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 5, 2018**

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))

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 ☒

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 1.01. Entry into a Material Definitive Agreement.

On October 5, 2018, Novan, Inc. (the "Company") and Sato Pharmaceutical Co., Ltd. ("Sato") entered into the second amendment (the "amendment") to the license agreement, as amended, between the Company and Sato dated January 17, 2017 (the "license agreement," the license agreement as amended by the amendment, the "amended license agreement"). The amendment expands the license agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections, in addition to SB204, the Company's drug candidate for the treatment of acne vulgaris.

Under the amended license agreement, the Company has granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of its intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB206 or SB204 in certain topical dosage forms for the treatment of viral skin infections or acne vulgaris, respectively, and to make the finished form of such products. The Company or its designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the active pharmaceutical ingredient (the "API") of SB206 or SB204; rather, the parties agreed to negotiate a commercial supply agreement pursuant to which the Company or its designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory.

Under the amendment, in exchange for the license rights granted to Sato, Sato agreed to pay the Company the following:

- An upfront payment of 1.25 billion JPY, payable in installments of 0.25 billion JPY, 0.5 billion JPY and 0.5 billion JPY on October 5, 2018, February 14, 2019 and September 13, 2019, respectively. This is in addition to the 1.25 billion JPY paid on January 19, 2017 following the execution of the license agreement on January 17, 2017.
- Up to an aggregate of 1.75 billion JPY (adjusted from 2.75 billion JPY in the license agreement) upon the achievement of various development and regulatory milestones. Included in the development and regulatory milestones is a payment of 0.25 billion JPY that the Company expects to receive in the fourth quarter of 2018 in connection with Sato's recent clinical development progress for SB204 in Japan.
- Up to an aggregate of 3.9 billion JPY (adjusted from 0.9 billion JPY in the license agreement) upon the achievement of various commercial milestones.
- A tiered royalty ranging from a mid-single digit to a low-double digit percentage (adjusted from a mid-single digit percentage in the license agreement) of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

The term of the amended license agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory.

All other material terms of the license agreement remain unchanged by the amendment.

The description of the amendment provided above is qualified in its entirety by reference to the amendment, which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission (the "Commission"), as permitted by the rules of the Commission. The Company intends to seek confidential treatment for certain portions of the license agreement pursuant to a Confidential Treatment Request to be submitted to the Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

A copy of the press release announcing the entry into the amendment is attached hereto as Exhibit 99.1 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 October 8, 2018.

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 9, 2018

By: /s/ Andrew J. Novak

Andrew J. Novak
Chief Accounting Officer

Exhibit 99.1

Novan Expands Nitric Oxide Dermatology Business Partnership with Sato in Japan

- Expanded license agreement adds SB206 for the treatment of viral skin infections
- Novan to receive upfront cash consideration of approximately 1.25 billion JPY (~$11.0 million), payable over the next 12 months
- Milestone and royalty payments due with clinical, regulatory and commercial progression
- Japan, the world's 2nd largest dermatology market, remains a strategic focus for Novan
- Novan continues to explore additional geographic markets and other business opportunities

MORRISVILLE, N.C. – October 8, 2018 – Novan, Inc. ("the Company" or "Novan") (Nasdaq:NOVN) today announced that the Company has expanded its partnership with Sato Pharmaceutical Co., Ltd. ("Sato"), a Japanese company with a prescription pharmaceutical business specializing in dermatology, to include Novan's topical nitric oxide-releasing product candidate SB206 for the treatment of viral skin infections including warts and molluscum contagiosum.

The initial licensing agreement executed in January of 2017 focused on the development and commercialization of SB204 for the treatment of acne vulgaris in Japan. This amended license agreement provides Sato with the exclusive rights to also develop and commercialize Novan's SB206 and related dosage forms for the treatment of viral skin infections in Japan. Under the terms of the amendment, Novan will receive an upfront payment from Sato of 1.25 billion JPY (approximately $11.0 million) to be paid in installments over the next 12 months. As part of the revised agreement, the parties adjusted potential future development and regulatory milestone payments, added additional sales-based milestone payments and adopted a tiered royalty structure on net sales of SB204 and SB206 in Japan.

"We are pleased to announce this expanded partnership with Sato to now include SB206," said Nathan Stasko, Ph.D., President and Chief Scientific Officer of Novan. "Japan is the second largest dermatology market in the world where skin diseases such as acne, molluscum and warts have substantial prevalences. Continued interest from a closely aligned and strong partner like Sato further reinforces the science behind our nitric oxide platform and its translation into a broad array of dermatological disorders." Dr. Stasko concluded his commentary by stating, "The potential opportunities across a multitude of global markets for our technology are significant. Expanding our activity within Japan is an important and tangible step in advancing that vision."

Paula Brown Stafford, Chief Development Officer of Novan, added, "In addition to the expansion of our partnership to include viral skin infections, Novan continues to support Sato's clinical activities with SB204 for acne in Japan. We are pleased to announce that based on Sato's progress, Novan is due to receive an SB204 milestone payment in the fourth quarter of 2018 and our team is committed to advancing acne care globally as a meaningful and important indication within dermatology."

While Novan and Sato will work closely together on the progression of these assets, Sato is responsible for funding the development and commercial costs for the programs that are specific to Japan. Novan retains the rights to manufacture the active pharmaceutical ingredient of SB204 and SB206, which Novan will supply to Sato for commercial purposes.

Novan's antiviral development program with SB206 includes a completed Phase 2 trial in patients with external genital warts and an ongoing Phase 2 trial in patients with molluscum contagiosum. As previously communicated, the 108-patient trial conducted in patients with external genital and perianal warts, demonstrated that topical application of SB206 12% once-daily demonstrated statistically significant complete clearance of genital warts compared to vehicle after 12 weeks of treatment. Additionally, the ascending dose Phase 2 trial in 256 patients with molluscum contagiosum enrolled ahead of schedule and

favorable tolerability with SB206 has allowed escalation to the highest dose of 12% twice-daily. Top line results for Cohorts 1 through 3 of this study are targeted no later than mid-November.

About Molluscum in the United States and Japan

Approximately 1.8 million patients are diagnosed with molluscum contagiosum in the United States each year[1] and up to 855,000 patients in Japan[2]. Patients are typically treated with painful in-office procedures, topical therapies not indicated specifically for the treatment of molluscum contagiosum or not treated at all given there are no therapies approved by the FDA for the treatment of molluscum contagiosum. Patient treatment tolerance has been cited as the most important unmet need for molluscum contagiosum and, in a study conducted by Novan, dermatologists in Japan who treat the disease indicated that SB206, if approved, could potentially replace nearly 50% of the current procedure usage in both first and second lines of treatment[2].

About Novan

Novan, Inc. is a clinical-stage biotechnology company focused on leveraging nitric oxide's natural antiviral and immunomodulatory mechanisms of action to treat dermatological and oncovirus-mediated diseases. We believe that our ability to conveniently deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to significantly improve patient outcomes in a variety of diseases.

References

[1]QuintilesIMS. Market Opportunity Assessment EGW, Common Warts and Molluscum, March 2017.
[2]IQVIA. Viral Skin Infection Opportunity Assessment in Japan, 2018.

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, our intention to advance development of certain product candidates, which is subject to our ability to obtain additional financing or enter into strategic relationships to enable such development, and the future prospects of our business and our product candidates. 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, 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; risks related to the manufacture of clinical trial materials and commercial supplies of any potentially approved product candidates, including the manufacture of our NVN1000 active pharmaceutical ingredient in our primary facility; our ability to obtain substantial additional funding for the further advancement and development of our product candidates; our ability to identify and enter into strategic relationships for the further development and potential commercialization of our product candidates; 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, 2017, in our subsequent filings with the SEC, and in the Form 8-K dated as of October 8, 2018 posted on the Company's website. 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.

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