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): **April 3, 2020**

Novan, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37880**	**20-4427682**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
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 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 April 3, 2020, Novan, Inc. (the "Company") issued a press release providing a SB206 program 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 April 3, 2020

The inclusion of Novan's 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, Novan's 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: April 3, 2020

By: /s/ John M. Gay

John M. Gay

Vice President, Finance

Exhibit 99.1

Novan Receives Verbal Guidance from FDA for SB206 and Announces Sato Program Advancement

- **Per verbal guidance, FDA to consider one additional pivotal trial**
- **FDA-generated minutes expected on or before May 1, 2020**
- **Sato Pharmaceutical to begin start-up of Phase 1 trial in Japan**

MORRISVILLE, N.C. - April 3, 2020 - Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has conducted its Type C meeting with the U.S. Food and Drug Administration ("FDA") regarding SB206 for the treatment of molluscum. The purpose of the meeting was to seek FDA feedback on the proposal to conduct one additional, well-controlled confirmatory study of SB206 to support a future New Drug Application ("NDA").

Based on guidance received during the meeting, the Company understands the FDA will consider one additional pivotal trial ("B-SIMPLE4"), if successful, to be supported by the previously completed B-SIMPLE2 trial. In addition, the FDA provided guidance with regard to both the study design for B-SIMPLE4 and expectations for a future NDA submission. FDA-generated minutes, expected on or before May 1, 2020, will serve as the meeting's official record.

"We are pleased with the promising dialogue that we had with the FDA and the clarity provided for a path forward for SB206," commented Paula Brown Stafford, Novan's President and Chief Executive Officer. Ms. Stafford further commented, "Our team is working diligently to incorporate the agency's suggestions and feedback into the B-SIMPLE4 study design as we seek to optimize execution success and minimize regulatory risk."

Novan's Japanese development and commercialization partner, Sato Pharmaceutical Co., Ltd. ("Sato"), has also informed the Company of Sato's intention to progress the SB206 development program in Japan with a Phase 1 clinical trial given the observed treatment benefit and favorable safety profile in the B-SIMPLE program.

"Upon review of the totality of the efficacy and safety data from the B-SIMPLE program, Novan and Sato share optimism for the continued progression of SB206 for molluscum in both the US and Japan," commented Ms. Stafford. "Sato is a tremendously valuable business and development partner and we look forward to continued collaboration to progress the program."

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 with significant unmet needs. 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, pharmaceutical development of nitric oxide-releasing product candidates and our intention to advance development of
certain product candidates, the expected timing and contents of meeting minutes from the FDA from our April 1, 2020 meeting regarding our B-SIMPLE program, the timing for the B-SIMPLE4 Phase 3 trial, Sato's progress of the clinical development program for SB206 in Japan and the timing of potential regulatory submissions. 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 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 and 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; the risk that the B-SIMPLE4 Phase 3 trial will be delayed or postponed and that results will not be received timely or will not achieve significance sufficient to support an NDA; risks and uncertainties related to our ability to obtain funding or enter into strategic relationships on a timely basis, or at all, to enable or complete the B-SIMPLE4 Phase 3 trial and to continue operations; our ability to reduce cash expenditures; 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 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, 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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