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Novan, Inc. (NOVN: NASDAQ)

2022 Results: Additional Capital Raised

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 (3/30/2023)	$1.20
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	**$0.79**
One-Year Return (%)	**-67.1**
Beta	**0.2**
Average Daily Volume (sh)	**185,865**
Shares Outstanding (mil)	**28.0**
Market Capitalization ($mil)	**30.8**
Short Interest Ratio (days)	**6.5**
Institutional Ownership (%)	**7.4**
Insider Ownership (%)	**2.9**
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	$10.5 A	$23.7 A
2023					$25.2 E
2024					$74.0 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	-$0.12 A	-$1.42 A
2023					-$0.22 E
2024					$0.18 E

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WHAT'S NEW

2022 Financial and Operational Results

On March 30, 2023, Novan Inc. (NASDAQ: NOVN) reported 2022 financial and operational results in a press release and in the filing of Form 10-K. A conference call and webcast were subsequently held to update investors on recent developments. The call highlighted the performance of the EPI Health assets and efforts related to SB206's New Drug Application (NDA) which has been assigned a target action date of January 25th, 2024. Novan entered an exclusive license agreement with Sato Pharmaceutical for Rhofade. Since the report of its third quarter, Novan has improved its position with three cash-augmenting transactions: a factoring agreement, a registered direct offering and a licensing agreement with long-time partner Sato.

Highlights for 2022 and to-date include:

- Publication of B-SIMPLE4 results in JAMA Dermatology – July 2022
- Payment and termination of seller note outstanding – July 2022
- Multiple presentations at the Fall Clinical Dermatology Conference – October 2022
- MoU with Sato for licensing of Rhofade – November 2022
- $15 million financing agreement (Bay View) – December 2022
- Sato license agreement for Rhofade in Japan – December 2022
- SB206 NDA submitted for molluscum contagiosum – January 2023
- NDA accepted for SB206 assigning 5JAN24 PDUFA date – March 2023
- $6 million registered direct offering – March 2023

With respect to financial performance, Novan generated $23.7 million in 2022 revenues versus $3.0 million in 2021, and posted a net loss of ($31.3) million or ($1.42) per share compared to a loss of ($29.7) million or ($1.74) per share in the prior year period.

For the year ending December 31, 2022 and versus the same prior year period:

- Revenues were $23.7 million, up 7x from $747,000. The increase is predominantly due to revenues from sales of dermatology products Wynzora, Rhofade, Minolira and Cloderm which did not contribute in the prior year period. License and collaboration revenues of $7.8 were primarily associated with the Sato Rhofade agreement ($5.0 million) Sato R&D upfront ($2.6 million) and the Prasco agreement for Cloderm ($0.2 million). There was also a small contribution from research and grant revenue;
- Cost of goods sold was $7.4 million vs. nil representing a 69% gross margin on total revenues;[1]
- Research & development expenses totaled $16.0 million, down 22% from $20.4 million. A reduction in spending on the SB206 program were offset by increases in other research and development expenses;
- Selling, general & administrative expenses were $34.1 million, up 180% from $12.3 million with the increase attributable to a variety of EPI Health related commercial and transaction related costs, spending on SB206 commercialization preparation, and higher personnel costs among other items;
- Net loss was ($31.3) million, or ($1.42) per basic and diluted share, compared to ($29.7) million, or ($1.74) per share.

As of December 31, 2022, cash and equivalents on the balance sheet totaled $12.3 million. This compares to cash holdings of $47.1 million at the end of 2021. Cash burn was ($35.2) million which was partially offset by $16.0 million of net contributions from financing related to the $15 million direct offering in June 2022, a small contribution from the at-the-market (ATM) facility and $10 million net from the factoring agreement in the fourth quarter. Novan repaid the $16.5 million note related to the EPI acquisition for $10 million.

[1] Note that a portion of license revenues that were received were paid out as a milestone and appeared in gross margin. If we remove the license amounts from revenues and cost of goods sold, product gross margin is approximately 61%.

Corporate Updates

Since reporting third quarter results last November, Novan 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 during 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. Despite the adversities, 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[2] 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. The funds are essentially a short-term credit line for receivables that is repaid when cash flows from distributors and customers arrive. As of year-end, Novan had drawn approximately $10 million net from the facility.

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 to this effect last 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[3] will help offset the cash burn from the other EPI assets.

Direct Offering
In mid-March, Novan entered into an agreement with HC Wainwright to offer approximately 5.0 million shares at $1.19 per share. Each share will include a warrant with an exercise price of $1.20 and a five-year life. The deal was closed on March 16th as 5,042,017 shares and a matching number of warrants were sold to raise $6.0 million in gross proceeds. As required as part of a previous financing, the exercise price of 5.3 million formerly issued warrants were reduced from $2.851 to $1.20.

NDA Submitted and Accepted
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. On March 7th, Novan announced that the FDA had accepted its NDA and assigned a Prescription Drug User Fee Act (PDUFA) date of January 5, 2024.

The NDA included 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. Shortly after Novan's submission, peer Verrica Pharmaceuticals (NASDAQ: VRCA) announced that it had resubmitted its NDA for VP-102, also for the treatment of molluscum contagiosum and later updated stakeholders sharing its July 23, 2023 PDUFA date. 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.

[2] 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.
[3] 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.

Corporate Branding
Since the acquisition of EPI Health, Novan has maintained two distinct brands. The change to all business being identified under the Novan brand reflects progress made in building a unified medical dermatology company. This will help prepare the market for the launch of SB206 following its anticipated approval early next year.

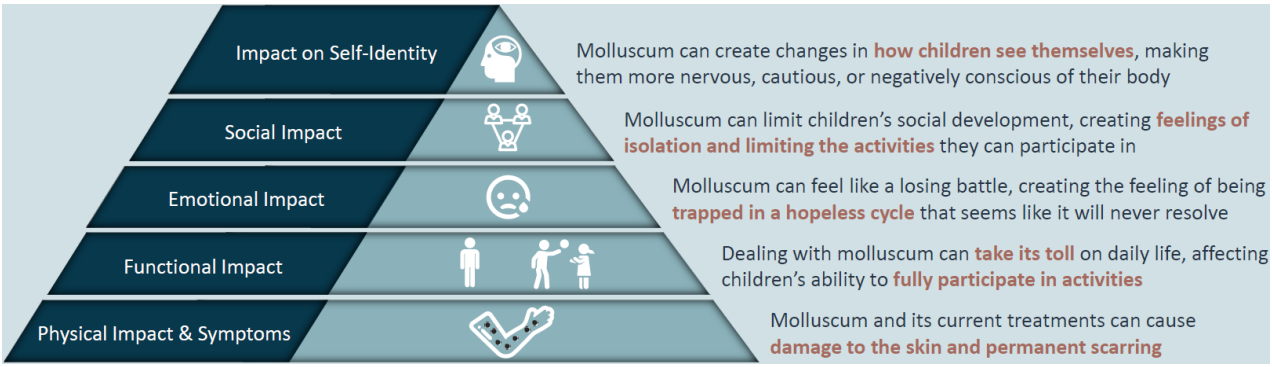
Investor & Scientific Conferences
Novan attended the Cantor Fitzgerald Medical and Aesthetic Dermatology, Ophthalmology and Medtech Conference last December and participated in a panel discussion entitled "Distraction or Destruction?: What's New/Next in the Industry." Management also participated in one-on-one investor meetings. The company later attended the Virtual Investor 2023 Companies to Watch event where CEO Paula Brown Stafford shared Novan's latest public details on January 19th, 2023. In mid-March, Novan participated in the Oppenheimer 33rd annual healthcare conference and also conducted 1:1 investor meetings. Novan's March 14th presentation at Oppenheimer is available here.

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[4]



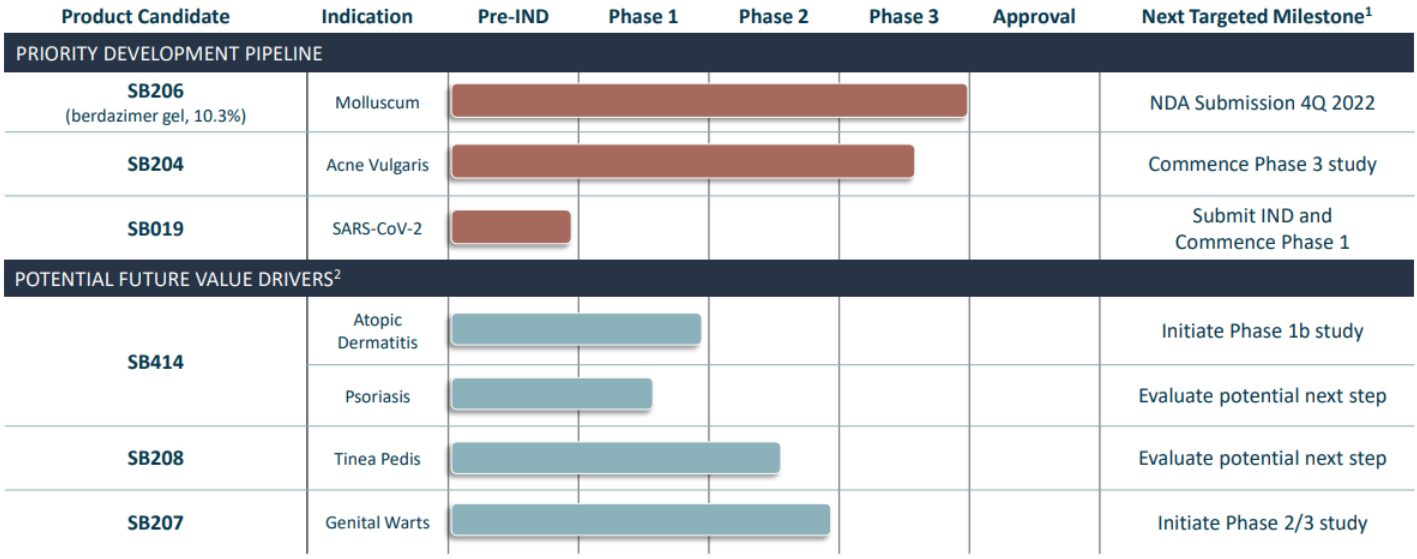
With respect to payors, pricing and reimbursement, Novan surmises that payors will be more favorably disposed to give access to a new product for pediatric patients. Payors rated SB206 highly in the survey, based on its performance and its ability to address an unmet need. Novan further expects that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

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

[4] Source: Novan March 2023 Corporate Presentation

Exhibit II - NDA-Track Novan Pipeline[5]



Summary

Since Novan's third quarter report in November, there have been a few favorable developments in operational and financial milestones. Most importantly, SB206 has been submitted to the FDA in an NDA and has been accepted. A target action date of January 25, 2024 has been assigned. The company has also accessed new capital as it grows its EPI business entering three transactions that will support operations over the near term.

Efforts continue with the approved product portfolio and year over year growth was impressive in the fourth quarter. Wynzora, Rhofade and Minolira all posted high double-digit growth rates in scripts. However, profitability has been elusive.

To prepare for its NDA and commercialization, Novan added to its commercial team, readied its manufacturing capabilities and concluded stability testing. We maintain our target price of $15.00 per share.

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

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[6]

Novan, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ($US)	**$2,958**	**$1,928**	**$6,158**	**$5,115**	**$10,481**	**$23,682**	**$25,220**	**$73,960**
YOY Growth	-40%	135%	724%	594%	1500%	701%	6%	
Product Cost of Goods Sold	$0	$206	$2,612	$1,440	$3,121	$7,379	$8,000	$16,271
Product Gross Margin	0%	71%	55%	69%	33%	53%	60%	78%
Research & Development	$20,416	$4,833	$3,144	$4,288	$3,725	$15,990	$14,617	$8,000
Selling, General & Administrative	$12,343	$9,994	$8,594	$8,562	$6,953	$34,103	$33,550	$39,522
Other	$114	$121	$94	$629	($404)	$440	$0	$0
Income from operations	($29,915)	($13,226)	($8,286)	($9,804)	($2,914)	($34,230)	($30,947)	$10,167
Operating Margin	*-1011%*	*-686%*	*-135%*	*-192%*	*-28%*	*-145%*	*-123%*	*14%*
Other Income	$210	($25)	$2	$4,371	($30)	$4,318	$0	$0
Interest Income	$13	($129)	($594)	($597)	($79)	($1,399)	$0	$0
Pre-Tax Income	($29,692)	($13,380)	($8,878)	($6,030)	($3,023)	($31,311)	($30,947)	$10,167
Provision for Income Tax	$0	$0	$0	$0	$0	$0	($12,042)	($5,578)
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*38.9%*	*-54.9%*
Net Income	**($29,692)**	**($13,380)**	**($8,878)**	**($6,030)**	**($3,023)**	**($31,311)**	**($18,905)**	**$15,745**
Net Margin	*-1004%*	*-694%*	*-144%*	*-118%*	*-29%*	*-132%*	*-75%*	*21.3%*
Reported EPS	**($1.74)**	**($0.71)**	**($0.44)**	**($0.25)**	**($0.12)**	**($1.42)**	**($0.22)**	**$0.18**
Basic Shares Outstanding	17,066	18,830	20,216	24,462	24,571	22,020	84,244	85,200

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

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

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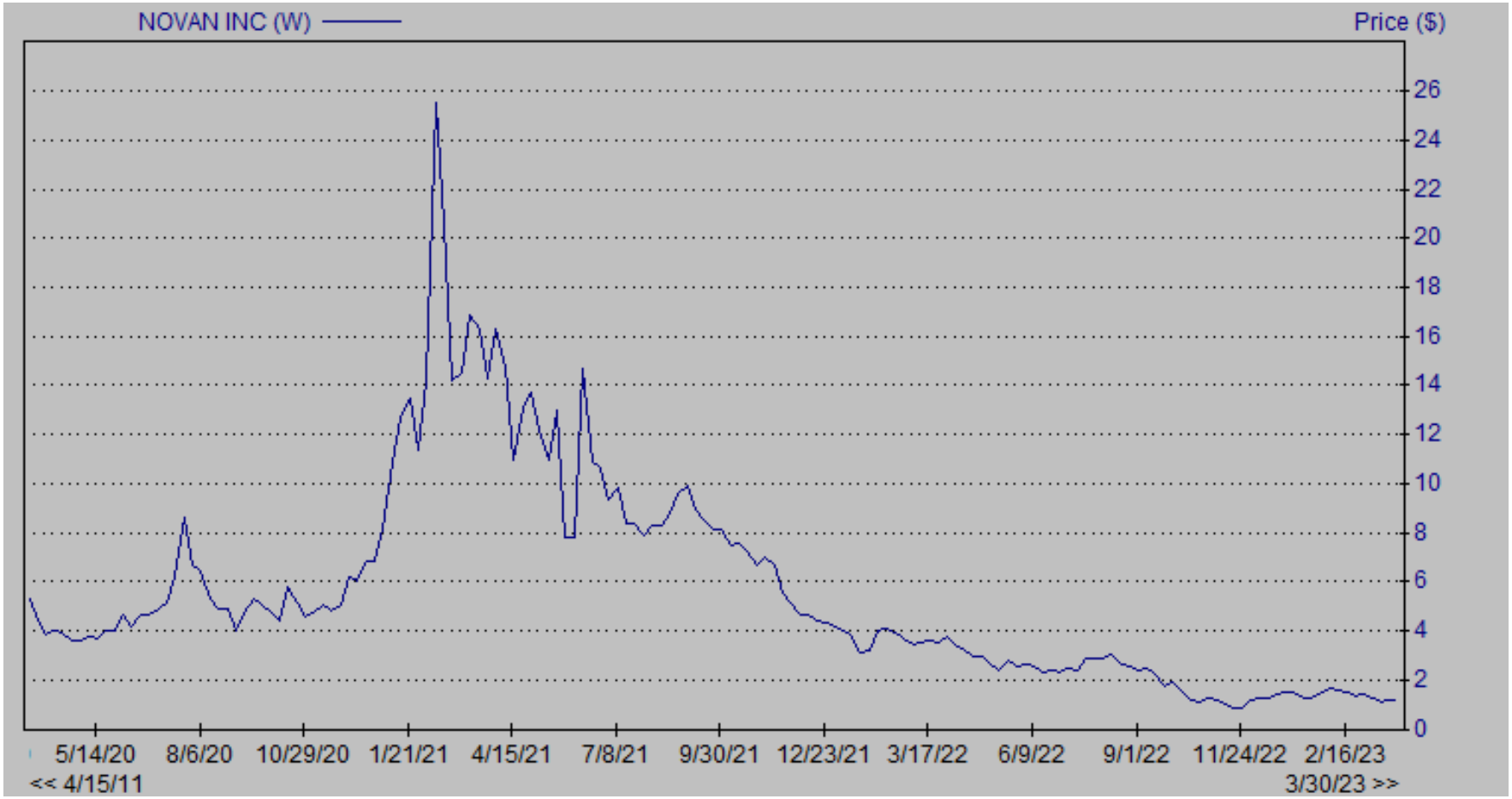
HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[7]



[7] Source: Zacks Research System

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