

**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 25, 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
(I.R.S. Employer
Identification No.)

4105 Hopson Road, Morrisville, North Carolina 27560
(Address of principal executive offices) (Zip Code)

(919) 485-8080
(Registrant's telephone number, include 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 in 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 June 25, 2020, Novan, Inc. (the “Company”) issued a press release providing an SB206 program and business update. 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 25, 2020

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: June 25, 2020

By: /s/ John M. Gay

John M. Gay

Vice President, Finance

Novan Anticipates Current Cash Position Provides Sufficient Capital to Conduct Additional SB206 Phase 3 Pivotal Trial

MORRISVILLE, N.C. - June 25, 2020 - Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company anticipates that its current cash position will be sufficient to fund costs associated with conducting an additional Phase 3 pivotal trial for SB206 as a treatment for molluscum, or B-SIMPLE4 (Berdazimer Sodium In Molluscum Patients with Lesions). Since June 1, 2020, the Company has secured approximately \$16.9 million in capital from the use of common stock purchase agreements with Aspire Capital Fund, LLC and the exercise of common stock warrants sold in its March 2020 public offering.

The Company is targeting enrolling the first patient for B-SIMPLE4 in September 2020 and, if the trial is initiated on this timetable and not further impacted by the COVID-19 pandemic, top-line efficacy results would be targeted for late in the second quarter of 2021.

"We are delighted to be in a position to proceed with the B-SIMPLE4 study," commented Paula Brown Stafford, Novan's President and Chief Executive Officer. "An unmet need remains for molluscum patients and their caregivers, and we look forward to advancing the SB206 program."

Currently there are no U.S. Food and Drug Administration-approved therapies for the treatment of molluscum. Treatment choices for patients, the majority of whom are below the age of 10, include in-office and often painful, physician-administered scraping, freezing, burning and blistering treatments. The only other choices appear to be off-label prescriptions and over-the-counter products with no clinical data that support a molluscum indication and therefore have no proven clinical efficacy and an unknown safety profile. The Company believes that SB206 as a topical, at-home, caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum.

About Novan

Novan, Inc. is a clinical development-stage biotechnology company focused on leveraging nitric oxide's naturally occurring anti-microbial and immunomodulatory mechanisms of action to treat a range of diseases. We believe that our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of dermatology, women's health and gastrointestinal diseases.

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 and our intention to advance development of certain product candidates, including the timing for the B-SIMPLE4 Phase 3 trial and anticipated top-line results, and the sufficiency of our cash position. 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 we may not be able to begin enrollment as planned or that enrollment in or the conduct of the B-SIMPLE4 Phase 3 trial may be delayed or otherwise impacted as a result of the COVID-19 pandemic or other factors; the risk that results from the B-SIMPLE4 Phase 3 trial will not be received timely or will not achieve significance sufficient to support a new drug application; the risk that the cost of the B-SIMPLE4 Phase 3 trial or other operational costs will exceed our expectations; our ability to obtain any additional funding that may become necessary to continue our business and the further development of our product candidates, including SB206 for molluscum; risks and uncertainties in the clinical development process, including, among others, length, expense, ability to enroll patients, reliance on third parties, potential for delays 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; 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 conduct of the B-SIMPLE4 Phase 3 trial; and other risks and uncertainties described in our annual report filed with the Securities and Exchange Commission on Form 10-K/A for the twelve months ended December 31, 2019, 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.

CONTACT:

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