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Novan Inc. (NOVN - NASDAQ)

Molluscum Phase III 30% Enrolled

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 (11/2/20)	$0.44
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 will pursue a confirmatory Ph3 trial later this year 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	**$3.72**
52-Week Low	**$0.22**
One-Year Return (%)	**-80.4**
Beta	**-0.25**
Average Daily Volume (sh)	**9,776,820**
Shares Outstanding (mil)	**141.5**
Market Capitalization ($mil)	**$62.8**
Short Interest Ratio (days)	**0.5**
Institutional Ownership (%)	**9.8**
Insider Ownership (%)	**18.2**
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	$1.2 E	$5.1 E
2021					$5.1 E
2022					$4.5 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	-$0.06 E	-$0.32 E
2021					-$0.14 E
2022					-$0.13 E

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WHAT'S NEW

Third Quarter 2020 Operational and Financial Results

On October 30, 2020 Novan Inc. (NASDAQ: NOVN) reported third quarter financial results concurrent with the filing of its third quarter 10-Q updating investors on financial and operational results. Novan reported revenues of $1.3 million for the period and net loss of ($8.4) million or ($0.06) per share. Highlights for the quarter and period to date include the start of the BSIMPLE4 study, 30% enrollment in the 850-patient trial, demonstration of anti-viral effect of berdazimer sodium against coronavirus and exploratory work in companion animal health. The company also added a new board member and elevated John Gay to chief financial officer.

Revenues of $1.3 million were reported in the third quarter, with $1.1 million in revenues related to the Sato agreement and $217,000 attributable to Department of Defense (DoD) and National Institute of Health (NIH) program grants. This compares to prior year second quarter revenues of $1.1 million and grant revenues of $216,000. Operational expenses of $7.9 million were 27% below prior year levels. This included $4.8 million of research and development expenses, down 44% year over year, and general and administrative expenses of $3.1 million, 36% higher than amounts in 3Q:19. R&D declined due to lower spend on the SB206 program and on the SB414 program as lower personnel costs in the R&D segment. G&A rose the recognition of a non-cash charge related to the issuance of commitment shares to Aspire and an increase in other administrative expenses. Novan also recognized a loss 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, net loss was ($8.4) million or ($0.06) per share which compares with 3Q:19 net loss of ($8.3) million and ($0.32) per share.

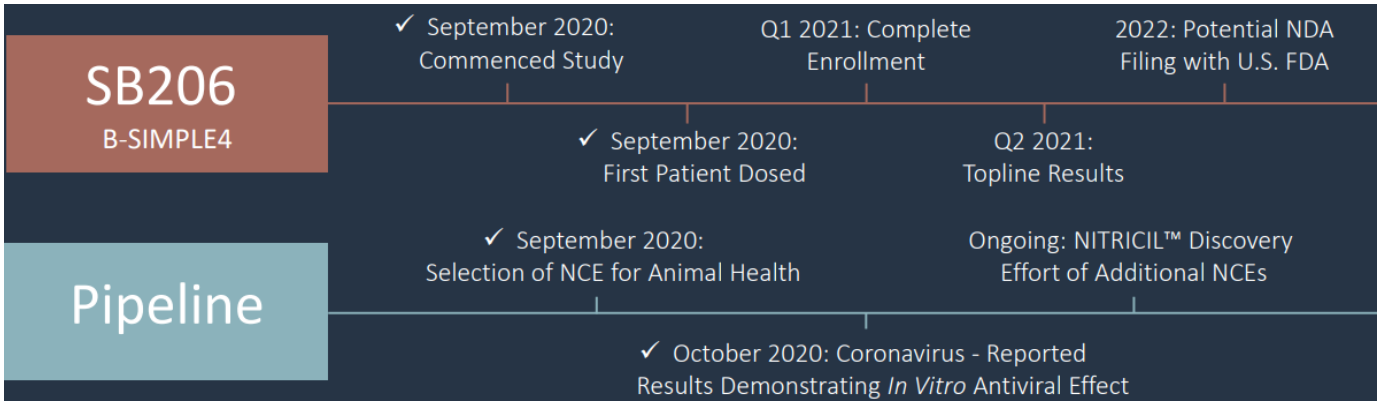
Cash and marketable securities balance was $43.1 million as of September 30, 2020. Apart from a $1.0 million paycheck protection program (PPP) loan, no debt is carried on the balance sheet. Cash burn for 3Q:20 was approximately ($7.8) million relative to cash from financing of $14.9 million, which was predominantly sourced from the common stock purchase agreement with Aspire.

B-SIMPLE4

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 that will be conducted across 50 sites. It is expected to enroll 850 subjects age six months and older presenting molluscum contagiosum (MC). Subjects will be randomized in a 1:1 ratio of active and placebo arms. SB206 will be administered once daily to all MC lesions for a minimum of four weeks and up to 12 weeks until all lesions are cleared.

Enrollment is expected to be complete in 1Q:21, slightly ahead of initial expectations due to a smooth start to enrollment which has seen more than 255 subjects randomized (30%) as of October 30. Topline efficacy results are expected to be made public in 2Q:21. Following 12 weeks of treatment, patients will have a follow-up visit at week 24.

Exhibit I – B-SIMPLE4 Timeline[1]



[1] Source: Novan November 2020 Corporate Overview Slide Deck

NASDAQ Compliance

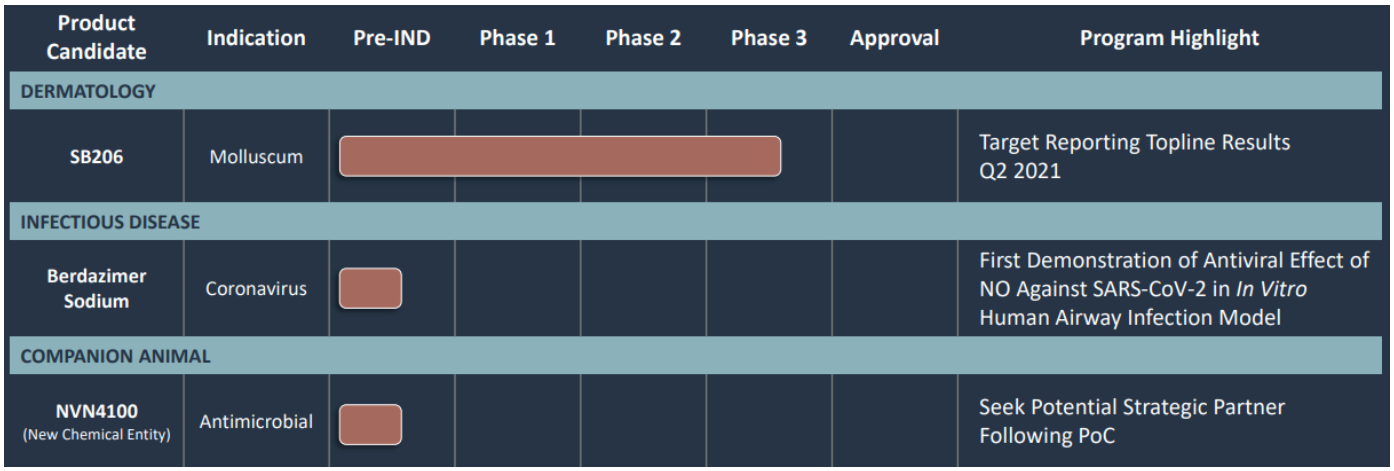
On February 19th, Novan received notice from the NASDAQ that it was not in compliance with exchange listing rules due to the share price trading below $1.00 for more than 30 consecutive business days. Due to the disruption related to the coronavirus, the NASDAQ provided an extension to regain compliance and Novan was granted additional time until November 2nd, 2020 to meet the minimum bid price requirement of $1.00. However, the shares continue to trade below $1.00. We anticipate that Novan will either shift trading of the shares to the NASDAQ Capital Market or execute a reverse stock split to meet the requirement. Novan will be eligible for additional time and an appeal if it moves to the NASDAQ Capital Market. We expect that the additional 180 days granted and the time to review an appeal will be sufficient to allow Novan to report topline results from the B-SIMPLE4 trial, supporting a positive revaluation of the stock assuming the trial has been successful.

Other Programs

Novan has expanded its efforts into early stage work for the use of berdazimer sodium against COVID-19 and in companion animal health. Efforts against the coronavirus targeted the reduction of viral burden in human bronchial epithelial cells in a 3-D tissue model. This work conducted at the Institute of Antiviral Research at Utah State University.

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.

Exhibit II – Novan Pipeline[2]



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 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 clears 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 effectiveness in trials. These approaches also have side effects, including pain and severe skin reactions, highlighting the need for a tolerable and effective treatment.

[2] Source: Novan November 2020 Corporate Overview Slide Deck

We see a fair estimate of an MC population of around six million in the United States and from 2 to 3 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, there will be a significant number of patients that will seek treatment given the availability of an approved medicine.

Key reasons to own Novan shares:

- **Phase III asset to address an unmet need in MC**
- **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 launched the trial, achieving 30% enrollment within two months. The data provided in previous trials 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. The trial is expected to enroll quickly and 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 E	2020 E	2021 E	2022 E
Total Revenues ($US)	**$4,896**	**$1,213**	**$1,321**	**$1,317**	**$1,224**	**$5,075**	**$5,100**	**$4,500**
YOY Growth	*-18%*	*10%*	*20%*	*0%*	*-11%*	*4%*	*0%*	
Research & Development	$25,172	$4,916	$3,761	$4,836	$7,500	$21,013	$18,250	$10,000
General & Administrative	$10,412	$2,507	$3,232	$3,108	$2,300	$11,147	$8,500	$14,000
Other	$0	$0	$2,421	$1,772		$4,193	$0	$0
Income from operations	($30,688)	($6,210)	($8,093)	($8,399)	($8,576)	($31,278)	($21,650)	($19,500)
Operating Margin	*-627%*	*-512%*	*-613%*	*-638%*	*-701%*	*-616%*	*-425%*	*-433%*
Other Income	$49	$8	($3)	($8)	$0	($3)	$0	$0
Interest Income	($2)	$35	$10	$2	$0	$47	$0	$0
Pre-Tax Income	($30,641)	($6,167)	($8,086)	($8,405)	($8,576)	($31,234)	($21,650)	($19,500)
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)**	**($8,576)**	**($31,234)**	**($21,650)**	**($19,500)**
Net Margin	*-626%*	*-508%*	*-612%*	*-638%*	*-701%*	*-615%*	*-425%*	*-433%*
Reported EPS	**($1.17)**	**($0.17)**	**($0.10)**	**($0.06)**	**($0.06)**	**($0.32)**	**($0.14)**	**($0.13)**
Basic Shares Outstanding	26,254	37,044	80,603	133,690	141,000	98,084	150,000	155,000

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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