Zacks Small-Cap Research

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Novan, Inc. (NOVN: NASDAQ)

NDA Submitted

Our valuation approach employs a DCF model and a 15% discount rate. We apply a blended 82% probability of ultimate approval and commercialization for SB206 for molluscum contagiosum and SB204 for acne vulgaris. EPI Health is valued at cost. The model includes contributions from the United States and Japan.

Current Price (3/2/2023)	$1.41
Valuation	**$15.00**

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.

In March 2022, Novan acquired EPI Health, a specialty dermatology firm with four marketed products that are growing at a rapid pace. The acquisition provides an asset ready to commercialize Novan's pipeline candidates if approved.

Our valuation assumes a 2023 regulatory approval and 2024 commercialization of SB206 in the US. Partner Sato will advance the candidate through the regulatory & commercialization process in Japan where we anticipate a 2026 regulatory submission and a 2027 launch. SB204 will soon begin a Ph3 study in the US for acne vulgaris, in a parallel development timeline with Sato in Japan.

SUMMARY DATA

52-Week High	**$4.09**
52-Week Low	**$0.79**
One-Year Return (%)	**-61.3**
Beta	**0.2**
Average Daily Volume (sh)	**220,881**
Shares Outstanding (mil)	**24.5**
Market Capitalization ($mil)	**34.5**
Short Interest Ratio (days)	**1.3**
Institutional Ownership (%)	**8.2**
Insider Ownership (%)	**3.2**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.8 A	$0.7 A	$0.7 A	$0.7 A	$3.0 A
2022	$1.9 A	$6.2 A	$5.1 A	$4.7 E	$17.9 E
2023					$25.2 E
2024					$109.4 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.60 A	-$0.39 A	-$0.34 A	-$0.44 A	-$1.74 A
2022	-$0.71 A	-$0.44 A	-$0.25 A	-$0.22 E	-$1.39 E
2023					-$0.31 E
2024					$0.19 E

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WHAT'S NEW

Mid Quarter Update

Since reporting third quarter financial and operational results on November 14, 2022, Novan Inc. (NASDAQ: NOVN) has raised additional capital, entered into an exclusive licensing agreement with Sato Pharmaceutical and submitted its new drug application (NDA) to the FDA for SB206. Management also participated in investor and scientific conferences over the period.

Financing – Receivables Factoring
The financing environment has been difficult over the last year or two and sizable deals are challenging even with late-stage assets. Novan was able to execute a factoring arrangement that can provide up to $15 million, based on accounts receivable that should extend the company's cash runway. The accounts receivable-backed factoring[1] arrangement is with Bay View Funding, a subsidiary of Heritage Bank of Commerce (NASDAQ: HTBK) which is headquartered in San Jose, California. The agreement will provide non-dilutive funding of up to 70% of EPI Health's gross eligible receivables.

Sato Licensing Agreement - RHOFADE
Novan has been speaking with Sato for some time regarding an agreement for developing, manufacturing and marketing Rhofade in Japan and announced a memorandum of understanding in November. As of late December, the company had formalized a licensing agreement providing a $5 million upfront payment, a $2.5 million milestone payment on marketing approval in Japan and royalty payments based on sales.

Sato will be responsible for obtaining regulatory approval in Japan and can use EPI Health's U.S. FDA-approval dossier for Rhofade. Sato will also have a right of first negotiation related for the product in other countries in the Asia Pacific region. A portion of the amounts of the upfront and milestone payments received from the Rhofade license will be passed through to a third party under related contractual obligations.

On November 11th, Novan entered into a nonbinding memorandum of understanding with Sato for a proposed licensing arrangement. When the deal is executed, Sato gains the right to develop, manufacture and market Rhofade for rosacea in Japan. The Rhofade agreement adds to the other arrangements with Sato for SB206 (molluscum contagiosum) and SB204 (acne vulgaris). The deal's upfront funds[2] will help offset the cash burn from the other EPI assets.

NDA Submitted
In the first week of 2023, Novan announced that it had submitted its long-awaited New Drug Application (NDA) to the FDA for berdazimer gel, 10.3% for the treatment of molluscum contagiosum (MC). The product, which was designated SB206 during the development process, completed the required stability and other analytical testing required as part of the application. Based on the submission date and a typical 10-month review following an initial acceptance period by the FDA, Novan expects to receive an approval in the first quarter of 2024.

The NDA will include the data from Novan's B-SIMPLE trial series as well as other safety and efficacy data from earlier trials. The press release announcing the submission noted that if approved, the product would be the first topical treatment indicated for molluscum with the convenience of self-application. A few weeks after Novan's announcement, peer Verrica Pharmaceuticals (NASDAQ: VRCA) announced that it had resubmitted its NDA for VP-102, also for the treatment of molluscum contagiosum. In contrast to the self-administration of SB206, VP-102 is applied by a medical professional in the office. We think that having two products for the same indication being commercialized simultaneously could drive faster uptake of treatment for MC, improving physician and patient awareness and offering a comparison and choice.

Investor & Scientific Conferences
Novan attended the Cantor Fitzgerald Medical and Aesthetic Dermatology, Ophthalmology and Medtech Conference last December and participated in a panel discussion entitled "Distraction or Destruction?: What's New/Next in the Industry." Management was also available for one-on-one investor meetings. The company later attended the

[1] Factoring in financial services is a process where a business sells its accounts receivable (unpaid invoices) to a third-party financial institution, known as a factor, in exchange for immediate cash. The factor typically pays a percentage of the value of the accounts receivable upfront, typically 70-90%, and then takes on the responsibility of collecting payment from the debtor.
[2] EPI Health is required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

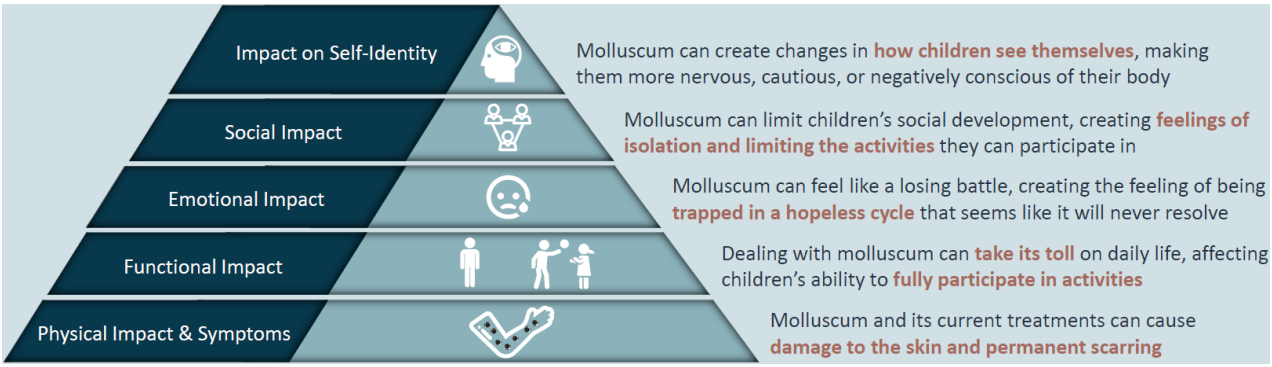
Virtual Investor 2023 Companies to Watch event. CEO Paula Brown Stafford shared Novan's latest public details on January 19th, 2023.

Marketing

It its January 2023 presentation, Novan makes a strong case for commercialization of MC identifying how MC treatment can change patient lives, address an unmet need and improve on existing approaches. In a survey sponsored by Novan, 87% of health care providers polled identified a moderate or high need for a new treatment for MC. An even greater proportion were willing to prescribe SB206 for MC, knowing its safety and efficacy profile.

Beyond the medical and health impacts of molluscum, there are other consequences on patients and families for this communicable disease. MC can impact how children see themselves and their self-confidence. It can cause them to be and feel isolated which carries an emotional and functional impact that prevents afflicted children from fully participating in activities. The condition can also cause permanent physical scarring.

Exhibit I Impact on Children and Families[3]



With respect to payors, pricing and reimbursement, Novan surmises that payors will be more favorably disposed to give access to a new product for pediatric patients. Payors rated SB206 highly in the survey, based on its performance and its ability to address an unmet need. Novan further expects that step edits and non-coverage were unlikely based on the lack of alternatives.

SB206

Novan has submitted its NDA to the FDA for SB206 and expects FDA approval in 1Q:24. Stability and other analytical testing was being conducted on SB206 prior to submission. The stability of registration batches has been completed and the NDA is waiting on the drug substance stability testing which is being conducted by a partner. Assuming a late 2023 approval by the FDA, SB206 could be launched in the first half of 2024.

Milestones:

- SB206 NDA-enabling stability testing – 2H:22
- Deal with Sato for Rhofade – December 2022
- SB206 NDA submission – January 2023
- Pivotal trial launch for SB204 in acne – 2023
- SB206 US launch – 1H:24
- NDA submission for SB204 – 2024
- SB206 approval in Japan (Sato) - 2027

[3] Source: Novan January 2023 Corporate Presentation

Exhibit II - NDA-Track Novan Pipeline[4]

Product Candidate	Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Approval	Next Targeted Milestone[1]
PRIORITY DEVELOPMENT PIPELINE							
SB206 (berdazimer gel, 10.3%)	Molluscum						NDA Submission 4Q 2022
SB204	Acne Vulgaris						Commence Phase 3 study
SB019	SARS-CoV-2						Submit IND and Commence Phase 1
POTENTIAL FUTURE VALUE DRIVERS[2]							
SB414	Atopic Dermatitis						Initiate Phase 1b study
	Psoriasis						Evaluate potential next step
SB208	Tinea Pedis						Evaluate potential next step
SB207	Genital Warts						Initiate Phase 2/3 study

Summary

Since Novan's third quarter report in November, there have been a few favorable developments in development and financial milestones. Most importantly, SB206 has been submitted to the FDA in an NDA. The company has also accessed new capital as it grows its EPI business entering a factoring and a licensing agreement. Given the favorable profile and the lack of alternatives for treating MC, we are optimistic on the prospects for regulatory approval of SB206 and anticipate a PDUFA date in January 2024.

With SB206 now in the hands of the FDA, the development focus now turns to SB204 in *acne vulgaris.* SB204 has already completed two positive Phase III studies in 2017. Experience and knowledge gained from SB204's previous trials and successful execution of SB206's B-SIMPLE4 will now be applied to the design of the next Phase III for SB204. The FDA recommended one additional successful Phase III trial to support approval of an NDA, which will be depending on capital availability. Novan management has guided toward a trial size of over 1,000 patients and will maintain its three co-primary endpoints. We anticipate further advancement of this asset following a successful capital raise.

To prepare for its NDA and commercialization, Novan added to its commercial team, readied its manufacturing capabilities and concluded stability testing. Capital permitting, Novan's SB204 in acne is slated to begin its pivotal trial in 2023, targeting NDA submission in 2024. We maintain our target price of $15.00 per share.

[4] Source: Novan's May 2022 Corporate Presentation. (1) Subject to additional funding (2) Not in active development.

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[5]

Novan, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US)	**$2,958**	**$1,928**	**$6,158**	**$5,115**	**$4,700**	**$17,901**	**$25,220**	**$109,413**
YOY Growth	-40%	135%	724%	594%	618%	505%	41%	
Product Cost of Goods Sold	$0	$206	$2,612	$1,440	$1,680	$5,938	$8,000	$24,071
Product Gross Margin	0%	71%	55%	69%	60%	67%	60%	78%
Research & Development	$20,416	$4,833	$3,144	$4,288	$3,100	$15,365	$20,000	$20,000
Selling, General & Administrative	$12,343	$9,994	$8,594	$8,562	$11,150	$38,300	$44,000	$50,731
Other	$114	$121	$94	$629	$0	$844	$0	$0
Income from operations	($29,915)	($13,226)	($8,286)	($9,804)	($11,230)	($42,546)	($46,780)	$14,611
Operating Margin	*-1011%*	*-686%*	*-135%*	*-192%*	*-239%*	*-238%*	*-185%*	*13%*
Other Income	$210	($25)	$2	$4,371	$0	$4,348	$0	$0
Interest Income	$13	($129)	($594)	($597)	$0	($1,320)	$0	$0
Pre-Tax Income	($29,692)	($13,380)	($8,878)	($6,030)	($11,230)	($39,518)	($46,780)	$14,611
Provision for Income Tax	$0	$0	$0	$0	$0	$0	($21,000)	($1,644)
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*44.9%*	*-11.3%*
Net Income	**($29,692)**	**($13,380)**	**($8,878)**	**($6,030)**	**($11,230)**	**($39,518)**	**($25,780)**	**$16,256**
Net Margin	*-1004%*	*-694%*	*-144%*	*-118%*	*-239%*	*-221%*	*-102%*	*14.9%*
Reported EPS	**($1.74)**	**($0.71)**	**($0.44)**	**($0.25)**	**($0.22)**	**($1.39)**	**($0.31)**	**$0.19**
Basic Shares Outstanding	17,066	18,830	20,216	24,462	50,500	28,502	84,244	85,200

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

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

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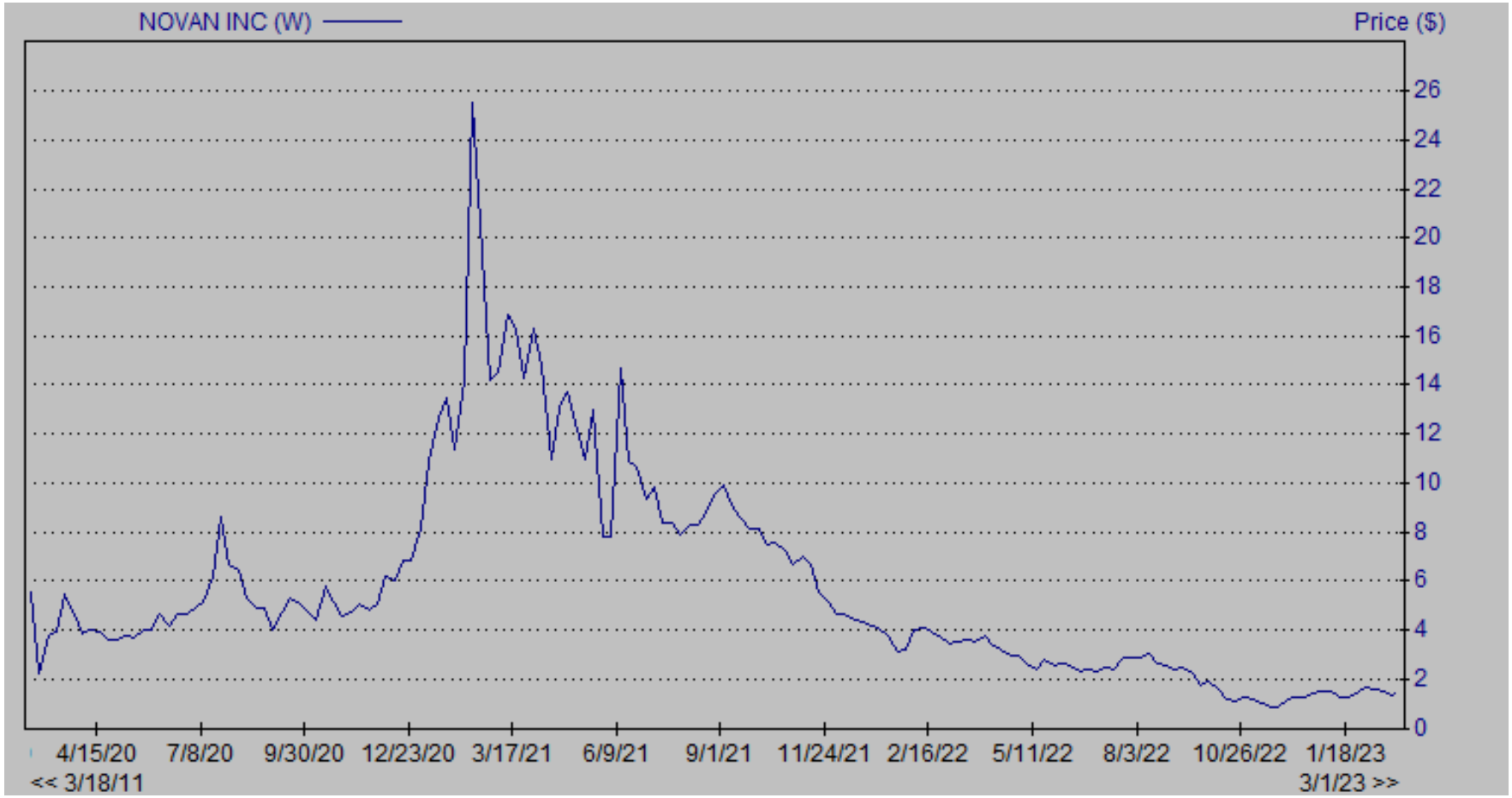
HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[6]



[6] Source: Zacks Research System

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