Zacks Small-Cap Research

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Novan, Inc. (NOVN - NASDAQ)

B-SIMPLE4 Safety Data

Based on our DCF model and a 15% discount rate, Novan is valued at approximately $72.00 per share. Our model applies a 85% probability of ultimate approval and commercialization for SB206 for molluscum contagiosum. The model includes contributions from the United States and Japan.

Current Price (9/23/2021)	$8.46
Valuation	**$72.00**

OUTLOOK

Novan is a research & development company which employs nitric oxide (NO) to address a number of infectious indications including molluscum contagiosum (MC), acne, dermatitis, psoriasis, warts, SARS-CoV-2 & HPV. Novan candidates store NO in large polymer macromolecules (Nitricil) which allows for stable and druggable NO. Novan uses its Nitricil technology to efficiently deliver NO to desired locations & release it at a controlled rate in human & animal health.

Lead candidate SB206 generated statistically significant topline results and is now in preparation for NDA submission in 3Q:22. Additional Nitricil compounds are now being forwarded, namely SB204 and SB019 in acne and COVID-19.

We expect a submission of an NDA in 3Q:22 for SB206. Our valuation assumes a 2023 regulatory approval and commercialization of SB206 in the US. Partner Sato will advance the candidate through the regulatory & commercialization process in Japan where we anticipate a 2023 regulatory submission followed by a 2024 launch.

SUMMARY DATA

52-Week High	**$25.90**
52-Week Low	**$4.33**
One-Year Return (%)	**61.1**
Beta	**-0.03**
Average Daily Volume (sh)	**658,753**
Shares Outstanding (mil)	**18.8**
Market Capitalization ($mil)	**159**
Short Interest Ratio (days)	**0.61**
Institutional Ownership (%)	**19.4**
Insider Ownership (%)	**5.86**
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 USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$1.2 A	$1.3 A	$1.3 A	$1.1 A	$4.9 A
2021	$0.8 A	$0.7 A	$0.8 E	$0.8 E	$2.6 E
2022					$3.6 E
2023					$172 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$1.66 A	-$1.00 A	-$0.63 A	-$0.46 A	-$2.96 A
2021	-$0.60 A	-$0.39 A	-$0.42 E	-$0.40 E	-$1.83 E
2022					-$1.08 E
2023					$4.17 E

WHAT'S NEW

B-SIMPLE4 Safety Data

In follow up to the June release of topline results for B-SIMPLE4 and additional detail provided in an update on September 9th, Novan reported safety data from its pivotal B-SIMPLE4 on September 23rd. The results were in line with previous trials and SB206 was well tolerated. Treatment emergent adverse events (TEAEs) through Week-24 maintained the same favorable profile as SB206's previous Phase III studies, B-SIMPLE1 and B-SIMPLE2 (see here). The TEAEs reported in greater than 5% of subjects in the SB206 treated groups included pain, erythema, pruritus, exfoliation, and dermatitis at the application site. The majority of these TEAEs were of mild or moderate severity. There were no serious adverse events.

Exhibit I - Overall Summary of TEAEs[1]

	B-SIMPLE4	
	SB206 (n=444)	Vehicle (n=447)
Subjects with at least one...		
TEAE	191 (43.0%)	103 (23.0%)
Treatment-related TEAE	163 (36.7%)	54 (12.1%)
TEAE leading to study drug discontinuation	18 (4.1%)	3 (0.7%)

In the SB206 arm, there were 191 (43.0%) subjects with at least one TEAE, of which 163 (36.7%) experienced at least one TEAE that was deemed treatment-related. This compared to 103 (23.0%) and 54 (12.1%) subjects in the vehicle arm, respectively. Some TEAEs led to study drug discontinuation, 18 (4.1%) subjects in the SB206 arm and 3 (0.7%) in the vehicle. Study drug discontinuation in the treatment arm were all due to application site reactions.

Exhibit II - Post-treatment Adverse Event Summary[2]

	B-SIMPLE4	
	SB206 (n=444)	Vehicle (n=447)
Subjects with at least one...		
Adverse Event ("AE")	75 (16.9%)	68 (15.2%)
Treatment-related AE	24 (5.4%)	14 (3.1%)

75 (16.9%) and 24 (5.4%) subjects experienced at least one adverse event and treatment-related adverse event, respectively, post treatment in SB206 administered patients. This compared to 68 (15.2%) and 14 (3.1%) subjects in vehicle arm post-treatment.

The incidence of scarring in the SB206 arm was lower than in the vehicle group at 4.7% and 6.3%, respectively. In the Week-24 visit, subjects treated with SB206 also exhibited lower occurrence of scarring compared to vehicle at 2.7% vs 4.0%, respectively. Though a subtle effect and less pronounced than what was observed in the B-SIMPLE1 and 2 safety assessment, the potential added benefit of reduced scarring can be a motivator and of benefit to patients to undergo treatment. Equipped with strong statistically significant endpoints and favorable safety profile, Novan now looks forward to sharing the data with the FDA in a pre-NDA meeting targeted in 1H:22.

September Update

On September 9, 2021, Novan hosted a corporate update conference call and webcast. The call was led by Novan President and CEO, Paula Brown Stafford, who reviewed recent milestones and plans over the next several years. Ms. Stafford detailed Novan's revenue prospects in the US which are expected to be primarily driven by SB206 for molluscum contagiosum in the near term and SB204 in acne vulgaris and SB019 in COVID-19 in later years. Ad-

[1] Novan Reports Safety Data from B-SIMPLE4 Pivotal Phase 3 Study of SB206 - Novan, Inc. (gcs-web.com)
[2] Novan Reports Safety Data from B-SIMPLE4 Pivotal Phase 3 Study of SB206 - Novan, Inc. (gcs-web.com)

vancing SB204 allows Novan the possible upside from a relatively small investment, with a large upside with the synergy of commercialization dollars for two dermatology products. Commercialization in the rest of the world is unencumbered from licensing obligations, opening up the field for future partnerships. Cash held on the balance sheet is expected to sustain Novan through NDA submission for SB206, and to support development activities for SB204 and SB019.

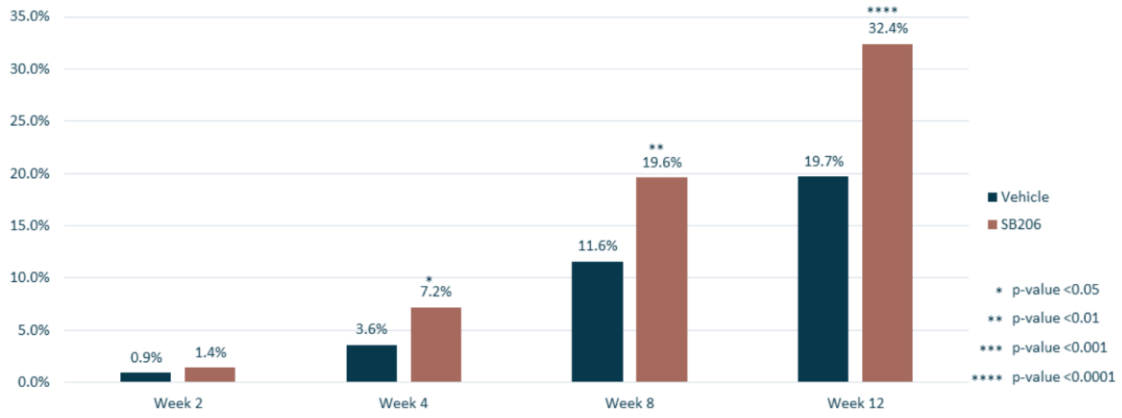
Exhibit III – Novan Pipeline[3]

Product Candidate	Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Approval	NDA Submission Targeted	Novan Revenue Retention[2]
DERMATOLOGY								
SB206	Molluscum						Q3 2022	~85% N. America[3] >95% ROW (ex. Japan[4])
SB204	Acne Vulgaris						2024[1]	~95% N. America >95% ROW (ex. Japan[4])
INFECTIOUS DISEASE								
SB019	SARS-CoV-2						2024[1]	>95% Worldwide

SB206 in Molluscum Contagiosum

CEO Stafford began the update call with a review of SB206's positive pivotal results in molluscum. Novan's lead program is expected to produce an NDA submission by 3Q:22. There is an unmet medical need for an at-home, topical solution to treat molluscum contagiosum. Prevalence is estimated at approximately 5-11% of the US population under the age of 16. Novan estimates the addressable market at 6 million individuals, believes payors will reimburse SB206 and the product will appear on formularies.

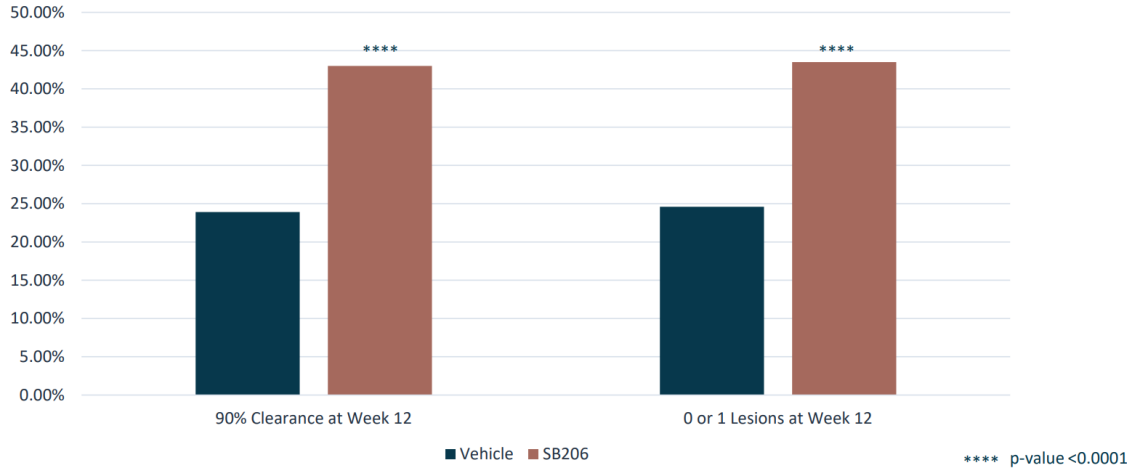
Exhibit IV - B-SIMPLE4 SB206 Complete Clearance Results vs Vehicle[4]



Topline results for B-SIMPLE4 were released in June, achieving a statistically significant primary endpoint of complete clearance of all treatable MC lesions at Week 12, with statistical efficacy observed as early as Week 4. Secondary outcome measures of one-lesion-or-less remaining and 90% clearance, both at Week 12, also showed statistically significant efficacy.

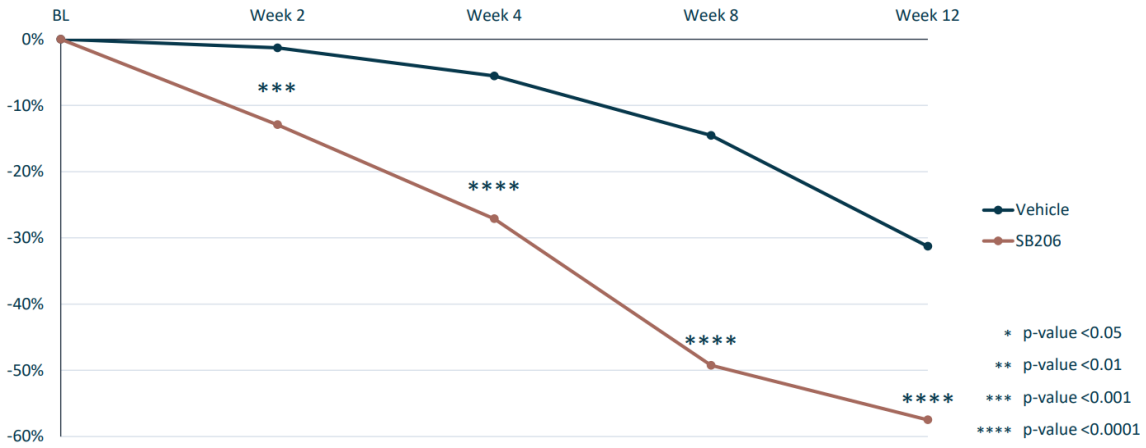
[3] Novan Corporate Presentation September 2021
[4] Novan Corporate Presentation September 2021

Exhibit V - 90% Clearance, 0 or 1 Lesions, Week 12[5]



Percent change from baseline, a secondary endpoint, demonstrated statistical significance at every measured time point starting at Week 2.

Exhibit VI - % Change from Baseline Lesion Count[6]



The CEO provided an update on Novan's plans for the next few quarters regarding SB206 which is included below:

- Pre-commercial preparation;
- Trial finalization;
- Week 24 readout - September 2021;
- Pre-NDA meeting with the FDA - 1H:22;
- NDA-enabling stability testing in 1H:22; and
- NDA submission - 3Q:22.

Summary

Novan reported favorable safety data, in line with its previous B-SIMPLE1 and B-SIMPLE2 Phase III trials. Equipped with safety data and strongly statistically significant primary endpoints, Novan is now preparing for its pre-NDA meeting with the FDA, expected in 1H:22 and for NDA submission in 2H:22. We maintain our target price of $72.00 per share.

[5] Novan Corporate Presentation September 2021
[6] Novan Corporate Presentation September 2021

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[7]

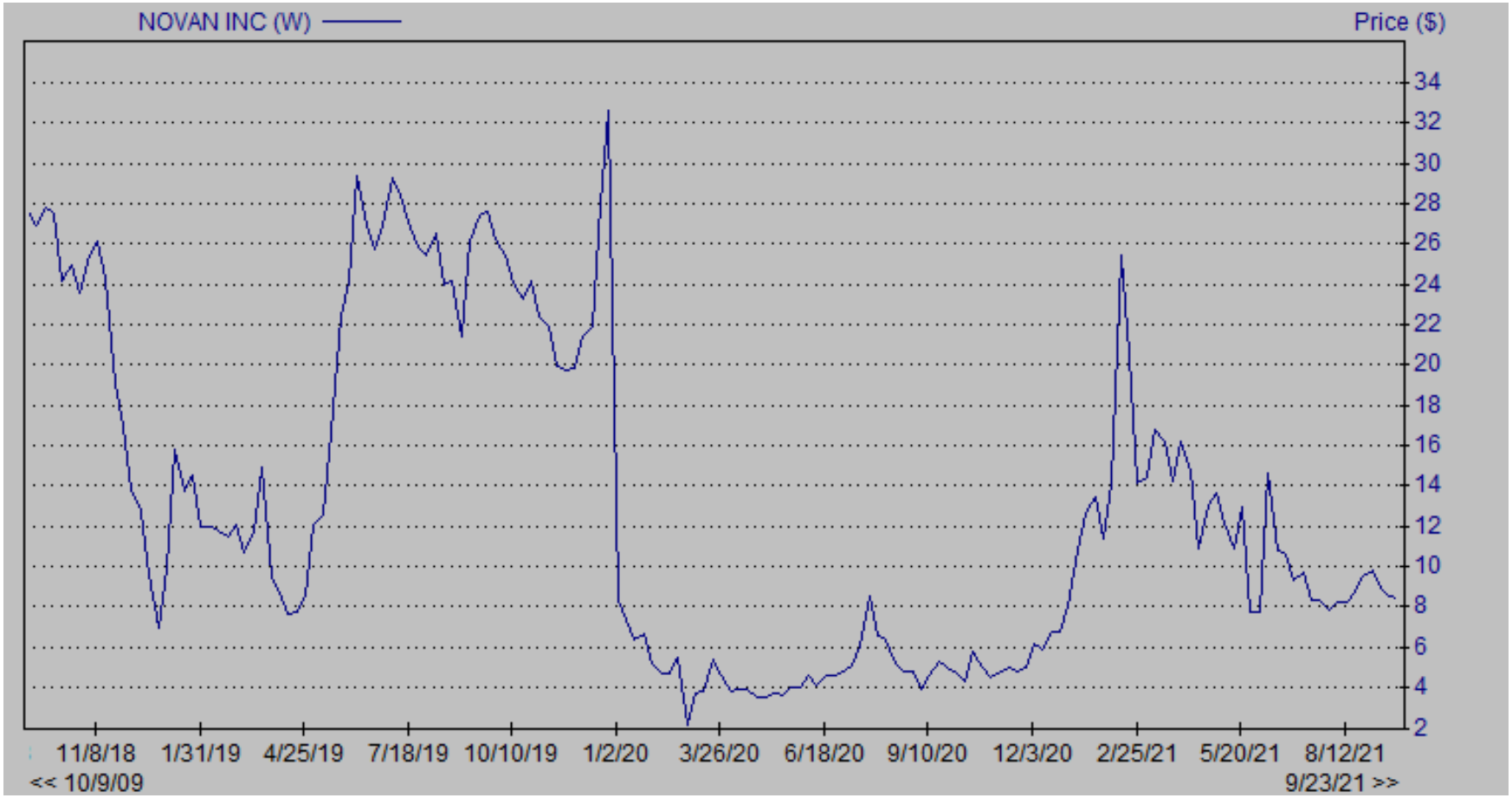
Novan, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US)	**$4,920**	**$819**	**$747**	**$840**	**$840**	**$2,599**	**$3,550**	**$172,105**
YOY Growth	*0%*	*-32%*	*-43%*	*-36%*	*-21%*	*-47%*		
Research & Development	$19,814	$6,418	$5,257	$5,800	$5,600	$23,075	$10,000	$5,000
Selling, General & Administrative	$11,271	$2,686	$2,431	$2,850	$2,800	$10,767	$14,000	$32,965
Other	$4,049	$0	$114	$0	$0	$0	$0	$0
Income from operations	($30,214)	($8,285)	($7,055)	($7,810)	($7,560)	($31,243)	($20,450)	$108,324
Operating Margin	*-614%*	*-1012%*	*-944%*	*-930%*	*-900%*	*-1202%*	*-576%*	*63%*
Other Income	$870	($670)	$1,029	$0	$0	$0	$0	$0
Interest Income	$51	$3	$3	$2	$2	$10	$0	$0
Pre-Tax Income	($29,293)	($8,952)	($6,023)	($7,808)	($7,558)	($31,233)	($20,450)	$108,324
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$27,081
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*25.0%*
Net Income	**($29,293)**	**($8,952)**	**($6,023)**	**($7,808)**	**($7,558)**	**($31,233)**	**($20,450)**	**$81,243**
Net Margin	*-595%*	*-1093%*	*-806%*	*-930%*	*-900%*	*-1202%*	*-576%*	*47%*
Reported EPS	**($2.96)**	**($0.60)**	**($0.39)**	**($0.42)**	**($0.40)**	**($1.83)**	**($1.08)**	**$4.17**
Basic Shares Outstanding	9,881	15,003	15,570	18,700	18,850	17,031	19,000	19,500

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

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

HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[8]



[8] Source: Zacks Research System

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