# 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): **November 10, 2021**

# 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.) |

**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:

| **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 ☒

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 2.02. Results of Operations and Financial Condition.**

On November 10, 2021, Novan, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2021. 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 November 10, 2021. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

*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: November 10, 2021

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

**Exhibit 99.1**

# Novan Provides Corporate Update and Reports Third Quarter 2021 Financial Results

*– Company executing on plans for three potential New Drug Application (NDA) filings in three years with the first submission targeted in Q3 2022 for lead program SB206 in molluscum contagiosum –*

*– Advancing priority development pipeline assets by progressing SB019, for the treatment of SARS-CoV-2, toward a Phase 1 study in 2022, and SB204, for the treatment of acne vulgaris, toward a registrational Phase 3 study in 2023 –*

*– Company to host update conference call and webcast today at 8:30 a.m. ET –*

**DURHAM, N.C. – November 10, 2021 –** Novan, Inc. ("the Company" or "Novan") (Nasdaq: NOVN), today announced its financial and operating results for the quarter ended September 30, 2021 and provided a corporate update. The Company will host a conference call and webcast, today, November 10, 2021, at 8:30 a.m. ET (details below).

"Over the course of the last quarter we have continued to execute on our preparations toward a potential NDA submission and commercialization for SB206, if approved, and advancing the rest of our priority development pipeline. We have bolstered our executive management team with the appointments of our Chief Medical Officer and Chief Commercial Officer, both of whom bring valuable expertise and insight as we work to unlock the full potential of Novan and our NITRICIL™ platform technology. I am incredibly proud of our team and the progress we have made in 2021. We are dedicated to finishing the year strong and positioning ourselves for an exciting 2022," commented Paula Brown Stafford, President and Chief Executive Officer of Novan.

## Recent Highlights

- Ended the third quarter of 2021 with a total cash and cash equivalents balance of $60.0 million and positive working capital of $48.8 million.
- Announced favorable preclinical safety and toxicity data for treatment of COVID-19 with SB019.
- Appointed Brian M. Johnson, who has considerable commercialization expertise with over 30 years of leadership spanning dermatology marketing, sales, sales management, digital marketing and managed care, as Chief Commercial Officer.
- Received conditional acceptance from the U.S. Food and Drug Administration (FDA) for use of KINSOLUS™ as the brand name for SB206, if approved.
- Reported a comprehensive, favorable safety data readout as part of the Company's B-SIMPLE4 pivotal Phase 3 study of SB206 for the treatment of molluscum contagiosum (molluscum).

- Selected late-stage product candidate, SB204, for the treatment of acne vulgaris (acne), to advance as second lead program toward a pivotal Phase 3 study.
- Engaged Syneos Health (Nasdaq: SYNH) as the Company's commercial solutions provider for SB206, if approved, for the treatment of molluscum.
- Appointed Tomoko Maeda-Chubachi, MD, PhD, MBA as Chief Medical Officer.

**Development Pipeline Update**

***SB206 – A Topical Antiviral Treatment for Molluscum Contagiosum***

In June 2021, Novan reported statistically significant positive topline results for the primary efficacy endpoint (p-value <0.0001) of complete clearance of all treatable lesions in its B-SIMPLE4 pivotal Phase 3 clinical study of SB206 for the treatment of molluscum. Additionally, and consistent with results from the Company's prior Phase 2 and Phase 3 studies, SB206 was found to be safe and well tolerated in the B-SIMPLE4 study and met Company expectations. No treatment-related serious adverse events were reported.

The Company has engaged Syneos Health, a fully integrated biopharmaceutical solutions organization, as its commercial solutions provider to interface with the internal commercial operations team for prelaunch strategy and commercial preparation, in addition to sales and marketing support, of SB206, if approved by the FDA.

**Upcoming Targeted Milestones:**

- Pre-NDA meeting with the FDA, as well as conduct of stability testing, targeted for the first half of 2022.
- Potential submission of an NDA targeted for Q3 2022.

There are currently no FDA approved therapies for the treatment of molluscum. The Company believes that SB206 as a topical, at-home, self- or caregiver-applied therapy with a rapid treatment benefit, if approved, would satisfy an important patient-care need for the treatment of molluscum.

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

***SB204 – A Novel Multi-Factorial Mechanism of Action for the Treatment of Acne Vulgaris***

Novan is developing SB204 as a topical monotherapy for the treatment of acne, a multi-factorial disease with varying disease pathology (inflammatory and bacterial). SB204 utilizes the same active pharmaceutical ingredient used in the Company's lead product candidate, SB206, and is formulated specifically to address acne via an anti-inflammatory and anti-bacterial mechanism.

In two previous Phase 3 studies, AC301 and AC302, SB204 demonstrated consistent and promising results across two of three co-primary endpoints. In addition, AC302 was a successful pivotal trial with respect to all three co-primary endpoints, including non-inflammatory lesions, inflammatory lesions, and Investigator's Global Assessment (IGA). Based on the recent positive pivotal Phase 3 results in the SB206 molluscum development program, the Company believes it can optimize the trial design of a new pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal study to support an NDA submission.

**Upcoming Targeted Milestones:**

- Prepare for pivotal Phase 3 study during 2022.
- Conduct planned pivotal Phase 3 trial targeted for 2023, subject to obtaining additional financing or strategic partnering.
- Potential submission of an NDA targeted for 2024.

***SB019 – An Intranasal Formulation for the Treatment of Infectious Disease, COVID-19***

In June 2021, Novan announced positive preclinical results demonstrating the anti-viral effect of the Company's NITRICIL™ platform technology, berdazimer sodium, against SARS-CoV-2, the virus that causes COVID-19.

The Company has completed additional studies assessing the preclinical toxicology of SB019 including recently reported favorable preclinical safety results with berdazimer sodium in a 14-day Good Laboratory Practices (GLP) repeat dose intranasal toxicity study. There were no treatment-related adverse events up to the highest dose tested of 14 mg/day berdazimer sodium and the SB019 formulation was concluded to be well-tolerated under the conditions of this GLP study. The Company also completed dose-range finding studies in SARS-CoV-2 infected golden Syrian hamsters. A significant reduction in the amount of virus in lung or nasal tissue of animals directly inoculated and infected with SARS-CoV-2 was observed and found to be dependent on both the concentration and dosing regimen (e.g., once daily vs. twice daily) of intranasally administered berdazimer sodium.

Based on the strong preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, the recently reported promising preclinical safety data, as well as a public health need to reduce breakthrough infections and transmission, the Company plans to advance its SB019 product candidate.

**Upcoming Targeted Milestones:**

- IND submission to initiate Phase 1 study in healthy volunteers targeted for no later than Q2 2022.
- Phase 2/3 study(ies) targeted for 2023, subject to obtaining additional financing or strategic partnering.
- Potential submission of an NDA targeted for 2024.

**Financial Update**

**Summary of Financial Results for Third Quarter 2021**

- Novan reported a net loss of $6.5 million for the three months ended September 30, 2021, compared to an $8.4 million net loss for the same period in 2020.
- As of September 30, 2021, Novan had a total cash and cash equivalents balance of $60.0 million and positive working capital of $48.8 million.

- The Company believes that its existing cash and cash equivalents balance as of September 30, 2021, plus expected contractual payments to be received in connection with existing licensing agreements, will provide it with adequate liquidity to fund its operating needs into the fourth quarter of 2022, based on management's projections and planned operating, development and commercial activities described in the Company's quarterly report on Form 10-Q for the nine month period ended September 30, 2021.

**Summary of Financial Results for Year-to-Date September 2021**

- Novan reported a net loss of $21.5 million for the nine months ended September 30, 2021, compared to a $22.7 million net loss for the same period in 2020.

- License and collaboration revenue was $2.2 million for the nine months ended September 30, 2021, compared to $3.2 million for the same period in 2020. The decrease from the prior year related to the change in the Company's estimated performance period related to the non-refundable upfront and expected milestone payments under one of the Company's license agreements, which was extended during the fourth quarter of 2020 and again in the third quarter of 2021.

- Research and development expenses were $15.9 million for the nine months ended September 30, 2021, compared to $13.5 million for the same period in 2020. The increase was primarily attributable to (i) net increased costs of $4.1 million related to the SB206 program, including the conduct and completion of the B-SIMPLE4 Phase 3 trial during the first nine months of 2021, compared to the relatively lower net cost B-SIMPLE trial activities in the prior year, and an increase in costs related to activities for the planned NDA submission for SB206; partially offset by (ii) a decrease of $1.4 million in other research and development expenses; and (iii) a $0.3 million decrease in costs related to the SB414 program. The decrease in other research and development expenses was primarily related to a $1.6 million decrease in research and development personnel costs, driven by a $0.9 million decrease in non-cash compensation expense.

- General and administrative expenses were $8.1 million for the nine months ended September 30, 2021, compared to $8.8 million for the same period in 2020. The decrease was primarily due to $1.7 million of non-cash expense recognized in the second and third quarters of 2020 related to the issuance of commitment shares in consideration for entering into the June 2020 Aspire Common Stock Purchase Agreement, offset by a $0.9 million increase in insurance premium expenses associated with directors' and officers' liability policies.

- Other income (expense), net was $0.4 million income for the nine months ended September 30, 2021. During the second quarter of 2021, the Company recognized a $1.0 million gain on debt extinguishment related to the forgiveness of its Paycheck Protection Program loan in June 2021. This gain was partially offset by $0.6 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to one of the Company's license agreements.

**Conference Call and Webcast**

Novan management will host a conference call and webcast presentation for investors, analysts, and other interested parties today, Wednesday, November 10, 2021, at 8:30 AM ET

Interested participants and investors may access the conference call by dialing (844) 707-0661 (domestic) or (703) 318-2240 (international) and referencing conference ID: 1142988. The live webcast will be accessible on the Events page of the Investors section of the Novan website, novan.com, and will be archived for 90 days.

**About Novan**

Novan, Inc. is a pre-commercial nitric oxide-based pharmaceutical company focused on dermatology and anti-infective therapies. We leverage our core synergies of science, capital, resources and patient needs to create value by bringing new nitric oxide-based medicines to market. Our goal is to create the world's leader in nitric oxide-based science, technology, and clinical translation in support of delivering safe and efficacious therapies using our proprietary nitric oxide-based technology platform, NITRICIL™ to generate macromolecular New Chemical Entities (NCEs) to treat multiple indications.

**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," 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, including SB206, the potential timing of FDA submissions, the plans for launch and commercialization of SB206, if approved, the Company's expected cash runway, the timing of anticipated results of the Company's preclinical development programs, 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 related to the regulatory approval process, which is lengthy, time-consuming and inherently unpredictable, including the risk that the FDA will not agree with the Company's approach to a potential NDA submission, that the Company's product candidates may not be approved or that additional studies may be required for approval or other delays may occur, that the Company may not have sufficient quantities of drug substance and/or drug product to support regulatory submissions and that the Company may not obtain funding sufficient to complete the regulatory or development process; the Company's limited experience as a company in obtaining regulatory approvals and commercializing pharmaceutical products, and our ability to recruit and retain qualified personnel and key talent; changes in the size and nature of the market for the Company's product candidates, including potential competition, patient and payer perceptions and reimbursement determinations; 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 obtain additional funding or enter into strategic or other business relationships necessary or useful for the further development or commercialization of

the Company's product candidates; risks related to the manufacture of raw materials, including the Company's active pharmaceutical ingredient and drug product components utilized in clinical trial materials, such as supply chain disruptions or delays, failure to transfer technology and processes to third parties effectively or failure of those third parties (or the Company in connection with the upfit of the Company's new facility) to obtain approval of and maintain compliance with the FDA or comparable regulatory authorities; the Company's reliance on arrangements with third parties to support its operations and its development, manufacturing and commercialization 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.

**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, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| License and collaboration revenue | $ 680 | $ 1,100 | $ 2,174 | $ 3,224 |
| Government research contracts and grants revenue | 57 | 217 | 129 | 627 |
| Total revenue | 737 | 1,317 | 2,303 | 3,851 |
| Operating expenses: | | | | |
| Research and development | 4,251 | 4,836 | 15,926 | 13,513 |
| General and administrative | 2,969 | 3,108 | 8,086 | 8,847 |
| Impairment loss on long-lived assets | — | — | 114 | 2,421 |
| Loss on facility asset group disposition | — | 1,772 | — | 1,772 |
| Total operating expenses | 7,220 | 9,716 | 24,126 | 26,553 |
| Operating loss | (6,483) | (8,399) | (21,823) | (22,702) |
| Other income (expense), net: | | | | |
| Interest income | 4 | 2 | 10 | 47 |
| Gain on debt extinguishment | — | — | 956 | — |
| Other income (expense) | (5) | (8) | (602) | (3) |
| Total other income (expense), net | (1) | (6) | 364 | 44 |
| Net loss and comprehensive loss | $ (6,484) | $ (8,405) | $ (21,459) | $ (22,658) |
| Net loss per share, basic and diluted | $ (0.34) | $ (0.63) | $ (1.30) | $ (2.70) |
| Weighted-average common shares outstanding, basic and diluted | 18,813,653 | 13,368,965 | 16,476,235 | 8,396,106 |

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash and cash equivalents | $ 59,960 | $ 35,879 |
| Total current assets | 61,514 | 44,007 |
| Total assets | 73,887 | 46,829 |
| Total current liabilities | 12,666 | 8,700 |
| Total liabilities | 47,702 | 43,852 |
| Total stockholders' equity | 26,185 | 2,977 |
| Total liabilities and stockholders' equity | $ 73,887 | $ 46,829 |

**INVESTOR AND MEDIA CONTACT:**
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