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Novan Inc. (NOVN - NASDAQ)

B-SIMPLE4 Enrollment Complete

Based on our DCF model and a 15% discount rate, Novan is valued at approximately $4.50 per share. Our model applies a 50% probability of ultimate approval and commercialization for SB206 for molluscum contagiosum. The model includes contributions from the United States and Japan.

Current Price (3/1/21)	$1.62
Valuation	**$4.50**

OUTLOOK

Novan is a research and development company which employs nitric oxide (NO) to address a number of indications for a variety of skin conditions including molluscum contagiosum (MC), acne, dermatitis, psoriasis, warts and HPV. Novan uses its Nitricil technology to efficiently deliver NO to desired locations and release it at a controlled rate. Novan's lead candidate, SB206 is now being investigated in a pivotal Ph3 trial for MC. SB206 and other Novan compounds store NO in large polymer macromolecules which allows for stable and druggable NO. Additional Nitricil compounds are in clinical and preclinical stages of development for other skin conditions. However, Novan is solely focused on developing SB206.

We expect pivotal trials for SB206 to generate registrational data for MC by 2021 followed by the submission of an NDA if data are supportive. Our valuation assumes a 2022 regulatory approval and 2023 commercialization of SB206 in the US. Partner Sato will advance the candidate through the regulatory and commercialization process in Japan and we anticipate a 2023 regulatory submission in that jurisdiction followed by a 2024 launch.

SUMMARY DATA

52-Week High	**$2.59**
52-Week Low	**$0.28**
One-Year Return (%)	**245**
Beta	**-0.08**
Average Daily Volume (sh)	**22,599,657**
Shares Outstanding (mil)	**151**
Market Capitalization ($mil)	**244**
Short Interest Ratio (days)	**0.26**
Institutional Ownership (%)	**8.03**
Insider Ownership (%)	**8.94**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$1.1 A	$1.1 A	$1.3 A	$1.4 A	$4.9 A
2020	$1.2 A	$1.3 A	$1.3 A	$1.1 A	$4.9 A
2021					$3.6 E
2022					$3.6 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.27 A	-$0.69 A	-$0.32 A	$0.11 A	-$1.17 A
2020	-$0.17 A	-$0.10 A	-$0.06 A	-$0.05 A	-$0.30 A
2021					-$0.21 E
2022					-$0.12 E

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WHAT'S NEW

Full Year 2020 Operational and Financial Results

On February 25, 2021, Novan Inc. (NASDAQ: NOVN) reported full year 2020 financial results, following the previous day's filing of the 2020 10-K. Novan announced revenues of $4.9 million for the period and a net loss of ($29.3) million or ($0.30) per share. Highlights for 2020 include the readout of the B-SIMPLE1 and B-SIMPLE2 Phase III clinical trials, the raise of additional capital in multiple transactions, interaction with the FDA and the launch of B-SIMPLE4 in August. A rapid pace of enrollment led to full enrollment of the trial by February 2021 and we anticipate topline to be reported before the end of the second quarter of 2021. Investor interest in Novan provided support for the share price and the company regained compliance with NASDAQ's minimum bid price requirement in January 2021. The full-year report comes as stakeholders eagerly await the results of B-SIMPLE4, Novan's pivotal trial investigating the safety and efficacy of lead candidate SB206 in the treatment of molluscum contagiosum.

2020 Financial Review

Novan reported revenues of $4.9 million for 2020. $4.2 million of the total was license and collaboration revenue related to the upfront and milestone payments related to the Sato agreement. The remaining $712,000 came from government research contracts and grants from Department of Defense (DoD) and National Institute of Health (NIH). This compares to 2019 revenues of $4.9 million comprised of $4.5 million in license and collaboration revenue and $419,000 in research contract and grant revenue. Operational expenses of $31.1 million were 13% below prior year levels. This included $19.8 million of research and development expenses and $11.3 million of general and administrative expenses. R&D declined 21% due to lower spend on the SB204, SB208, SB414 and other R&D programs partially offset by an increase in the SB206 program. The 8% increase in G&A was attributable to the recognition of a non-cash charge related to the issuance of commitment shares to Aspire offset by a decrease in G&A personnel expenses and lower other G&A expenses. Novan also recognized an impairment loss on long-lived assets of $2.3 million and a loss on facility assets of $1.8 million related to the lease break for the Morrisville, North Carolina facility. After a small adjustment for interest income and other items, 2020 net loss was ($29.3) million or ($0.30) per share which compares with the 2019 net loss of ($30.6) million and ($1.17) per share.

Cash and marketable securities balance was $35.9 million as of December 31, 2020. Apart from a $1.0 million paycheck protection program (PPP) loan, no debt is carried on the balance sheet. Cash burn for 2020 was approximately ($31.2) million relative to cash from financing of $52.8 million, which was predominantly sourced from the common stock purchase agreement with Aspire.

B-SIMPLE Series Studies

Berdazimer Sodium In Molluscum Patients with Lesions (B-SIMPLE) designates a set of studies that examine the safety and efficacy of berdazimer sodium (SB206) on molluscum contagiosum. There have been four studies with the B-SIMPLE designation. With the exception of B-SIMPLE3, all were all multi-center, randomized, double-blind, vehicle-controlled studies. B-SIMPLE1, 2 and 3 have been completed, while B-SIMPLE4 remains active. Each is summarized below:

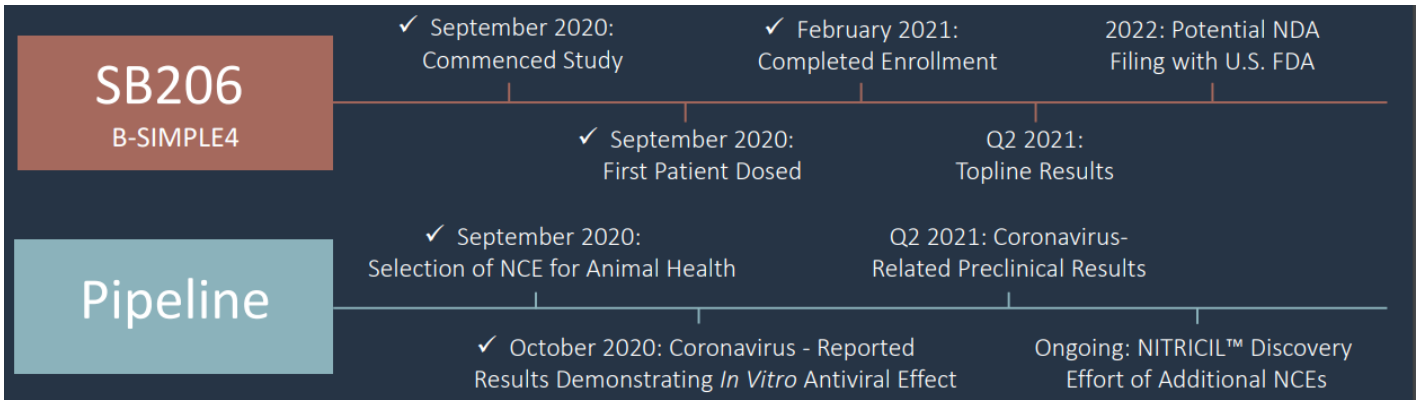
- B-SIMPLE1 – Phase III; launched 2Q:19; full efficacy data available March 2020, 352 patients enrolled.
- B-SIMPLE2 – Phase III; launched 2Q:19; full efficacy data available March 2020, 355 patients enrolled.
- B-SIMPLE3 – Phase I open label study assessing safety, tolerability & pharmacokinetics; launched 2Q:20; final study report completed in 3Q:20. 34 patients enrolled.
- B-SIMPLE4 – Pivotal Phase III launched August 2020; topline expected 2Q:21; 891 patients enrolled.

B-SIMPLE4

Novan announced on January 19, 2021 that it had achieved 90% enrollment in its B-SIMPLE4 study. Two weeks later, enrollment in the trial was announced as complete. It had targeted enrollment of ~850 patients across 55 clinical sites. We estimate that the last patient enrolled will complete the 12 weeks of treatment no later than May, with the final 24-week follow-up completed by August. After the last patient's last visit, Novan would then need to close out the study and complete the clinical study report before NDA submission, which is expected to occur in 3Q:22.

Novan announced the launch of the B-SIMPLE4 trial on August 31st and enrolled and dosed its first patient a few days later. The B-SIMPLE4 trial is a pivotal, Phase III, multi-center, randomized, double-blind, vehicle controlled, parallel group study conducted across 55 sites. Enrollment was reported to be well distributed among the sites, with no risk concentration in any one location. Subjects are age six months and older presenting molluscum contagiosum (MC) and randomized in a 1:1 ratio of active and placebo arms. SB206 is administered once daily to all MC lesions for a minimum of four weeks and up to 12 weeks until all lesions are cleared. Following 12 weeks of treatment, patients will receive a follow-up visit at week 24. Enrollment was completed by the beginning of February, ahead of initial expectations due to a smooth start and steady acceleration in enrollment. Topline efficacy results are expected to be made public in 2Q:21.

Exhibit I – B-SIMPLE4 Timeline[1]



Sato

In April 2020, Japanese partner Sato announced that it would launch a Phase I study for SB206 in molluscum based on the results of Novan's B-SIMPLE1 and 2 studies. In November, Sato announced that the design of the trial would be modified to use lower dose strengths which is expected to delay the project timeline by 1.75 years. This will cause Novan to extend the period over which they will recognize upfront revenues from the partnership, resulting in lower revenue numbers than what was previously expected.

NASDAQ Compliance

On February 19th, 2020, the NASDAQ notified Novan that it was not in compliance with exchange listing rules due to the share price trading below $1.00 for more than 30 consecutive business days. Due to the disruption related to the coronavirus, the NASDAQ provided an extension to regain compliance and Novan was granted additional time to meet the minimum bid price requirement. In January 2021, Novan shares traded above $1.00 per share for ten consecutive days and by the end of the month had regained compliance with the NASDAQ listing rule.

Corporate Headquarters in Durham, North Carolina

In 2020 Novan moved out of its old 51,350 square foot facility in Morrisville, North Carolina in an effort to become a more asset-light research and development company. The Morrisville facility offered a large scale manufacturing site that enabled substantial research and development work to be conducted and pilot scale current good manufacturing practices (cGMP) to be performed. The company has entered into lease agreement for 15,000 square feet space in Durham, North Carolina, which will serve as headquarters for Novan's business operations, as well as provide space for R&D and small scale manufacturing.

[1] Source: Novan February 2021 Corporate Overview Slide Deck

Other Programs: SB019 / NVN4100

In early 2020, Novan announced that it was conducting preclinical work on berdazimer sodium (SB019) to serve as a topical, oral or nasal treatment option for COVID-19. The decision to move forward with this effort is based on nitric oxide's demonstrated ability to inhibit viral replication. Novan has conducted extensive research at the Institute of Antiviral Research at Utah State University that shows berdazimer sodium's ability to act as an anti-viral. These efforts targeted the reduction of viral burden in human bronchial epithelial cells in a 3-D tissue model. Novan believes that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates. Other efforts to advance SB019 include a master services agreement with Catalent, Inc. to support chemistry, manufacturing and control activities and development of an intranasal formulation of berdazimer sodium for the company's COVID-19 program.

Although there are few details, Novan is also working on a new chemical entity designated NVN4100 as a potential product candidate for antimicrobial indications in companion animal health. Product feasibility and market potential are being reviewed with animal health experts. If the data, which are expected to be available soon, are supportive of further development, a partner will be found to advance the program further.

Exhibit II – Novan Pipeline[2]

Product Candidates	Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Program Highlight
DERMATOLOGY						
SB204	Acne Vulgaris					Two Phase 3's completed; One confirmatory Phase 3 needed; Protocol finalized
SB208	Tinea Pedis					Phase 2 trial complete; Phase 1 in nail growth complete
SB414	Atopic Dermatitis					Phase 1b trial complete; Phase 2 protocol finalized
	Psoriasis					Phase 1b trial complete; Potential to explore lower doses
MEN'S AND WOMEN'S HEALTH						
SB207	Genital Warts					End of Phase 2 meeting with FDA complete; Phase 3 protocols designed
WH504	High-Risk HPV					Formulation development ongoing; Funded by federal grants
WH602	High-Risk HPV					Formulation development ongoing; Funded by federal grants
GASTROENTEROLOGY						
Undisclosed	Various					Seeking grants to progress

Our Thesis

Novan's lead candidate, SB206, uses its Nitricil platform to suspend nitric oxide (NO) in a gel that allows for controlled release. Nitricil can be used to deliver a variable dose of NO to the epithelium to address a broad variety of skin lesions including molluscum contagiosum. NO presents a unique mechanism of action and a favorable safety and scarring profile. As a component of Nitricil, the agent has been tested in approximately 3,400 patients in clinical work, with a 24 week safety assessment for the B-SIMPLE trials. Of the 700+ patients in the completed Phase III trials, there was only one serious treatment emergent adverse event (TEAE) in each of the SB206 and vehicle arms. TEAEs in greater than 5% of subjects were for pain and irritation and were mostly mild or moderate.

There is no standard of care for MC and most healthy individuals clear the virus on their own. In the population where treatment is desired, the lesions can be physically removed or oral and topical therapies can be administered. Some of the more common topical approaches include the use of cantharidin, ZymaDerm and imiquimod; however, none have been approved for treatment for MC and demonstrated consistent efficacy in clinical evaluation. Alternate approaches also have side effects, including pain and severe skin reactions, highlighting the need for a tolerable and effective treatment.

We see a fair estimate of an MC population of around six million in the United States and from two to three million in Japan. We anticipate that the availability of an approved, effective and safe treatment may increase the number of diagnoses and the addressable population could be larger. While a portion of the addressable market will prefer to wait it out, we anticipate there will be a significant number of patients that will seek treatment given the availability of an approved medicine.

[2] Source: Novan February 2021 Corporate Overview Slide Deck

Key reasons to own Novan shares:

- **Phase III asset to address an unmet need in MC**
  - **B-SIMPLE4 enrollment complete**
- **MC presents a large addressable market with no approved therapies**
- **SB206 statistically significant (p=0.038) on primary endpoint using integrated trial data**
- **Nitricil presents multiple mechanisms for therapeutic effect**
  - **Anti-viral**
  - **Anti-bacterial**
  - **Anti-inflammatory**
  - **Anti-fungal**
- **Broad portfolio of dermatology indications in clinical development**
  - **Acne Vulgaris**
  - **Tinea Pedis**
  - **Genital Warts**
  - **Others**
- **Favorable drug safety profile with no reported drug-related serious adverse events**
- **Intellectual property protection until 2035 for SB206**
- **North American rights to intellectual property**
- **Partner pursuing commercialization in Japan**
  - **Rights to milestones and royalties**

Summary

Since our initiation, Novan has raised sufficient capital to move forward with its pivotal Phase III trial for SB206 and has since completed enrollment of the trial. The data provided in previous work were supportive of efficacy despite not achieving statistical significance. These results give us confidence that B-SIMPLE4 will be successful with a larger population and improved protocols. B-SIMPLE4 should provide topline data by 2Q:21. Based on the pace achieved so far, we are confident in management's target for an NDA filing by 2022 assuming results are supportive. We maintain our target price of $4.50 per share.

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[3]

Novan, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues ($US)	**$4,896**	**$1,213**	**$1,321**	**$1,317**	**$1,069**	**$4,920**	**$3,560**	**$3,550**
YOY Growth	*-18%*	*10%*	*20%*	*0%*	*-22%*	*0%*	*-28%*	
Research & Development	$25,172	$4,916	$3,761	$4,836	$6,301	$19,814	$25,850	$10,000
General & Administrative	$10,412	$2,507	$3,232	$3,108	$2,424	$11,271	$11,760	$14,000
Other	$0	$0	$2,421	$1,772	($144)	$4,049	$0	$0
Income from operations	($30,688)	($6,210)	($8,093)	($8,399)	($7,512)	($30,214)	($34,050)	($20,450)
Operating Margin	*-627%*	*-512%*	*-613%*	*-638%*	*-703%*	*-614%*	*-956%*	*-576%*
Other Income	$49	$8	($3)	($8)	$873	$870	$0	$0
Interest Income	($2)	$35	$10	$2	$4	$51	$0	$0
Pre-Tax Income	($30,641)	($6,167)	($8,086)	($8,405)	($6,635)	($29,293)	($34,050)	($20,450)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($30,641)**	**($6,167)**	**($8,086)**	**($8,405)**	**($6,635)**	**($29,293)**	**($34,050)**	**($20,450)**
Net Margin	*-626%*	*-508%*	*-612%*	*-638%*	*-621%*	*-595%*	*-956%*	*-576%*
Reported EPS	**($1.17)**	**($0.17)**	**($0.10)**	**($0.06)**	**($0.05)**	**($0.30)**	**($0.21)**	**($0.12)**
Basic Shares Outstanding	26,254	37,044	80,603	133,690	143,896	98,808	165,000	170,000

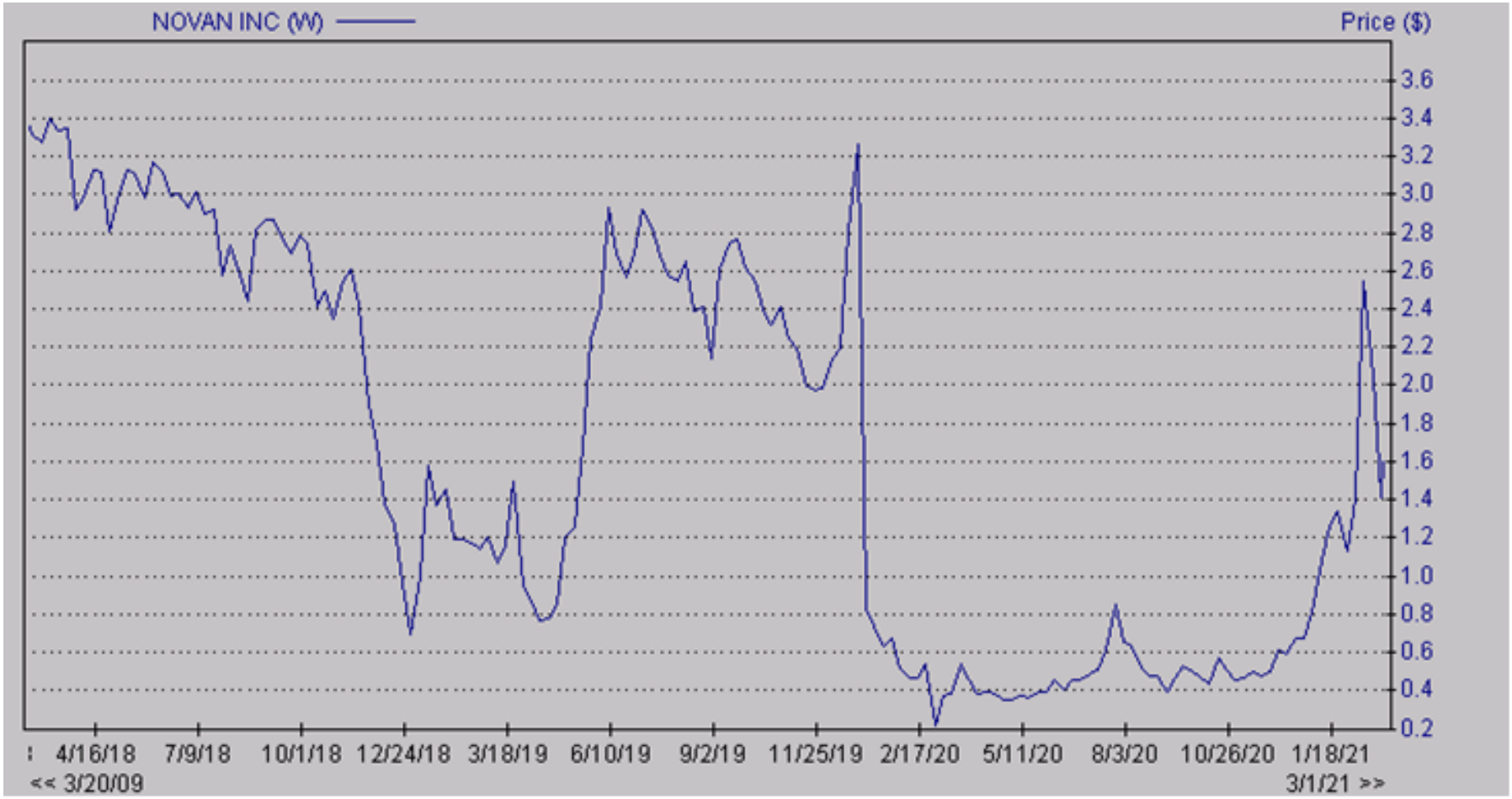
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[3] Financial statement information presents data as originally reported.

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HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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