

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **June 7, 2021**

Novan, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-37880
(Commission
File Number)

20-4427682
(IRS Employer
Identification No.)

4020 Stirrup Creek Drive, Suite 110, Durham, North Carolina 27703
(Address of principal executive offices) (Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company X

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

Item 8.01. Other Events.

On June 7, 2021, Novan, Inc. (the “Company”) issued a press release announcing results from its exploratory studies on the antimicrobial effect of its NITRICIL™ Platform Technology for Companion Animal Health.

The full text of the Company’s press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated June 7, 2021.

The inclusion of any website address in this Form 8-K, and any exhibit thereto, is intended to be an inactive textual reference only and not an active hyperlink. The information contained in, or that can be accessed through, such website is not part of or incorporated into this Form 8-K.

SIGNATURES

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

Date: June 7, 2021

Novan, Inc.

By: /s/ John M. Gay
John M. Gay
Chief Financial Officer



Results from Novan’s Exploratory Studies Further Demonstrate Antimicrobial Effect of NITRICIL™ Platform Technology with NVN4100 in Companion Animal Health

- *Positive in vitro results demonstrate antimicrobial effect of NVN4100 against a wide variety of bacteria and suggest a promising bactericidal mode of action –*
- *Novel in vivo canine pyoderma model established which serves as a tool for continued assessment and optimization of next steps –*
- *Additional formulation and preclinical evaluations are contemplated as the Company explores potential strategic partnership opportunities –*

DURHAM, N.C. – June 7, 2021 – Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced positive proof-of-concept *in vitro* results and informative *in vivo* results with its new chemical entity (NCE), NVN4100, explored as a potential product candidate for topical antimicrobial indications in companion animal health.

Novan initiated exploratory work to evaluate NVN4100 and engaged with animal health experts at Scullion Strategy Group, LLC to oversee the Company’s initial animal health studies and to assess technical feasibility and market potential. The *in vivo* and *in vitro* studies were conducted by independent third party animal health research organizations.

“We are pleased with results that further validate the anti-bacterial capabilities of our NITRICIL™ platform technology, specifically with NVN4100, a new chemical entity. The results from these exploratory studies bolster our confidence in Novan’s strategy to continue building a data package to support our strategic partnering efforts for an animal health program. These exploratory studies were an important step in confirming our initial premise that there is an opportunity for the NITRICIL™ platform technology in animal health and we believe further development and evaluations are necessary,” commented Paula Brown Stafford, President and Chief Executive Officer of Novan.

The exploratory studies were conducted to determine the minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) of NVN4100 using broth dilution antimicrobial susceptibility testing against a set of clinically relevant microorganisms. Results from the *in vitro* assay demonstrated that NVN4100 had both inhibitory and bactericidal effects for a variety of pathogens. The tested pathogens include both antimicrobial resistant and antimicrobial susceptible strains of the most prevalent species associated with skin and ear conditions in animal health, including *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus pseudintermedius*, and *Staphylococcus schleiferi*.

Additionally, in collaboration with an independent third party animal health research organization, Novan established a model of canine pyoderma, one of the most common skin conditions of dogs that is often resistant to first-line antimicrobials, to evaluate topically applied

NVN4100 in an *in vivo* setting. The *in vivo* results suggest that the canine pyoderma model may serve as an appropriate tool to facilitate further development of NVN4100 as an alternative therapy to systemic and topical antimicrobials for treatment of canine superficial pyoderma or other dermatology indications.

Dr. Carri Geer, Chief Technology Officer of Novan added, “Among the results from these studies, one of the most valuable and informative outcomes of the exploratory work to date is the establishment and optimization of a clinically relevant model for canine pyoderma. The antimicrobial activity witnessed in the *in vitro* studies provides us with confidence in the potential broad utility of NVN4100. Those findings coupled with the establishment of the *in vivo* model will enable Novan to more efficiently and rapidly screen product candidates and optimize animal health targeted formulations as the development program progresses.”

“The results from the *in vitro* studies showed valuable insight into the potential of Novan’s innovative platform technology and the potential of NVN4100 to treat resistant strains and minimize risk of developing resistance to antibiotics in animals. Importantly, NVN4100 demonstrated that it was effective, in cultures, against a wide variety of clinically relevant bacteria including a number of *Staphylococcus pseudintermedius* strains, which is encouraging as the Company looks to advance its animal health program. We are encouraged by these preliminary results and look forward to further confirmation of efficacy in clinical studies, unlocking value of this program,” stated Dr. Thierry Olivry, DrVet, PhD, DECVD, DACVD, scientific advisor for Novan, and a board-certified veterinary dermatologist on Faculty for more than 26 years at North Carolina State University College of Veterinary Medicine.

Based on the results to date and the availability of funding, Novan intends to conduct additional studies and formulation work with NVN4100 to build a robust data set and engage with potential collaborators and strategic partners moving forward. The Company seeks to publish the full data set from the companion animal health exploratory studies at an upcoming scientific congress and/or in a peer-reviewed publication.

About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging its proprietary nitric oxide (NO) based technology platform, NITRICIL™ to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications in dermatology, men’s and women’s health, infectious diseases, and gastroenterology conditions with significant unmet needs. The Company’s lead product candidate, SB206, a topical antiviral gel, for the treatment of molluscum contagiosum, is currently being evaluated in the B-SIMPLE4 pivotal Phase 3 clinical study. The Company believes that SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would address an important patient-care need for the treatment of molluscum.

About NITRICIL™

Novan’s innovative NITRICIL™ technology leverages nitric oxide’s naturally occurring antimicrobial and immunomodulatory effects to develop new therapies for unmet medical needs across multiple therapeutic areas. NITRICIL™ stores the gaseous species on large polymers, which allow nitric oxide to be applied as timed-release chemical entities. This technology allows

Novan to control the level of nitric oxide storage, the rate of release, and the molecule size for targeted delivery. The result is stabilized, druggable nitric oxide that is optimized for a specific indication.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “target,” “anticipate,” “may,” “plan,” “potential,” “will,” “intends” and similar expressions, and are based on the Company’s current beliefs and expectations. These forward-looking statements include, but are not limited to, statements related to the potential therapeutic value of the Company’s NITRICIL™ platform technology, the Company’s pharmaceutical development of nitric oxide-releasing product candidates, the Company’s intention to advance development of certain product candidates, including the potential for NVN4100 for antimicrobial indications in companion animal health, and the Company’s intention to partner with third parties. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from the Company’s expectations, including, but not limited to, risks and uncertainties in the Company’s ongoing or future product development activities and preclinical studies, which may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even if successful may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of the Company’s product candidates; any operational or other disruptions as a result of the COVID-19 pandemic; the Company’s ability to enter into arrangements with third parties to support its development efforts on terms that are acceptable to the Company or at all; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, potential for delays or other impacts, whether as a result of the COVID-19 pandemic or other factors, and that results of earlier research and preclinical or clinical trials may not be predictive of results, conclusions or interpretations of later research activities or additional trials; risks related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable; the Company’s ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development of the Company’s product candidates; the Company’s reliance on arrangements with third parties to support its operations and development efforts and the risk that such parties will not successfully carry out their contractual duties or meet expected deadlines; and other risks and uncertainties described in the Company’s annual report filed with the Securities and Exchange Commission on Form 10-K for the twelve months ended December 31, 2020, and in the Company’s subsequent filings with the Securities and Exchange Commission. Such 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.

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