

**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): **October 14, 2020**

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.)

4105 Hopson Road, Morrisville, North Carolina 27560
(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 | Nasdaq Global Market |

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

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.

Item 8.01. Other Events.

On October 14, 2020, Novan, Inc. (the “Company”) issued a press release announcing its *in vitro* results showing the potential efficacy of its NITRICIL™ platform technology as an antiviral against SARS-CoV-2, the virus that causes COVID-19.

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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release date October 14, 2020. |

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.

Novan, Inc.

Date: October 14, 2020

By: /s/ John M. Gay

John M. Gay

Chief Financial Officer



Novan's NITRICIL™ Technology Shows *In Vitro* Antiviral Effect Against SARS-CoV-2 in Human Airway Infection Model

- *First demonstration of antiviral effect of nitric oxide-based medicine against SARS-CoV-2 in an in vitro model that mimics the human airway epithelium*

- *Company believes preclinical results demonstrate high potential for clinical translation*

- *Company plans to initiate Chemistry, Manufacturing, and Controls (CMC) work to develop intranasal formulation of berdazimer sodium for use in coronavirus program*

MORRISVILLE, N.C. - October 14, 2020 - Novan, Inc. (“the Company” or “Novan”) (Nasdaq: NOVN), today announced positive *in vitro* results showing the potential efficacy of its NITRICIL™ platform technology as an antiviral against SARS-CoV-2, the virus that causes COVID-19. To evaluate the ability of its NITRICIL™ platform technology as a potential nasal treatment option for COVID-19, the Company initiated *in vitro* assessments targeting the reduction of viral burden in differentiated normal human bronchial epithelial cells. The studies were conducted at the Institute for Antiviral Research at Utah State University and these results demonstrate the first instance of an antiviral effect from a nitric oxide-based medicine in a 3-D tissue model that has similar structure to the human airway epithelium.

The results from the *in vitro* assessment of concentrations as low as 0.75 mg/mL demonstrated that berdazimer sodium reduced 90% of virus after repeat dosing, once daily.

“COVID-19 continues to have a major ongoing impact on global health and there remains a direct need for a safe and effective antiviral therapy. The naturally occurring antiviral effects of nitric oxide and the results we have generated from this assessment, provide us with confidence that our NITRICIL™ platform technology may be an effective treatment for COVID-19. We also believe the data from this sophisticated model of the human respiratory tract demonstrate a high potential for clinical translation,” commented Paula Brown Stafford, Chairman and Chief Executive Officer of Novan.

Novan plans to initiate Chemistry, Manufacturing, and Controls (CMC) work with a global leader in providing integrated services, superior delivery technologies and manufacturing solutions to develop an intranasal formulation of berdazimer sodium for use in the Company’s COVID-19 program.

Dr. Carri Geer, Senior Vice President and Chief Technology Officer added, “With these encouraging *in vitro* results in hand, the next step is to advance our program into preclinical IND-enabling studies to further confirm the safety of our NITRICIL™ technology when administered intranasally. We are in the process of finalizing arrangements with a global leader in drug development to assist in our development activities as we work toward a potential IND filing targeted in 2021.”

Based on the scientific literature and data available to-date with berdazimer sodium and Novan’s product candidate SB206, Novan believes that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

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.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, statements related to the potential therapeutic value of our NITRICIL™ platform technology, our pharmaceutical development of nitric oxide-releasing product candidates, our intention to advance development of certain product candidates, and our 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 our expectations, including, but not limited to, risks and uncertainties in our 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 our product candidates; our ability to enter arrangements with third parties to support our development efforts on terms that are acceptable to us or at all; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, 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, including the risk that our product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that we may not obtain funding sufficient to complete the regulatory or development process; our ability to obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development of our product candidates; the risk that disruptions at the FDA or other agencies could cause such agencies to cancel or postpone meetings or otherwise impact the ability of such agencies to provide regulatory guidance or feedback or timely review and process our regulatory submissions, all of which could have a material adverse effect on our business; risks related to the manufacture of clinical trial materials; any operational or other disruptions as a result of the COVID-19 pandemic, including any delays or disruptions to the enrollment in and conduct of the B-SIMPLE4 Phase 3 trial; and other risks and uncertainties described in our annual report filed with the SEC on Form 10-K for the twelve months ended December 31, 2019, as amended, and in our 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.

INVESTOR AND MEDIA CONTACT:

Jenene Thomas
JTC Team, LLC
833-475-8247
NOVN@jtcir.com

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