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Novan, Inc. (NOVN - NASDAQ)

KINSOLUS: A Solution for Molluscum

Based on our DCF model and a 15% discount rate, Novan is valued at approximately $70.00 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 (11/9/2021)	$7.09
Valuation	**$70.00**

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, with conditionally accepted brand name Kinsolus, 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	**$4.61**
One-Year Return (%)	**43.8**
Beta	**-0.03**
Average Daily Volume (sh)	**455,172**
Shares Outstanding (mil)	**18.8**
Market Capitalization ($mil)	**133**
Short Interest Ratio (days)	**2.0**
Institutional Ownership (%)	**19.6**
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	$0.7 A	$0.8 E	$3.1 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	-$0.34 A	-$0.42 E	-$1.74 E
2022					-$2.52 E
2023					$4.17 E

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WHAT'S NEW

Third Quarter 2021 Results

On November 10, 2021, Novan Inc. (NASDAQ: NOVN) reported third quarter financial results in a press release concurrent with the filing of Form 10-Q. A conference call and webcast was also held to update investors on financial and operational results. Most recently, the FDA conditionally accepted the proposed brand name for SB206: KINSOLUS™.

Highlights for the third quarter ending September 30, 2021 and to-date include:

- Last patient, last visit (24-week) - B-SIMPLE4 - July 2021
- Tomoko Maeda-Chubachi, MD, PhD, MBA appointed Chief Medical Officer - August 2021
- Novan engages Syneos Health as commercialization solutions provider - September 2021
- Update on SB206 and announcement of intent to advance SB204 and SB019 - September 2021
- Safety data from B-SIMPLE4 - September 2021
- Brian M. Johnson appointed Chief Commercial Officer - November 2021
- FDA conditional acceptance of proposed brand name KINSOLUS for SB206 - November 2021
- Favorable preclinical safety data for SB019 in COVID-19 - November 2021

With respect to financial performance, Novan generated $0.7 million in revenue in 3Q:21, comprising license and collaboration and government research contracts and grants revenues, versus $1.3 million in the same quarter last year, and posted a net loss of ($6.5) million or ($0.34) per share compared to a loss of ($8.4) million or ($0.63) per share for the prior year period.

For the third quarter ending September 30, 2021 and versus the prior year third quarter:

- Revenues were $0.7 million, down 44% from $1.3 million. Amounts are related to recognition of the upfront and expected milestone payments under the Sato Agreement and grants revenue from government research contracts related to Department of Defense projects;
- Research & development expenses totaled $4.3 million, down 12% from $4.8 million related to a $1.1 million net decrease in SB206 spending partially offset by a $0.5 million increase in other research and development expenses;
- General & administrative expenses were $3.0 million, down 4% from $3.1 million on lower non-cash commitment share expense partially offset by higher directors and officers insurance, greater personnel costs and an increase in SB206 commercialization preparation costs;
- Net loss was ($6.5) million, or ($0.34) per basic and diluted share, compared to ($8.4) million, or ($0.63) per basic and diluted share.

As of September 30, 2021, cash and equivalents on the balance sheet totaled $60.0 million, compared to $35.9 million at the end of 2020, supported by net financing cash flows of $44 million. In June 2021, Novan raised net proceeds of $37.2 million as part of an underwriting agreement with Cantor Fitzgerald. 3,636,364 shares of common stock were issued at $11.00 per share. Cash burn for the first nine months of 2021 totaled approximately ($19.5) million versus approximately ($22.0) million in the prior year period.

Capital expenditures year to date have been ($4.5) million in part offset by landlord reimbursements of $1.0 million. The facility project includes both the corporate offices for Novan and a small scale research and development facility that can support API manufacturing, clinical trial material manufacture and limited drug product manufacturing. We expect the construction to be complete around the turn of the year; however, some cash costs will continue into 2022.

B-SIMPLE4 Safety Data

In follow up to the June release of topline results for B-SIMPLE4 and an update on September 9th, Novan reported safety data from its pivotal B-SIMPLE4 trial on September 23rd. The results were in line with previous results indicating that SB206 was well tolerated. Treatment emergent adverse events (TEAEs) through Week-24 maintained

the same favorable profile as those in 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.

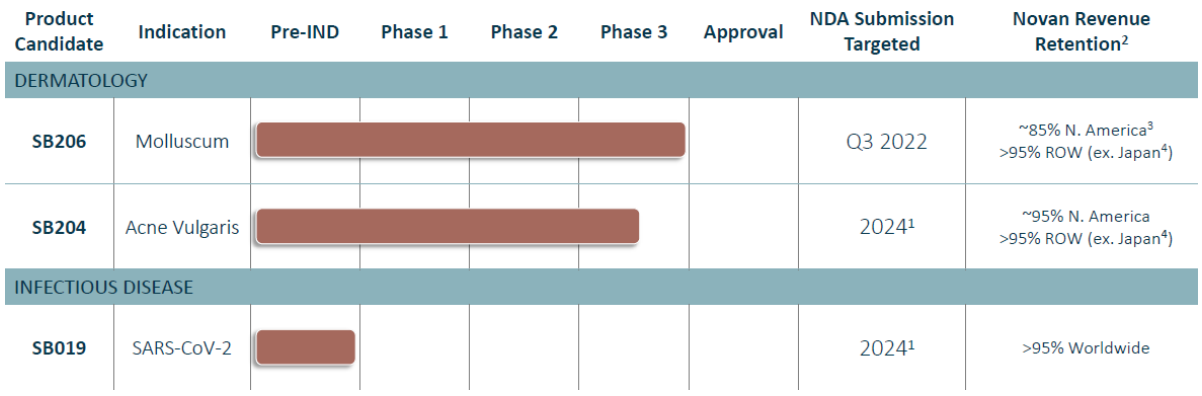
Exhibit II - Post-treatment Adverse Event Summary[2]

	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.

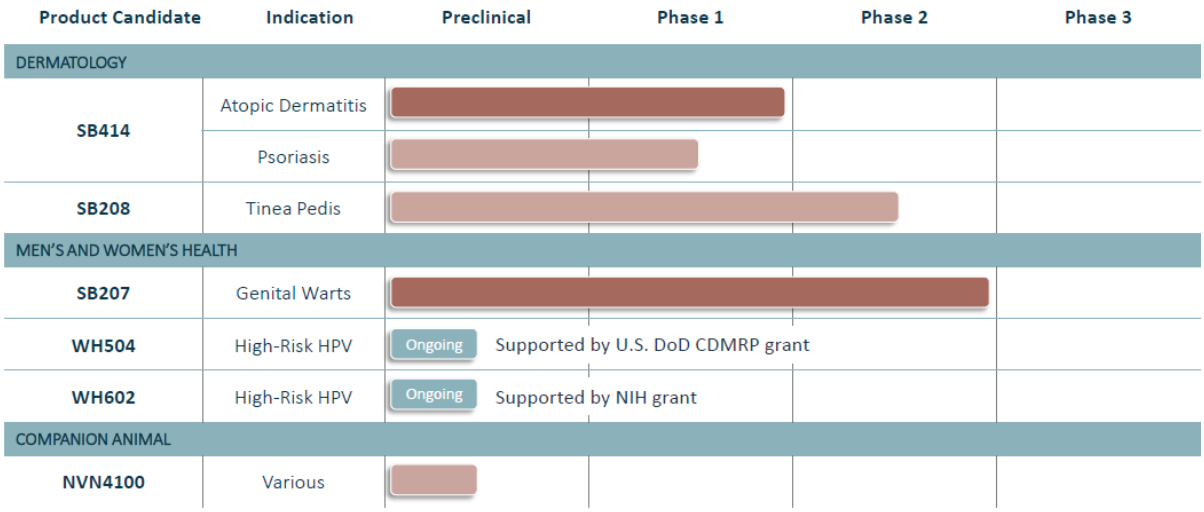
The incidence of scarring in the SB206 arm was lower than in the vehicle group at 4.7% and 6.3%, respectively. In the Week-24 visit, subjects treated with SB206 also exhibited lower occurrence of scarring compared to vehicle at 2.7% vs 4.0%, respectively. Though a subtle effect and less pronounced than 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 plans to share the data with the FDA in a pre-NDA meeting targeted for 1H:22.

Exhibit III – NDA-Track Novan Pipeline[3]



[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)
[3] Novan Corporate Presentation, Third Quarter Update 2021

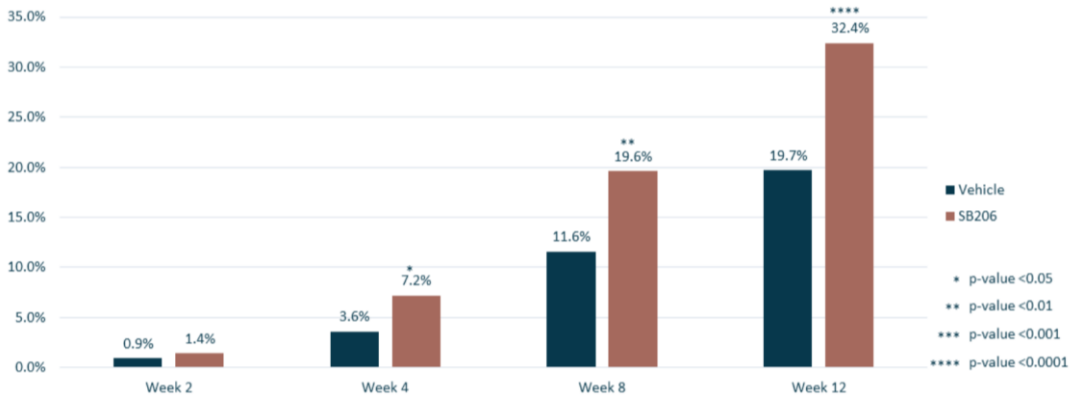
Exhibit IV – Earlier Stage Novan Pipeline[4]



Kinsolus Regulatory Submission and Commercialization

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 for this in-home solution.

Exhibit V - B-SIMPLE4 SB206 Complete Clearance Results vs Vehicle[5]



Near term milestones related to Novan's portfolio include:

- SB206 Week 24 readout - September 2021
- Launch pre commercial activities for SB206 (Kinsolus) – 3Q:21
- Kinsolus Pre-NDA meeting with the FDA - 1H:22
- Kinsolus NDA-enabling stability testing - 1H:22
- Kinsolus NDA submission - 3Q:22
- SB019 Phase I – 1H:22
- SB204 pivotal Phase III study - 2023
- SB204 NDA submission – 2024
- SB019 NDA submission - 2024
- SB206 approval in Japan (Sato) - 2027

[4] Novan Corporate Presentation, Third Quarter Update 2021
[5] Novan Corporate Presentation September 2021

Commercialization with Syneos Health

On September 8, 2021, Novan announced that it 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 experts. Novan's new partner will develop a holistic, three-phase approach to marketing SB206 that is expected to build awareness and drive sales.

Exhibit VI – Kinsolus Commercial Approach[6]



Favorable Preclinical Safety Data for SB019

On November 9, 2021, Novan announced promising preclinical safety results with its COVID-19 candidate, SB019, in a 14-day, *in vivo,* Good Laboratory Practice (GLP) repeat dose intranasal toxicity study. Dosing was five times per day and after the 14-day dosing period, a 7-day recovery period, without drug exposure, followed. There were no treatment-related adverse events up to the highest dose tested, 14 mg/day. The results support Novan's further pursuit of the candidate in human trials. The data showed that intranasal administration of SB019 was well tolerated and safe. Novan is currently preparing for an IND with submission expected no later than 2Q:22, and is targeting a Phase I study, pending additional financing or strategic partnership. Novan has made the FDA aware of its SB019 program through engagement with the FDA's Coronavirus Treatment Acceleration Program (CTAP).

In the same release, Novan informed that it had completed additional dose-range finding studies in SARS-CoV-2 infected golden Syrian hamsters through work conducted at the Institute for Antiviral Research at Utah State University. Significant reduction in the amount of virus in lung or nasal tissue of SARS-CoV-2 infected animals was observed and was found to be dependent on both concentration and dosing regimen (e.g., once daily vs. twice daily).

Appointments

Tomoko Maeda-Chubachi, MD, PhD, MBA Appointed CMO
On August 24, 2021, Novan announced that Dr. Tomoko Maeda-Chubachi had been promoted from Senior Vice President, Medical, to Chief Medical Officer. Dr. Maeda-Chubachi was instrumental in the execution of B-SIMPLE4. Dr. Maeda-Chubachi joined Novan as VP, Medical Dermatology in September of 2017 and was promoted to SVP, Medical in March of 2021. Prior to joining, Dr. Maeda-Chubachi served as Senior Medical Director at Glaxo Smith Kline (GSK), leading clinical development projects for psoriasis, atopic dermatitis, pemphigus, and androgenic alopecia. Prior to GSK, she held clinical and medical affairs roles at Eli Lilly and Pfizer. Before then, Dr. Maeda-Chubachi was an academic physician and dermatologist for ten years before making the switch into industry. She received her MD and PhD from Osaka University.

Brian M. Johnson Appointed Chief Commercial Officer
On November 2nd, Novan announced that Brian M. Johnson had been appointed its Chief Commercial Officer, featuring intimate knowledge of Novan and expertise in dermatology to support SB206's pre-launch and commercialization efforts. Johnson brings more than three decades of commercialization experience for products in multiple therapeutic areas. His successful track record includes Ortho Pharmaceutical Corporation, Medicis, and Galderma. Most recently, he served as Principal at Two Hearts Group, a pharma and life science consulting firm where he act-

[6] Novan Corporate Presentation September 2021

ed as UCB's Head, Digital Marketing, Psoriasis in the Global Mission for bimekizumab. During his time at Galderma, he served as Vice President of Prescription Marketing and Chief Digital Officer, where he and his team successfully launched seven products and quadrupled sales from $275 million to over $1 billion, namely with Epiduo®, Clobex® and Oracea® products. In the past he also served as President, Revian, Inc and Director, Peer to Peer Marketing at Novartis. Johnson had served before as Chief Commercial Officer of Novan from 2015 to 2018 where he led pre-commercialization activities including assessment of molluscum and acne markets. Johnson holds an MBA from Southern Methodist University and a BS in business administration from the University of Kansas. He is a member of American Acne and Rosacea Society, Masters of Dermatologic Society, Women's Dermatology Society and the American Academy of Dermatology.

Valuation

We adjust our discounted cash flow model to reflect the July 2021 change by Sato in its estimated development plan and updated expenditures related to development and commercialization. Previously, Sato had estimated that it would complete its SB206 and SB204 programs in 2026; however, SB206 is now expected to be complete in 2027. We anticipate that Sato will begin Phase I work for SB206 in 2022. We also update our R&D estimates for 2022 to reflect increased spend for regulatory activities for SB206 and clinical trial preparatory expenditures for SB204. Novan is also expected to ramp up its selling function in 2022 and we further consider increased selling costs in 2022. The net of these changes to our model reflecting a delay to Sato's development plan and increased near term spending reduces our valuation from $72 to $70.

Summary

Novan's third quarter 2021 saw the reporting of B-SIMPLE4's safety data, the appointment of Tomoko Maeda-Chubachi as its Chief Medical Officer, and the engagement of Syneos Health as a commercialization solutions provider. Brian Johnson returned to Novan and holds the position of Chief Commercial Officer. The FDA also conditionally accepted SB206' brand name: KINSOLUS. With this candidate targeting commercialization, Novan also informed investors that candidates SB204, in acne vulgaris, and SB019, in COVID-19, would now progress towards an NDA. Equipped with B-SIMPLE4 safety data and strongly statistically significant primary endpoints, Novan is now preparing for its pre-NDA meeting with the FDA regarding KINSOLUS, expected in 1H:22 and for NDA submission in 2H:22. We offer a target price of $70.00 per share.

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[7]

Novan, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US)	**$4,920**	**$819**	**$747**	**$737**	**$840**	**$3,143**	**$3,550**	**$172,105**
YOY Growth	*0%*	*-32%*	*-43%*	*-44%*	*-21%*	*-36%*		
Research & Development	$19,814	$6,418	$5,257	$4,251	$5,600	$21,526	$30,000	$5,000
Selling, General & Administrative	$11,271	$2,686	$2,431	$2,969	$3,200	$11,286	$21,443	$32,965
Other	$4,049	$0	$114	$0	$0	$0	$0	$0
Income from operations	($30,214)	($8,285)	($7,055)	($6,483)	($7,960)	($29,669)	($47,893)	$108,324
Operating Margin	*-614%*	*-1012%*	*-944%*	*-880%*	*-948%*	*-944%*	*-1349%*	*63%*
Other Income	$870	($670)	$1,029	($5)	$0	$0	$0	$0
Interest Income	$51	$3	$3	$4	$2	$12	$0	$0
Pre-Tax Income	($29,293)	($8,952)	($6,023)	($6,484)	($7,958)	($29,657)	($47,893)	$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)**	**($6,484)**	**($7,958)**	**($29,657)**	**($47,893)**	**$81,243**
Net Margin	*-595%*	*-1093%*	*-806%*	*-880%*	*-947%*	*-944%*	*-1349%*	*47%*
Reported EPS	**($2.96)**	**($0.60)**	**($0.39)**	**($0.34)**	**($0.42)**	**($1.74)**	**($2.52)**	**$4.17**
Basic Shares Outstanding	9,881	15,003	15,570	18,814	18,850	17,059	19,000	19,500

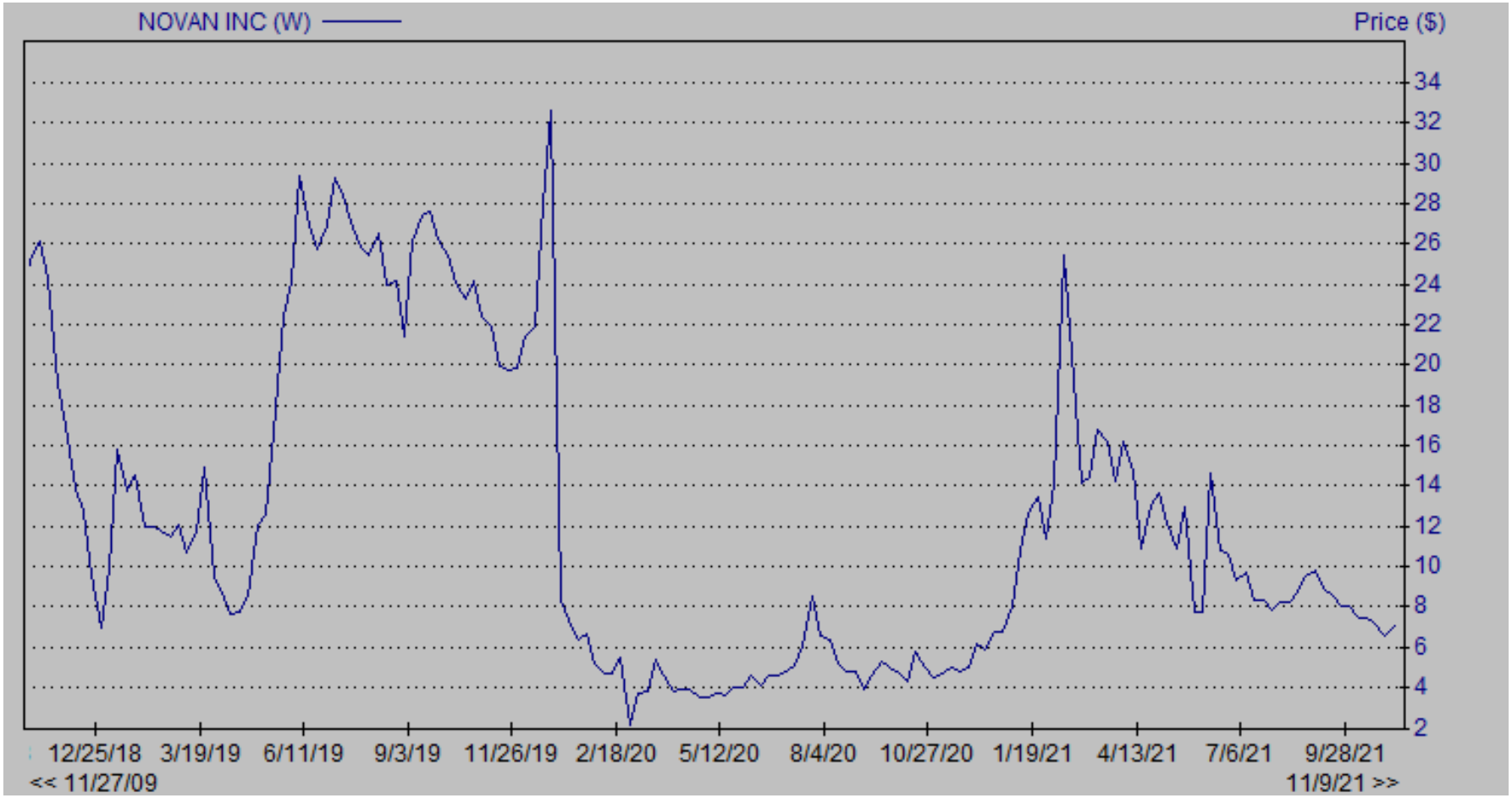
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[8]



[8] Source: Zacks Research System

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