



# Novan Reports Fourth Quarter and Full Year 2016 Financial Results

## Company Provides Updates on Upcoming Milestones Across the Development Platform

MORRISVILLE, N.C., March 20, 2017 -- Novan, Inc. ("the Company" or "Novan") (NASDAQ:NOVN) today announced the Company's financial results for the fourth quarter and full year 2016. Total operating expenses for the three months ended Dec. 31, 2016, were approximately \$13.1 million, which includes research and development, or R&D, expenses totaling approximately \$9.1 million and general and administrative, or G&A, expenses totaling approximately \$4.0 million. Total operating expenses for the three months ended Dec. 31, 2015, were approximately \$10.1 million, which included R&D expenses totaling approximately \$6.7 million and G&A expenses totaling approximately \$3.4 million. The approximately \$2.4 million year-over-year increase in R&D expenses was due primarily to increased development costs related to the Phase 3 program for SB204.

Total operating expenses for the twelve months ended Dec. 31, 2016, were approximately \$59.8 million, which includes R&D expenses totaling approximately \$46.5 million and G&A expenses totaling approximately \$13.3 million. Total operating expenses for the twelve months ended Dec. 31, 2015, were approximately \$25.8 million, which included R&D expenses totaling approximately \$16.6 million and G&A expenses totaling approximately \$9.3 million. The approximately \$29.9 million year-over-year increase in R&D expenses was due primarily to increased development and personnel costs related to the Phase 3 pivotal clinical trials for SB204 and Phase 2 clinical trial for SB208. The approximately \$4.1 million year-over-year increase in G&A expenses was due primarily to increased costs associated with operating as a public company and increased commercial market research activities across the pipeline.

Novan announced on Sept. 26, 2016, the closing of the Company's initial public offering, or IPO, of 4,715,000 shares of common stock at a price to the public of \$11.00 per share, which included the exercise in full by the underwriters of their option to purchase from the Company an additional 615,000 shares of common stock. Net proceeds to the Company from the sale of the shares, after deducting underwriters' discounts and commissions and offering expenses, totaled approximately \$44.6 million.

As of Dec. 31, 2016, Novan's cash and cash equivalents totaled approximately \$34.6 million. This does not include the upfront payment of approximately \$10.8 million received in January 2017 from Sato Pharmaceutical Co., Ltd., or Sato, related to the Company's license agreement for exclusive rights to develop and commercialize in Japan SB204 and related dosage forms for the treatment of acne vulgaris. Novan continues to believe that the Company's cash on hand is sufficient to fund operations at least through the end of 2017, advancing each of the Company's development programs through its nearest-term milestone. Novan is currently evaluating a number of financing options, from non-dilutive partnership opportunities across the Company's pipeline to traditional private and public equity raises, to provide additional funding that will be required to support development of SB204 through the FDA process, including the cost of an additional well-controlled trial, and to fund operations for platform programs beyond 2017, including the cost of two Phase 3 pivotal clinical trials of SB206.



“We are pleased to announce the results of Novan’s first year-end as a public company,” said Nathan Stasko, Ph.D., President and Chief Executive Officer of Novan. “This past year we were able to complete our IPO in extremely challenging market conditions and meaningfully increased our drug development infrastructure. As a result, we were able to advance our nitric oxide platform by initiating our Phase 3 clinical program for SB204, completing our Phase 2 clinical trial for SB206, commencing our Phase 2 proof-of-concept trial for SB208 and generating preclinical data that encourages us to accelerate clinical development of our SB414 candidate for inflammatory skin diseases. As we look ahead into 2017, we are eager to expand upon the budding knowledge of nitric oxide’s role in dermatological diseases and to provide new evidence to support advancing each of our pipeline candidates. In the second quarter alone, we expect to hold our SB206 end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, release top-line results of our SB208 anti-fungal Phase 2 trial and submit our Investigational New Drug application, or IND, for SB414 as a potential treatment for patients with mild to moderate psoriasis. Each of these clinical-stage candidates may provide non-dilutive financing opportunities as we look to expand upon our number of industry collaborations. Additionally, we look forward to our pre-submission meeting with the FDA for SB204 and continuing toward our goal of developing and launching the first new chemical entity approved for the treatment of acne in over 20 years.”

#### **Upcoming Development Milestones (by program)**

- SB204 for the treatment of acne vulgaris. Novan intends to pursue a pre-submission meeting with the FDA to discuss the entirety of the SB204 development program in the third quarter of 2017, which could lead to a new drug application, or NDA, submission in the first quarter of 2018, assuming among other things successful completion of the Company’s ongoing long-term safety study. Following the pre-NDA meeting, Novan expects to finalize plans for an additional well-controlled clinical trial with SB204 to be conducted in parallel with the FDA review to support NDA approval.
- SB206 for the treatment of viral skin infections caused by human papillomavirus, or HPV. The Company is planning to discuss the entirety of the SB206 development program with the FDA in the second quarter of 2017, including a discussion of parallel clinical studies that could be conducted to support a broader indication that would encompass all warts, including genital, plantar and common warts, which together result in a total of approximately four million office visits per year in the United States. Assuming a successful end-of-Phase 2 meeting with the FDA, Novan plans to initiate two Phase 3 pivotal clinical trials of SB206 for the treatment of external genital warts by the end of 2017.
- SB208 for the treatment of infections of the skin and nails, including tinea pedis and onychomycosis. Both of these diseases are caused by the same dermatophyte, *Trichophyton rubrum*, or *T. rubrum*. The Company commenced a Phase 2



proof-of-concept trial in patients with tinea pedis in July 2016, completed enrollment in December 2016 and expects to report top-line results in the second quarter of 2017.

- SB414 for the treatment of inflammatory skin diseases such as psoriasis and atopic dermatitis. Novan expects to initiate clinical development of SB414 following an IND submission in the second quarter of 2017 with a Phase 2 proof-of-concept study in patients with psoriasis, which will include an active head-to-head comparator. The Phase 2 study is also designed to evaluate key biomarkers such as IL-17 in lesions in patients in the treatment arm with the strongest response. The Company expects to present new preclinical data furthering the mechanistic understanding of how nitric oxide may regulate key inflammatory cytokines and other aspects of inflammatory disease pathology at upcoming scientific meetings.

### **About Novan**

Novan, Inc. is a late-stage pharmaceutical company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company's nitric oxide-releasing 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. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need. 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 and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company's website at [www.Novan.com](http://www.Novan.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-releasing product candidates, including further development of SB204 and related regulatory submissions, the value proposition of our nitric oxide platform and future prospects of our business. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations, including, but not limited to, the risk that the FDA is not amenable to our plan for SB204 or requires additional studies or information before we can submit our NDA; the risk that additional studies are inconsistent with our expectations; the risks that we are delayed in making an NDA submission, the FDA does not accept our submission for filing, disagrees with our analysis of endpoints or that the FDA requires us to conduct additional studies to support the submission; the risk that the FDA does not approve our NDA or approves our NDA with limitations or subject to additional studies; uncertainties and risks in the clinical development process generally, including, among others, length, expense, ability to enroll patients, reliance on third parties and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research or trials; the risk that we could incur



additional expenses in connection with further analyses of any of our clinical-stage programs and whether we will be able to obtain additional funding when needed, or at all; and other risks and uncertainties described in our prospectus dated Sept. 20, 2016, filed with the Securities and Exchange Commission, or SEC, in our quarterly report filed with the SEC on Form 10-Q for the three months ended Sept. 30, 2016, and in any subsequent filings with the SEC. These forward-looking statements speak only as of the date of this press release, and Novan disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

**Novan, Inc.**  
**Condensed Consolidated Statements of Operations**  
(in thousands, except for share and per share data)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	(unaudited)			
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Operating expenses:				
Research and development	\$ 9,128	\$ 6,694	\$ 46,489	\$ 16,569
General and administrative	4,010	3,407	13,337	9,265
Total operating expenses	<u>13,138</u>	<u>10,101</u>	<u>59,826</u>	<u>25,834</u>
Operating loss	<u>(13,138)</u>	<u>(10,101)</u>	<u>(59,826)</u>	<u>(25,834)</u>
Other income, net	<u>77</u>	<u>18</u>	<u>127</u>	<u>48</u>
Loss from continuing operations	(13,061)	(10,083)	(59,699)	(25,786)
Loss from discontinued operations	—	(1,083)	—	(2,274)
Net loss and comprehensive loss	<u>\$ (13,061)</u>	<u>\$ (11,166)</u>	<u>\$ (59,699)</u>	<u>\$ (28,060)</u>
Loss per share, basic and diluted: <sup>1</sup>				
Continuing operations	\$ (0.82)	\$ (4.37)	\$ (9.97)	\$ (11.36)
Discontinued operations	—	(0.47)	—	(1.01)
Net loss per share, basic and diluted	<u>\$ (0.82)</u>	<u>\$ (4.84)</u>	<u>\$ (9.97)</u>	<u>\$ (12.37)</u>
Weighted-average common shares outstanding, basic and diluted <sup>2</sup>	<u>15,938,941</u>	<u>2,306,476</u>	<u>5,985,985</u>	<u>2,269,124</u>

<sup>1</sup> 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. Potentially dilutive securities include convertible preferred stock and stock options outstanding during the periods presented.

<sup>2</sup> Upon closing of the IPO on Sept. 26, 2016, all outstanding shares of the Company's non-voting common stock and convertible preferred stock were automatically converted into 8,967,321 shares of common stock. As of Dec. 31, 2016, there were 15,939,992 shares of common stock outstanding.



**Novan, Inc.**  
**Selected Consolidated Balance Sheet Data**  
**(in thousands)**

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Cash and cash equivalents	\$ 34,611	\$ 45,688
Total assets	52,473	49,816
Total current liabilities	13,377	5,095
Total liabilities	21,407	5,099
Total convertible preferred stock	—	104,798
Total stockholders' equity (deficit)	31,066	(60,081 )
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	52,473	49,816

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