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 30, 2020**

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

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
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 2.02. Results of Operations and Financial Condition.

On October 30, 2020, Novan, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated October 30, 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 30, 2020

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

Exhibit 99.1

Novan Reports Third Quarter 2020 Financial Results and Provides Corporate Update

– Lead product candidate, SB206 currently being evaluated in B-SIMPLE4 pivotal Phase 3 study in molluscum contagiosum with topline data targeted for Q2 2021 –

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

– Exploratory work to evaluate NITRICIL™ for antimicrobial indications in companion animal health initiated –

– Company actively seeking opportunities to leverage broader pipeline to secure next phase of growth –

MORRISVILLE, N.C. – October 30, 2020 – Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced its financial results for the quarter ended September 30, 2020 and provided a corporate update.

"The last few months have been marked by many significant achievements for the Company and the advancement of our priority development pipeline. We initiated our pivotal Phase 3 study, B-SIMPLE4, and even during the current global pandemic, I am pleased to report that enrollment has remained on track and is targeted to complete in the first quarter of 2021. We also recently reported positive *in vitro* results demonstrating antiviral effect of our NITRICIL platform against coronavirus (SAR-CoV-2) and the next step would be to advance this program into preclinical IND-enabling studies. Additionally, we have taken deliberate actions to strengthen our balance sheet and believe we have sufficient capital to fund operations through the fourth quarter of 2021," commented Paula Brown Stafford, President and Chief Executive Officer of Novan.

Recent Highlights

- Initiated enrollment and dosed first patients in B-SIMPLE4 pivotal Phase 3 study of SB206, a topical antiviral gel, for treatment of molluscum;
- Demonstrated *in vitro* antiviral effect of proprietary NITRICIL™ technology against SARS-CoV-2 in human airway infection in a 3D-model;
- Commenced exploratory work to evaluate NITRICIL™ for antimicrobial indications in companion animal health;
- Continued ongoing review of existing programs and opportunities to expand priority development pipeline;
- Announced the appointment of John M. Gay to serve as the Company's Chief Financial Officer and the appointment of James L. Bierman to the Company's Board of Directors;
- Announced an expanded role of Paula Brown Stafford, President and Chief Executive Officer of Novan, to also include Chairman of Novan's Board of Directors; and
- Since January 1, 2020, secured approximately $50 million in capital from multiple sources including the use of common stock purchase agreements with Aspire Capital

Fund, LLC, a March 2020 public offering (and the exercise of related common stock warrants), and a March 2020 registered direct offering.

"While over the past few months we have raised capital to progress our lead asset for molluscum and provide an expected cash runway past our targeted topline results for our B-SIMPLE4 trial, maintaining our listing on Nasdaq remains a critical priority for the Company. We continue to pursue a course of action intended to allow us to work toward regaining compliance in a manner that we believe is in the best interests of the Company and its stockholders," commented John M. Gay, Chief Financial Officer. "Recognizing the importance of this process to our stockholders, we expect to provide an update on this matter in the near-term."

Priority Development Pipeline Update

SB206 – a Topical Antiviral Treatment for Viral Skin Infections (Molluscum Contagiosum)
The Company commenced patient enrollment and dosing for B-SIMPLE4 in September 2020. B-SIMPLE4 is a multi-center, double-blind, randomized, vehicle-controlled study expected to enroll approximately 850 patients (1:1 randomization), across 50 clinical sites, who will be treated for 12 weeks with a follow-up visit at Week 24. To-date, the Company has completed more than 30% of the total expected patient enrollment for the study.

Upcoming Targeted Milestones:

- Completion of enrollment targeted in Q1 2021; and
- Topline efficacy results targeted in Q2 2021, if the trial is not further impacted by the COVID-19 pandemic.

For more information about the B-SIMPLE4 trial, please visit clinicaltrials.gov and reference identifier: NCT04535531.

Infectious Disease, Coronaviridae (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.

Upcoming Targeted Milestones:

- 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.

Companion Animal Health
Novan has initiated exploratory work to evaluate the Company's new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. Additionally, the Company has engaged animal health experts to assess technical feasibility and market potential.

Upcoming Targeted Milestones:

- Currently intend to seek a potential strategic partner or collaborator following initial proof-of-concept work.

Financial Update

Summary of Financial Results for Third Quarter 2020

- Novan reported a net loss of $8.4 million for the three months ended September 30, 2020, compared to a $9.5 million net loss for the same period in 2019.

- As of September 30, 2020, Novan had a total cash and cash equivalents balance of $43.1 million and positive working capital of $36.7 million.

- The Company believes that its existing cash and cash equivalents balance as of September 30, 2020, and expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its operating needs through the fourth quarter of 2021, based on management's projections and planned priority development activities described in the Company's quarterly report on Form 10-Q for the three month period ended September 30, 2020.

Summary of Financial Results for Year-to-Date September 2020

- Novan reported a net loss of $22.7 million for the nine months ended September 30, 2020, compared to a $24.4 million net loss for the same period in 2019.

- License and collaboration revenue was $3.2 million for the nine months ended September 30, 2020, compared to $3.3 million for the same period in 2019, associated with the Company's performance during the period and the related amortization of the non-refundable upfront and expected milestone payments under one of the Company's license agreements.

- Research and development expenses were $13.5 million for the nine months ended September 30, 2020, compared to $19.6 million for the same period in 2019. The decrease was primarily attributable to (i) net decreased costs of $1.7 million related to Novan's relative timing of the B-SIMPLE4 trial's enrollment initiation, which occurred in late third quarter of 2020, compared to enrollment initiations for the previous Phase 3 trials (B-SIMPLE1 and B-SIMPLE2), which occurred in late second quarter of 2019; and (ii) a decrease of $3.4 million in other research and development expenses, primarily related to a $2.1 million net decrease in research and development personnel costs, and a $0.9 million decrease in costs primarily associated with manufacturing technology transfer projects to third-party manufacturers.

- General and administrative expenses were $8.8 million for the nine months ended September 30, 2020, compared to $8.6 million for the same period in 2019. The increase was primarily due to $1.7 million of non-cash expense related to the issuance of commitment shares as consideration for entering into common stock purchase arrangements with Aspire Capital, partially offset by a $1.4 million decrease in general and administrative personnel and related costs.

- For the nine months ended September 30, 2020, the Company recognized $2.4 million of non-cash impairment charges related to the July 2020 termination of its previous primary facility lease and a $1.8 million loss on the disposition of related assets, of which $0.8 million was a non-cash charge.

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

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," "may," "plan," "potential," "will," 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, the Company's expected cash runway, the Company's plans to regain compliance with the Nasdaq listing standards 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; the Company's ability to enter 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, 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 the Company's product candidates may not be approved or that additional studies may be required for approval or other delays may occur and that the Company may not obtain funding sufficient to complete the regulatory or development process; 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 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 the Company's regulatory submissions, all of which could have a material adverse effect on the Company's business; risks related to the manufacture of raw materials, including the Company's active pharmaceutical ingredient, and drug product components utilized in clinical trial materials, including failure to transfer technology and processes to third parties effectively or failure of those third parties to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities; 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 the Company's annual report filed with the SEC on Form 10-K for the twelve months ended December 31, 2019, as amended, and in the Company's subsequent filings with the SEC, including the Company's quarterly report on Form 10-Q for the three months ended September 30, 2020. 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 and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License and collaboration revenue	$ 1,100	$ 1,100	$ 3,224	$ 3,301
Government research contracts and grants revenue	217	216	627	216
Total revenue	1,317	1,316	3,851	3,517
Operating expenses:				
Research and development	4,836	8,598	13,513	19,614
General and administrative	3,108	2,290	8,847	8,595
Impairment loss on long-lived assets	—	—	2,421	—
Loss on facility asset group disposition	1,772	—	1,772	—
Total operating expenses	9,716	10,888	26,553	28,209
Operating loss	(8,399)	(9,572)	(22,702)	(24,692)
Other (expense) income, net:				
Interest income	2	53	47	149
Interest expense	—	—	—	(1)
Other (expense) income	(8)	23	(3)	115
Total other (expense) income, net	(6)	76	44	263
Net loss and comprehensive loss	$ (8,405)	$ (9,496)	$ (22,658)	$ (24,429)
Net loss per share, basic and diluted	$ (0.06)	$ (0.36)	$ (0.27)	$ (0.94)
Weighted-average common shares outstanding, basic and diluted	133,689,645	26,189,454	83,961,052	26,108,870

NOVAN, INC.
Selected Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 43,072	$ 13,711
Total current assets	44,755	15,724
Total assets	46,570	29,097
Total current liabilities	8,049	12,899
Total liabilities	39,117	51,380
Total stockholders' equity (deficit)	7,453	(22,283)
Total liabilities and stockholders' equity (deficit)	$ 46,570	$ 29,097

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