplying such otherwise payable retainer(s) by a fraction, the numerator of which is the number of days during which the Non-Employee

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Director serves as a Non-Employee Director or in the applicable positions described in Section 1(b) during the applicable calendar quarter and the denominator of which is the number of days in the applicable calendar quarter.

2. **Equity Compensation.** Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2016 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "**Equity Plan**") and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all equity grants hereunder are subject in all respects to the terms of the Equity Plan.

(a) **IPO Awards.** Each Non-Employee Director who (i) serves on the Board as of the date the IPO price of the shares of the Company's common stock, par value \$0.0001 per share ("**Common Stock**") is established in connection with the Company's IPO (the "**Pricing Date**") and (ii) will continue to serve as a Non-Employee Director immediately following the Pricing Date shall be automatically granted, on the Pricing Date, an option to purchase the number of shares of the Company's common stock (at a per-share exercise price equal to the IPO price) that have an aggregate fair market value on the date of grant of \$100,000 (as determined in accordance with FASB Accounting Standards Codification Topic 718 ("**ASC 718**") (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(a) shall be referred to herein as the "**IPO Awards**").

(b) **Annual Awards.** A Non-Employee Director who (i) serves on the Board as of the date of any annual meeting of the Company's stockholders (an "**Annual Meeting**") after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such Annual Meeting shall be automatically granted, on the date of such Annual Meeting, an option to purchase the number of shares of the Company's common stock (at a per-share exercise price equal to the closing price per share of the Company's common stock on the date of such annual meeting (or on the last preceding trading day if the date of the annual meeting is not a trading day) that have an aggregate fair value on the date of grant of \$100,000 (as determined in accordance with ASC 718) (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(b) shall be referred to as the "**Annual Awards.**" Notwithstanding the foregoing, the Board in its sole discretion may determine that the Annual Awards for any year be granted in the form of restricted stock units with equivalent value on the date of grant (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an Annual Meeting shall only receive an Annual Award in connection with such election, and shall not receive any Initial Award (as defined below) on the date of such Annual Meeting as well.

(c) **Initial Awards.** Except as otherwise determined by the Board, each Non-Employee Director who is initially elected or appointed to the Board after the Pricing Date on any date other than the date of an Annual Meeting shall be automatically granted, on the date of such Non-Employee Director's initial election or appointment (such Non-Employee Director's "**Start Date**"), an option to purchase shares of the Company's common stock (at a per-share exercise price equal to the [closing price per share of the Company's common stock on the date of such annual meeting (or on the last preceding trading day if the date of the annual meeting is not a trading day)] that have an aggregate fair value on such Non-Employee Director's Start Date equal to the product of (i) \$100,000 (as determined in accordance with ASC 718), and (ii) a fraction, the numerator of which is (x) 365 minus (y) the number of days in the period beginning on the date of the Annual Meeting immediately preceding such Non-Employee Director's Start Date (or, if no such Annual Meeting has occurred, the effective date of the Company's IPO) and ending on such Non-Employee Director's Start Date and the denominator of which is 365 (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(c) shall be referred to as "**Initial Awards.**" Notwithstanding the foregoing, the Board in its sole discretion may determine that the Initial Award for any Non-Employee Director be granted in the form of restricted stock units with equivalent value on the date of grant (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). For the avoidance of doubt, no Non-Employee Director shall be granted more than one Initial Award.

(d) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(c) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Awards as described in Section 2(b) above.

(e) Vesting of Awards Granted to Non-Employee Directors. Each IPO Award, Annual Award and Initial Award shall vest and become exercisable in four equal quarterly installments, such that each such award shall be fully vested and exercisable on the first anniversary of the date of grant, subject to the Non-Employee Director's continued service on the Board as a Non-Employee Director through each applicable vesting date. No portion of an IPO Award, Annual Award or Initial Award that is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall become vested and exercisable thereafter. All of a Non-Employee Director's IPO Awards, Annual Awards and Initial Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

\* \* \* \* \*

August 10, 2017

William L. Hodges  
401 May Court  
Raleigh, North Carolina 27609

Dear Bill,

I am pleased to extend the terms of your employment with Novan, Inc. (the "Company") as interim Chief Financial Officer until November 15, 2017 (the "Extension Period"). This letter amends the terms of your employment, as described in the offer letter dated March 21, 2017 and further amended on June 28, 2017 (the "Offer Letter") during the Extension Period.

Except as otherwise described below, your compensation during the Extension Period will be governed by this paragraph. Your base salary during the Extension Period will continue as described in the Offer Letter. You will continue to be eligible to participate in employee benefits and paid time off in accordance with the Company's current policies.

Please sign and date one (1) copy of this letter and return it to me by August 10, 2017. Please let me know if you have any questions.

Regards,

/s/ G. Kelly Martin

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G. Kelly Martin  
Interim Chief Executive Officer

I agree to the amended terms of employment described above, this 10<sup>th</sup> day of August, 2017.

/s/ William L. Hodges

\_\_\_\_\_  
William L. Hodges

**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)) 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) 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
  - (c) 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: August 11, 2017

/s/ G. Kelly Martin  
G. Kelly Martin  
*Interim Chief Executive Officer*  
(Principal Executive Officer)

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

I, William L. Hodges, 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)) 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) 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
  - (c) 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: August 11, 2017

/s/ William L. Hodges  
\_\_\_\_\_  
William L. Hodges  
*Interim Chief Financial Officer*  
(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, Interim 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 June 30, 2017 (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: August 11, 2017

/s/ G. Kelly Martin  
G. Kelly Martin  
*Interim 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, William L. Hodges, Interim Chief Financial Officer of Novan, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2017 (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: August 11, 2017

/s/ William L. Hodges  
William L. Hodges  
*Interim Chief Financial Officer*  
(Principal Financial Officer)

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

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

