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Novan Inc. (NOVN - NASDAQ)

Aspire Capital Infusion Gives A Nitro Boost

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 (8/17/20)	$0.56
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	**$0.22**
One-Year Return (%)	**-76.7**
Beta	**-0.06**
Average Daily Volume (sh)	**29,187,590**
Shares Outstanding (mil)	**137.5**
Market Capitalization ($mil)	**$77.0**
Short Interest Ratio (days)	**0.1**
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	$1.2 E	$1.2 E	$5.0 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 E	-$0.06 E	-$0.29 E
2021					-$0.12 E
2022					-$0.13 E

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WHAT'S NEW

Second Quarter 2020 Operational and Financial Results

On August 14, 2020 Novan Inc. (NASDAQ: NOVN) filed its second quarter 10-Q updating investors on its second quarter. Novan reported revenues of $1.3 million for the period and net loss of ($8.1) million or ($0.10) per share. Highlights for the second quarter and period to date began with verbal guidance from the FDA requiring only one successful additional trial to support a new drug application for SB206. The verbal guidance was followed by written minutes, further clarifying the path forward for the molluscum indication. Novan was also successfully working to raise sufficient capital to conduct the necessary additional trial and gathered over $33 million in funding from April 1st to date. In July, company CEO, Paula Brown Stafford was named as Chairman of the Board.

The most important news is the planned launch of the B-SIMPLE4 trial, which is expecting to enroll its first patient in September 2020. This suggests that top-line data could be available to share with the investment community by mid-year 2021.

Revenues of $1.3 million were reported in the second quarter, with $1.1 million representing the recognition of revenues from the Sato agreement and $221,000 attributable to the Department of Defense cancer research program grant. This compares to prior year second quarter revenues of $1.1 million that did not include any grant funding. Operational expenses of $7.0 million were 26% below prior year levels. This included $3.8 million of research and development expenses, down 39% year over year, and general and administrative expenses of $3.2 million, 2% lower than amounts in 2Q:19. R&D declined due to lower spend on the SB206 program and on the SB414 program as substantial costs were incurred to launch and enroll the B-SIMPLE trials in the prior year period. G&A fell on lower personnel and related costs partially offset by the value of commitment shares issued for the Aspire agreement. Novan also recognized an impairment charge of $2.4 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 ($8.1) million or ($0.10) per share which compares with 2Q:19 net loss of ($18.1) million and ($0.69) per share.

Cash and marketable securities balance was $35.5 million as of June 30, 2020. Apart from a $1.0 million paycheck protection program (PPP) loan, no debt is carried on the balance sheet. Cash burn for 2Q:20 was approximately ($6.4) million relative to cash from financing of $20.0 million, which was sourced from the PPP loan, warrant exercises and issuance of stock under the common stock purchase agreement with Aspire. Following the end of the reporting period, Novan submitted a share purchase notice to Aspire and sold additional shares raising another $13.1 million.

Since Our Initiation

Since our initiation on June 15th, Novan has raised sufficient capital to launch its pivotal Phase III study which will evaluate SB206 as a treatment for molluscum. In addition to the fund raise in June, Novan was able to raise additional capital through a new agreement with Aspire providing sufficient capital to complete the upcoming Phase III. The company also entered into a lease termination agreement with its landlord. Novan had previously used its 51,350 square foot facility for its corporate headquarters and for research and development. However, with the shift to an asset-lite model decided earlier this year, management will eliminate the overhead related to this space and exit the lease. Some of the impairment related to this change was recognized in the second quarter. An additional $1.3 million in cash costs are expected as the termination agreement completes.

A leading competitor in the effort to obtain approval for a molluscum treatment received a complete response letter (CRL) from the FDA in mid-July. The agency returned the application for Verrica Pharmaceuticals' (NASDAQ: VRCA) cantharidin-based product YCANTH citing the need for more information and additional Human Factors validation. We discuss the details of the CRL in a note found here.[1]

[1] https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2020/NOVN-RD-Update-for-Molluscum/default.aspx

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.

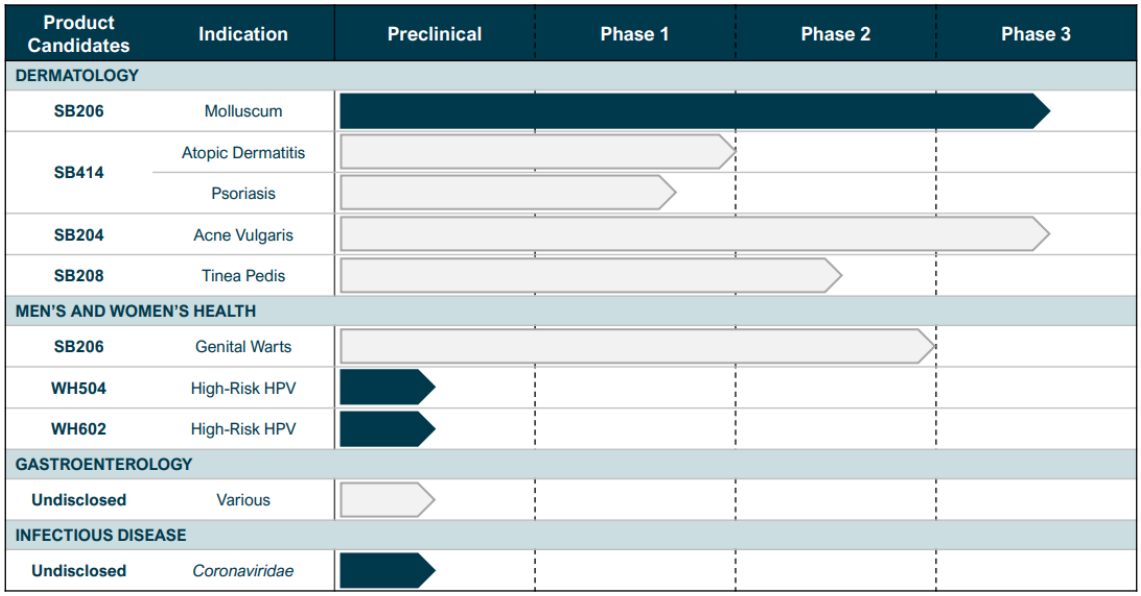
There is no standard of care for MC and for most healthy individuals, the virus clears on its own. In the population where treatment is desired, the lesions can be physically removed or oral and topical therapies can be administered. Some of the more common topical approaches include the use of cantharidin, 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.

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**

Exhibit I – Novan Pipeline[2]



Summary

Since our initiation, Novan has raised sufficient capital to move forward with its pivotal Phase III trial for SB206. The data provided by the prior trials were supportive of efficacy despite not reaching statistical significance. We believe that the larger B-SIMPLE4 trial will be able to generate statistically significant results with improved protocols and a larger population in this unmet need for children. Novan was able to raise sufficient capital to launch its Phase III pivotal trial in molluscum which is targeting first patient enrollment in September. The trial is expected to be short and produce topline data by the middle of 2021. Compared to our projections, Novan was able to raise funds at a higher price than we expected, reducing the anticipated impact from dilution. As a result, we increase our target price to $4.50 per share to reflect fewer than expected shares outstanding.

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

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[3]

Novan, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($US)	**$4,896**	**$1,213**	**$1,321**	**$1,224**	**$1,224**	**$4,982**	**$5,100**	**$4,500**
YOY Growth	*-18%*	*10%*	*20%*	*-7%*	*-11%*	*2%*	*2%*	
Research & Development	$25,172	$4,916	$3,761	$7,500	$7,500	$23,677	$15,000	$10,000
General & Administrative	$10,412	$2,507	$3,232	$2,100	$1,800	$9,639	$8,500	$14,000
Income from operations	($30,688)	($6,210)	($8,093)	($8,376)	($8,076)	($28,334)	($18,400)	($19,500)
Operating Margin	*-627%*	*-512%*	*-613%*	*-684%*	*-660%*	*-569%*	*-361%*	*-433%*
Other Income	$49	$8	($3)	$0	$0	$5	$0	$0
Interest Income	($2)	$35	$10	$0	$0	$45	$0	$0
Pre-Tax Income	($30,641)	($6,167)	($8,086)	($8,376)	($8,076)	($28,284)	($18,400)	($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)**	**($8,376)**	**($8,076)**	**($28,284)**	**($18,400)**	**($19,500)**
Net Margin	*-626%*	*-508%*	*-612%*	*-684%*	*-660%*	*-568%*	*-361%*	*-433%*
Reported EPS	**($1.17)**	**($0.17)**	**($0.10)**	**($0.06)**	**($0.06)**	**($0.29)**	**($0.12)**	**($0.13)**
Basic Shares Outstanding	26,254	37,044	80,603	137,000	140,000	98,662	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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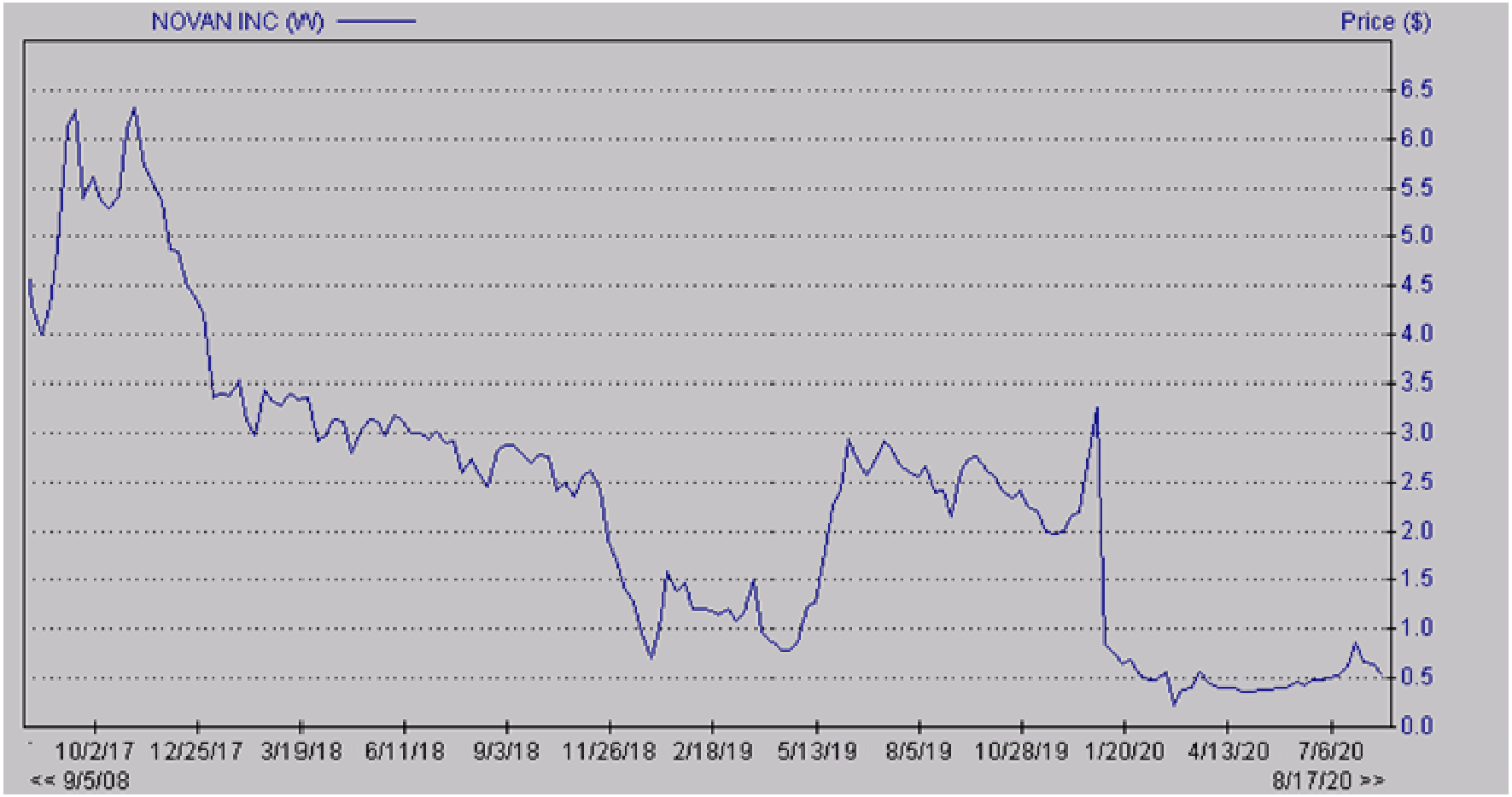
HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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