

Novan Inc. (NOVN - NASDAQ)

Syneos Selected as Commercialization Partner

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 (9/14/21) **\$8.27**
 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 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. SB206 & other Novan compounds store NO in large polymer macromolecules which allows for stable and druggable NO. 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 (%) **55.4**
 Beta **-0.03**
 Average Daily Volume (sh) **1,843,346**

Shares Outstanding (mil) **18.8**
 Market Capitalization (\$mil) **155**
 Short Interest Ratio (days) **0.61**
 Institutional Ownership (%) **19.2**
 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 \$US)				
	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					\$172.1 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

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. Advancing 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.

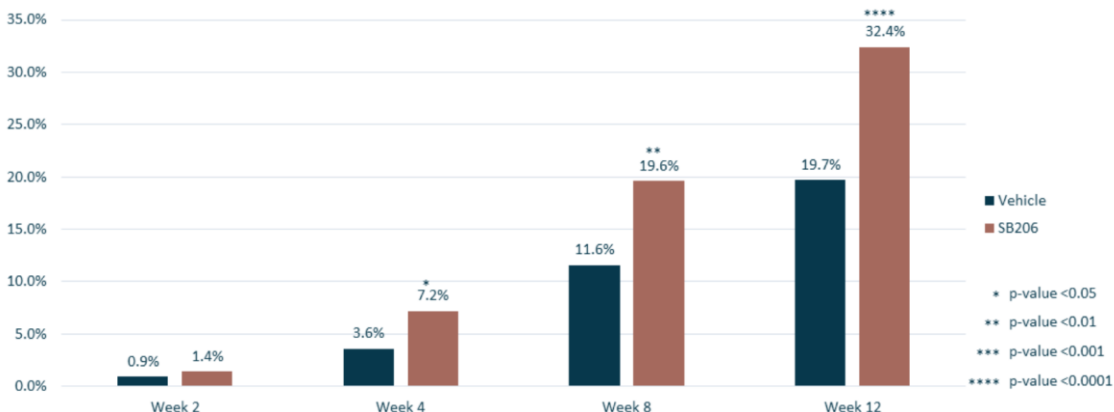
Exhibit I – Novan Pipeline¹

Product Candidate	Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Approval	NDA Submission Targeted	Novan Revenue Retention ²
DERMATOLOGY								
SB206	Molluscum	[Progress bar]					Q3 2022	~85% N. America ³ >95% ROW (ex. Japan ⁴)
SB204	Acne Vulgaris	[Progress bar]					2024 ¹	~95% N. America >95% ROW (ex. Japan ⁴)
INFECTIOUS DISEASE								
SB019	SARS-CoV-2	[Progress bar]					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, and believes that payors will reimburse SB206 and the product will appear on formularies.

Exhibit II - B-SIMPLE4 SB206 Complete Clearance Results vs Vehicle²

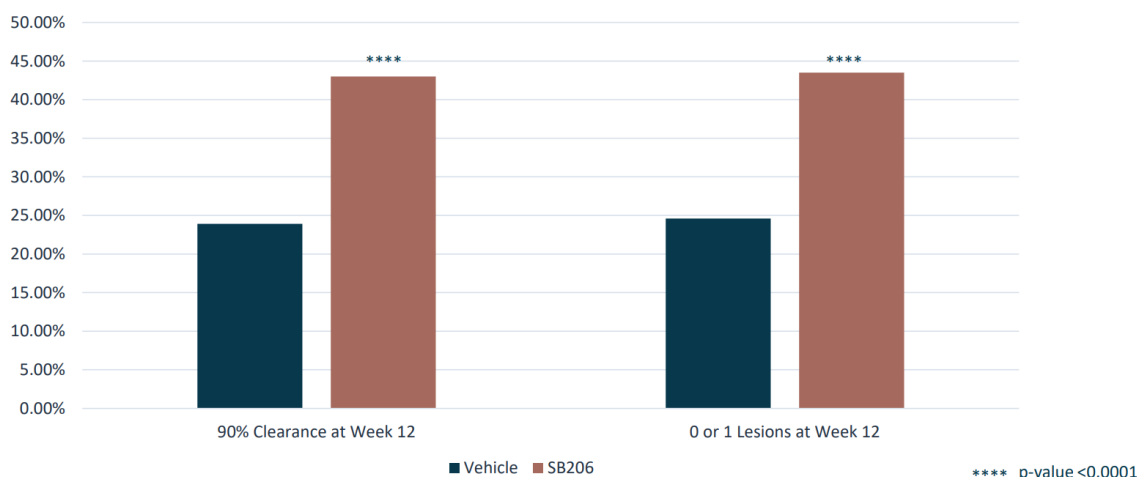


Topline results for B-SIMPLE4 were [released](#) in June, achieving a statistically significant primary endpoint of complete clearance of all treatable MC lesions at Week 12, with statistical efficacy observed as early as Week 4. Secondary outcome measures of one-lesion-or-less remaining and 90% clearance,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

¹ Novan Corporate Presentation September 2021

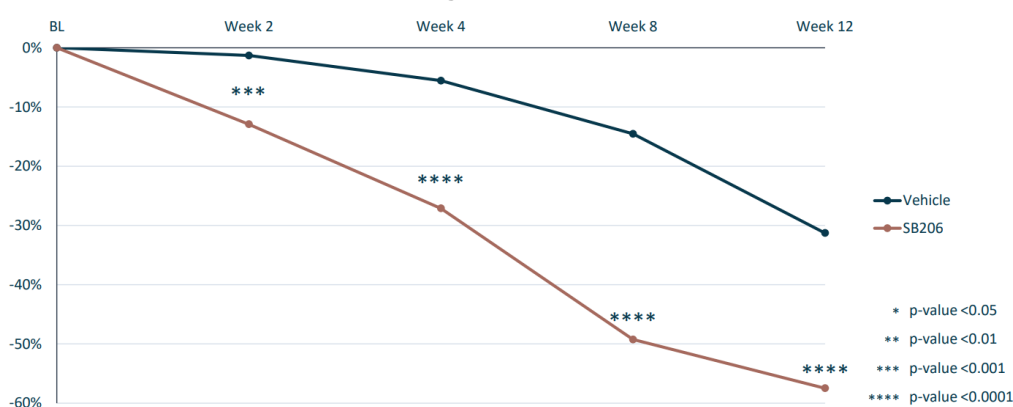
² Novan Corporate Presentation September 2021

Exhibit III - 90% Clearance, 0 or 1 Lesions, Week 12³



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

Exhibit IV - % Change from Baseline Lesion Count⁴



The CEO provided an update on Novan’s plans for the next few months regarding SB206. Investors should expect Novan to complete and share progress on the following:

- Pre-commercial preparation;
- Trial finalization;
- Week 24 readout - 3Q:21;
- Pre-NDA meeting with the FDA;
- NDA-enabling stability testing in 1H:22; and
- NDA submission - 3Q:22.

Commercialization with Syneos Health

Among important updates was the [announcement](#) on September 8, 2021 that Novan had selected Syneos Health (NASDAQ: SYNH) as a commercial solutions provider for SB206. The strategic partnership will focus on implementing SB206 prelaunch strategy and commercial preparation, followed by commercialization and sales pending FDA approval. Novan and Syneos began work together in 2019 to assess the molluscum market. Since then, the relationship has grown and Syneos has assembled a leadership team and incorporated full-service commercialization solutions to support Novan’s program. In addition, company leadership emphasized Syneos’ abilities as a proven end-to-end commercial solution provider with successful commercial launches. Syneos provides immediate access to commercial infrastructure and commercial execution strategically guided by a small group of internal ex-

³ Novan Corporate Presentation September 2021

⁴ Novan Corporate Presentation September 2021

perts. Novan’s new partner will develop a holistic, three-phase approach to marketing SB206 that is expected to build awareness and drive sales.

SB204 in Acne Vulgaris

With impressive clinical success in SB206, Novan has turned its attention to the next priorities in the pipeline, namely SB204 in acne vulgaris. SB204 offers the same active ingredient as SB206 but with special formulation that modifies NO strength and release characteristics. The candidate is both antibacterial and anti-inflammatory, has a convenient once-daily application, offers excellent tolerability and safety, and does not bleach, stain or irritate the skin. SB204 has data generated from three Phase III trials in 2017 and based on further communications with the FDA, may qualify for a new drug application with one more successful Phase III trial.

Exhibit V - Results from NI-AC302 (NCT02667444) for SB204 in Acne⁵

NI-AC302	
ITT* (n = 1327)	
Non-Inflammatory Lesion Reduction	
SB204	-14.8
Vehicle	-12.1
p-value	p=0.001
Inflammatory Lesion Reduction	
SB204	-12.8
Vehicle	-10.5
p-value	p<0.001
Investigator Global Assessment Success	
SB204	18.9%
Vehicle	14.3%
p-value	p=0.038

In the wake of Novan’s successful Phase III re-try of SB206 in molluscum, Novan now aims to run a pivotal trial in SB204, equipped with new study design and execution informed by previous Phase III studies. Similar to molluscum, Novan will target one pivotal trial for acne. CEO Stafford estimates a trial size in excess of 1,000 subjects and anticipates three primary endpoints of non-inflammatory lesion reduction, inflammatory lesion reduction, and Investigator Global Assessment success. The trial is targeting execution in 2023 and an NDA submission in 2024. Acne represents a much larger market than molluscum, with an estimated 50 million who suffer from the infection in the US and over 700 million worldwide.

SB019 in COVID-19

Stafford concluded the update highlighting Novan’s pursuit in COVID-19. Novan is pursuing COVID-19 after successful *in vitro* and *in vivo* studies of intranasal SB019. IND-enabling studies have already been completed, assuming they are sufficient for clearance. The targeted timeline includes Phase I in human volunteers in 2022, a Phase II/III drug-device combination study in 2023 and a potential NDA submission in 2024.

Summary

Novan updated investors on expected accomplishments over the next several years. Management is targeting the submission of three new drug applications to the FDA over the next three years in molluscum contagiosum, acne vulgaris and COVID-19. The most important asset of the three is SB206, which is expected to be submitted to the FDA in the third quarter of 2022 after finalization of safety data, agency meetings and stability testing. SB204 will now move front and center in the development pipeline and we expect to see one additional Phase III trial in acne patients which, if successful, will lead to a second NDA submission. The opportunity for a third NDA submission comes from SB019, which will require an accelerated effort.

⁵ Novan Corporate Presentation September 2021

PROJECTED FINANCIALS

Novan, Inc. - Income Statement⁶

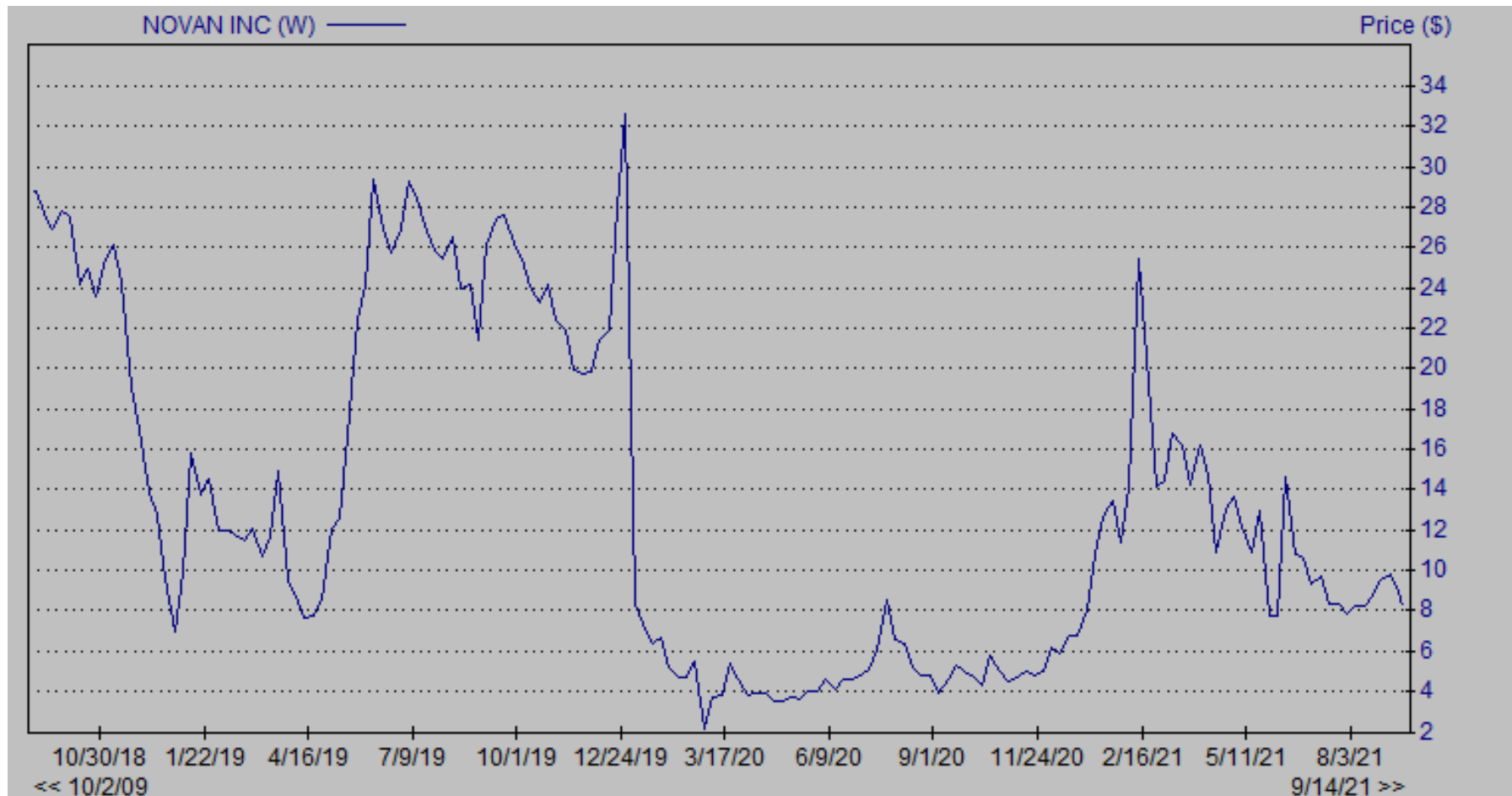
Novan, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues (\$US)	\$4,920	\$819	\$747	\$840	\$840	\$2,599	\$3,550	\$172,105
<i>YOY Growth</i>	0%	-32%	-43%	-36%	-21%	-47%		
Research & Development	\$19,814	\$6,418	\$5,257	\$5,800	\$5,600	\$23,075	\$10,000	\$5,000
Selling, General & Administrative	\$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
<i>Operating Margin</i>	-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
<i>Tax Rate</i>	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
<i>Net Margin</i>	-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

⁶ Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart⁷



⁷ Source: Zacks Research System

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