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Novan Inc. (NOVN - NASDAQ)

Hard to Top Novan's Big June: Study Readouts, Capital Raise & Russell Inclusion

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 (8/11/21)	$8.36
Valuation	**$72.00**

OUTLOOK

Novan is a research & development company which employs nitric oxide (NO) to address a number of indications for a variety of skin conditions 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 is being investigated in a pivotal Ph3 trial for MC. SB206 & other Novan compounds store NO in large polymer macromolecules which allows for stable and druggable NO. Additional Nitricil compounds are in clinical & preclinical stages of development for other skin conditions. However, Novan is primarily focused on developing SB206.

We expect pivotal trials for SB206 to generate registrational data for MC in 2021 followed by the submission of an NDA in 3Q:22 if data are supportive. 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 and we anticipate a 2023 regulatory submission in that jurisdiction followed by a 2024 launch.

SUMMARY DATA

52-Week High	**$25.90**
52-Week Low	**$3.00**
One-Year Return (%)	**34.8**
Beta	**-0.06**
Average Daily Volume (sh)	**3,891,863**
Shares Outstanding (mil)	**18.8**
Market Capitalization ($mil)	**157**
Short Interest Ratio (days)	**1.36**
Institutional Ownership (%)	**9.79**
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

Second Quarter 2021 Results

On August 12, 2021, Novan Inc. (NASDAQ: NOVN) reported second quarter financial results in a press release concurrent with the filing of Form 10-Q. A conference call and webcast with supporting presentation was also held to update investors on financial and operational results. The period included a big month for the company with readouts from multiple trials in animal health, COVID, and most importantly SB206 for molluscum.

Highlights for the second quarter ending June 30, 2021 and to-date include:

- 1-for-10 reverse stock split - May 2021
- Antimicrobial effect of NVN4100 presented in animal health exploratory studies - June 2021
- Positive preclinical data in SB019 COVID-19 antiviral therapy - June 2021
- Positive topline from B-SIMPLE4 - June 2021
- Announced/priced/closed $40 million public offer - June 2021
- Included in Russell Microcap Index - June 2021
- Last patient, last visit (24-week) - B-SIMPLE4 - July 2021

With respect to financial performance, Novan generated $0.7 million in license and collaboration revenue in 2Q:21 versus $1.3 million in the same quarter last year, and posted a net loss of ($6.0) million or ($0.39) per share compared to a loss of ($8.1) million or ($1.00) per share for the prior year period.

For the second quarter ending June 30, 2021 and versus the prior year quarter ending June 30, 2020:

- Research & development expenses totaled $5.3 million, up 40% from last year's $3.8 million due to increased costs related to Novan's ongoing conduct and treatment phase activities of the B-SIMPLE4 trial compared to the relatively lower cost of wind down activities for its B-SIMPLE1 and B-SIMPLE2 in 2Q:20 partially offset by a decrease in other research and development expenses and a decrease in costs related to the SB414 program. The decrease in other research and development expenses was primarily related to a $1.4 million contraction in research and development personnel costs, driven by a decrease in non-cash compensation expense, a decrease in non-cash compensation expense associated with stock option compensation and a decrease in recurring salary and benefit costs due to fewer research and development personnel in the 2Q:21 period;
- General & administrative expenses tumbled 25% to $2.4 million from $3.2 million with the change driven by the absence of a non-cash expense in 2Q:20 that did not appear in the most recent period, a decline in rent and depreciation and lower other expenses. Insurance premium expenses rose partially offsetting increases elsewhere;
- A gain on debt extinguishment related to forgiveness of the Paycheck Protection Program (PPP) loan along with interest income and other income led to $1.0 million in other income;
- Net loss was ($6.0) million, or ($0.39) per basic and diluted share, compared to ($8.1) million, or ($1.00) per basic and diluted share;

As of June 30, 2021, cash and equivalents on the balance sheet totaled $65.8 million, compared to $35.5 million twelve months prior. The increase was driven primarily by $61 million in net contributions from financing cash flows over the prior four quarters. Cash burn for the second quarter totaled approximately $4.26 million versus approximately $6.36 million in the prior year period.

B-SIMPLE4 Topline Results

After years of investment in the SB206 program, on June 11, 2021, Novan announced statistically significant and positive results for its primary and secondary endpoints for B-SIMPLE4. The pivotal trial investigated the use of SB206 in molluscum contagiosum to clear lesions related to the disease. Topline results were announced in a press release and discussed in a conference call held the morning of the announcement. The trial demonstrated an

almost 13 percentage point improvement in complete clearance in SB206-treated molluscum contagiosum patients compared with vehicle, significant at the 0.01% level (p<0.0001).

In prior Phase III trials run for SB206, enrollment of 340 subjects was targeted for each and subjects were randomized 2:1 under a QD (once per day) dosing regimen. The primary endpoint was the proportion of patients with complete clearance (CC) by week 12. Secondary and exploratory endpoints included proportion of patients:

- 100% clearance of lesions by week 8;
- 95% of lesions at week 12, 90% of lesions at week 12; and
- 75% of lesions by week 12.

Results from B-SIMPLE1 and 2 were insufficient to support a new drug application (NDA), despite an improvement in outcomes for SB206 patients. Dropouts, results for households with multiple children and a high hurdle of complete clearance negatively impacted the results. After consultation with the FDA regarding the results of the trials, the agency encouraged the attempt of another pivotal trial which, if successful, could rely on B-SIMPLE2 results to serve as the confirmatory trial in an NDA submission. Equipped with a statistically significant primary endpoint in B-SIMPLE4, Novan is now able to proceed.

Similar to B-SIMPLE1 and 2, B-SIMPLE4 was a multi-center, double-blind, randomized, vehicle-controlled study with a primary endpoint of proportion of patients achieving CC using the once-daily (QD), 12% berdazimer sodium concentration. B-SIMPLE4 improved on previous trials by enrolling 891 (vs. ~700) patients, randomizing 1:1 instead of 2:1, and ensuring adequate representation of multi-child households. The primary endpoint of percentage of patients with CC, treated versus vehicle, was statistically significant ($p < 0.0001$). Management attributed the successful results to a two-fold combination of increasing subject count in the trial and enhanced training for clinical site personnel. A shortcoming of previous pivotal trials was the loss of a relatively high proportion of patients to discontinuation. These patients were counted as failures. Enhanced training for B-SIMPLE4 site managers helped improve the discontinuation rate. In B-SIMPLE4, the discontinuation rate fell to 11.3% in the SB206 arm versus 18.2% and 19.8% in the SB206 arms for B-SIMPLE1 and 2, respectively, illustrating the success of improved training and protocols. In the first two Phase III trials, loss to follow up was a leading reason for discontinuing treatment early and almost certainly contributed to the endpoint miss. Consistent with previous clinical results, B-SIMPLE4 observed no treatment-related serious adverse events.

Exhibit I - B-SIMPLE4 Topline Results[1]

	SB206 (N=444)	Vehicle (N=447)	p-value
Complete Clearance of All Lesions at Week 12*	32.4%	19.7%	p < 0.0001
Proportion Achieving a Lesion Count of 0 or 1 at Week 12**	43.5%	24.6%	p < 0.0001
Proportion Achieving ≥90% Clearance of Lesions at Week 12**	43.0%	23.9%	p < 0.0001
Complete Clearance of All Lesions at Week 8**	19.6%	11.6%	p = 0.0014

*Primary Endpoint, **Secondary Endpoint

Topline results for the trial included a statistically significant primary endpoint, a significant milestone for Novan after failing to meet primary endpoints in B-SIMPLE1 and B-SIMPLE2, arming Novan with the missing piece required for an NDA submission. Not only did the results present substantially improved p-values, but the percentage point difference for the primary endpoint was greater as well.[2] Furthermore, when relaxing the strict criteria of complete clearance to allow for one lesion or less remaining, the efficacy of SB206 is even more apparent, with 43.5% of subjects clearing almost completely versus 24.6% of patients receiving the vehicle. Subjects were almost twice as likely (77%) to almost or completely clear their lesions at twelve weeks than those that were administered vehicle alone. Even 8 weeks of treatment was sufficient to observe a statistically significant improvement in clearance. Finally, the differences witnessed between one- and two-subject households in the previous B-SIMPLE trials were not observed in B-SIMPLE4.

[1] Compiled from Company Press Release
[2] B-SIMPLE4 generated a 12.7 percentage point improvement between the two arms (32.4% - 19.7%) whereas the B-SIMPLE1 and B-SIMPLE2 trials generated a 4.2 and 9.7 percentage point improvement respectively.

Exhibit II - B-SIMPLE4 Subjects, Sites and Baseline Lesions[3]

	SB206	Vehicle
ITT Population	444	447
Completed 12 Weeks of Treatment	394	400
Premature Discontinuation	11.3%	10.5%
% of Sites Dermatologists	58.6%	59.3%
Mean Age	6.6	6.5
% Ages 2 to 17	95%	96%
Female	51.4%	47.7%
Male	48.6%	52.3%
Mean Baseline Lesion Count (Median)	23.1 (18.5)	20.5 (15.0)

The B-SIMPLE4 SB206 arm presented a higher mean and median baseline lesion count compared with the vehicle arm, setting a higher hurdle for complete clearance. Premature discontinuation by subjects in the trial is comparable between SB206 and vehicle arms, a function of enhanced site training implemented by Novan.

Exhibit III - B-SIMPLE4 Safety and Tolerability[4]

	B-SIMPLE4		B-SIMPLE2	
	SB206 (n = 444)	Vehicle (n = 447)	SB206 (n = 237)	Vehicle (n = 117)
Subjects with at least one TEAE	189 (42.6%)	103 (23.0%)	120 (50.6%)	29 (24.8%)
Application site				
Pain	83 (18.7%)	23 (5.1%)	36 (15.2%)	2 (1.7%)
Erythema	51 (11.5%)	6 (1.3%)	26 (11.0%)	0
Pruritus	33 (7.4%)	5 (1.1%)	8 (3.4%)	2 (1.7%)
Exfoliation	26 (5.9%)	0	9 (3.8%)	0
Dermatitis	25 (5.6%)	3 (0.7%)	11 (4.6%)	1 (0.9%)
Total	169 (38.1%)	103 (23.0%)	85 (35.9%)	29 (24.8%)

SB206 was safe and well tolerated and there were no serious adverse events. The SB206 arm adverse event profile did differ from vehicle. The most common adverse events reported were pain, erythema and pruritus, all at application sites. Pain category lacks the resolution of finer descriptors such as ‘stinging’ or ‘burning’, which may be expected when applying an active topical treatment to lesions. Safety results were comparable to B-SIMPLE2.

Next Steps

Collection of safety data has been completed as memorialized in an announcement on July 28 and final results are expected soon. Management has guided toward a final data readout in 3Q:21. Management then expects to request and conduct a pre-NDA meeting with the FDA, prepare the NDA, and then submit no later than 3Q:22. Management also expects commercial production of SB206 to begin by the end of 2021. Commercialization options remain open, with internal, external and hybrid pursuits all on the table. Novan has spoken with potential commercialization partners in the past, some of whom deferred interest until B-SIMPLE4 results were available. We expect that the positive topline results will stimulate additional partnership discussions.

[3] Sourced from Company Presentation
[4] Sourced from Company Presentation

Preclinical Data for SB019 in COVID-19

Novan announced positive preclinical data for SB019 in COVID-19 anti-viral therapy program in a June 10th press release. Two *in vivo* studies were conducted in Syrian hamsters at the Institute for Antiviral Research at Utah State University. The results from both the study and its confirmatory repeat independently demonstrated the ability of berdazimer sodium to reduce viral burden in SARS-CoV-2 infected animals and to deter inter-animal transmission. Berdazimer sodium (NITRICIL) was able to prevent progression of the infection into the lungs after transmission and limited disease severity significantly. In light of the positive results, Novan is exploring opportunities to develop its platform in the COVID-19 indication both internally and through partnership.

The preclinical work evaluated SB019's ability to limit the infection in exposed animals, and also the effect on transmissibility. SARS-CoV-2 infected animals were co-housed with healthy animals to create the conditions for transmission. Berdazimer sodium was administered once daily at various doses versus placebo control. Endpoints evaluated disease severity and included nasal and lung tissue viral count and body weight change, as a proxy for infection.[5]

Dose-dependent, statistically significant reduction ($p < 0.0001$) in lung viral count was observed in treated animals at a dose as low as 2 mg/mL. Healthy hamsters cohabitated with infected hamsters and treated with berdazimer sodium had average viral counts reduced by greater than 99.99% compared to placebo, with detectable levels of virus absent in lung tissue for over half the animals.

Novan plans to submit a request to the FDA to discuss paths to evaluate SB019 in human COVID-19 patients. Novan is considering the development and submission of an investigational new drug (IND) application that would require regulatory guidance, successful IND-enabling toxicology studies, and financing or strategic partnering.

Exhibit IV - Hamster Exercising CDC Safety Recommendation[6]

NVN4100 *In Vitro* Assay, and Canine Pyoderma Model Development

On June 7, 2021, Novan issued a press release disclosing results from an exploratory study of the company's NITRICIL technology in canine pyoderma. The candidate, NVN4100, targets topical use in canines and represents Novan's expansion into the companion animal health space. The results of the *in vivo* trial were positive and demonstrated NVN4100's antimicrobial effect against a wide variety of relevant bacteria. Based on the results, Novan is now contemplating additional formulation and preclinical evaluations, as well as exploring strategic partnership opportunities. Grand View Research estimated that the total global companion animal health market to be over $18 billion in 2020.[7]

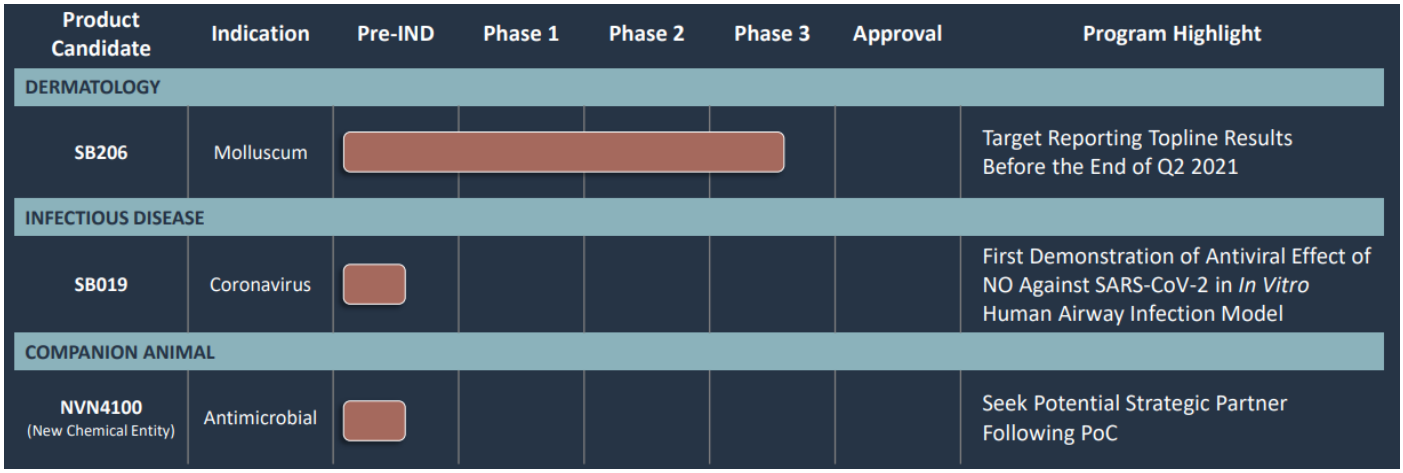
[5] Muñoz-Fontela, C., Dowling, W.E., Funnell, S.G.P. *et al.* Animal models for COVID-19. *Nature* **586,** 509–515 (2020). https://doi.org/10.1038/s41586-020-2787-6
[6] Shutterstock.com
[7] Companion Animal Health Market Size Report, 2021-2028 (grandviewresearch.com)

The *in vivo* and *in vitro* work was conducted by third parties and arranged by Scullion Strategy Group, LLC, experts in animal health who oversaw the studies and assessed technical feasibility and market potential. The work determined the minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) of NVN4100 using broth dilution antimicrobial susceptibility testing against a set of relevant microorganisms. *In vitro* results showed that NVN4100 provided both inhibitory and bactericidal effects against a variety of pathogens, including antimicrobial resistant and susceptible strains commonly associated with animal skin and ear conditions.

The *in vitro* work supported the potential efficacy of NVN4100 against common companion animal health bacterial strains, and development of the pyoderma canine model is promising in the further development of this candidate.

Through another collaboration with an animal health research organization, a canine pyoderma model was established. Pyoderma is one of the most common skin conditions in dogs and is often resistant to first-line antimicrobials. The results suggest that the canine model may support additional development of topical NVN4100 as an alternative to current systemic and topical antimicrobials. The establishment of the pyoderma model was a significant result of the exploratory work.

Exhibit V – Priority Development Pipeline[8]



$40 Million Public Offer

Following positive topline results for B-SIMPLE4, Novan announced, priced, and closed a $40 million public offer of common stock in June. The offer comprised 3,636,364 common shares at $11.00 per share. The underwriter was granted a 30-day option to purchase an additional 545,454 shares. Gross proceeds were approximately $40 million before underwriting discounts and commissions. Cantor Fitzgerald & Co. acted as sole book-running manager for the offer. ROTH Capital Partners, LLC acted as financial advisor to Novan. Proceeds from the offer, along with existing cash, are intended for use in R&D including actions toward regulatory approval of SB206, planning for potential commercialization of SB206 and continuing work on SB204 for acne vulgaris, as well as for general corporate purposes.

1-for-10 Reverse Stock Split

Novan filed a press release on May 25th declaring a 1-for-10 reverse stock split, and on May 26 the shares traded on a split-adjusted basis. At the company's 2020 Annual Meeting of Stockholders,[9] shareholders approved the amendment to effect a reverse stock split in a ratio of anywhere between 1:2 to 1:15 which allows the Board to determine the implementation and timing of the action. Prior to the split, Novan was close to reaching its authorized number of shares outstanding given the share balance and warrant, option and other obligations. With commercialization and a potential partnering arrangement anticipated in the near future, Novan will require sufficient capital to execute a decisive launch of SB206.

[8] Source: Novan May 2021 Corporate Overview Slide Deck
[9] See related SEC filing here: https://novan.gcs-web.com/static-files/08be3180-1bdb-427e-bb99-84b73c3f8d63

Valuation

We adjust our valuation to reflect the share count following the $40 million public offering and updated option and warrant balances. Our enterprise value for the company does not change. Based on the outstanding share count of 18.8 million and the dilutive effect of options, warrants and stock appreciation rights our updated share price valuation is $72.

Exhibit VI – Novan Expansion Pipeline[10]

Product Candidates	Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Program Highlight
DERMATOLOGY						
SB204	Acne Vulgaris					Two Phase 3's completed; One confirmatory Phase 3 needed; Protocol finalized
SB208	Tinea Pedis					Phase 2 trial complete; Phase 1 in nail growth complete
SB414	Atopic Dermatitis					Phase 1b trial complete; Phase 2 protocol finalized
	Psoriasis					Phase 1b trial complete; Potential to explore lower doses
MEN'S AND WOMEN'S HEALTH						
SB207	Genital Warts					End of Phase 2 meeting with FDA complete; Phase 3 protocols designed
WH504	High-Risk HPV					Formulation development ongoing; Funded by federal grants
WH602	High-Risk HPV					Formulation development ongoing; Funded by federal grants
GASTROENTEROLOGY						
Undisclosed	Various					Seeking grants to progress

Milestones

- NVN4100 Canine PoC *in vitro* results – June 2021
- SB019 preclinical COVID results – June 2021
- B-SIMPLE4 Topline Results – June 2021
- $40 million capital raise – June 2021
- Addition as constituent in Russell Microcap Index – June 2021
- B-SIMPLE4 Last Patient Last Visit and trial completion – July 2021
- Development services agreement with 3rd party API manufacturer – July 2021
- Full data readout for B-SIMPLE4 – 3Q:21
- GLP repeat dose intranasal study in canines (SB019) – 3Q:21
- Finalize analysis of safety for B-SIMPLE4 – 3Q:21
- Strategic update and product prioritization – 3Q:21
- Completion of build for new facility – 2H:21
- B-SIMPLE4 final report – 4Q:21
- Potential SB019 COVID Phase I study – 4Q:21
- Conduct stability studies for drug product and substance for SB206 – 2H:21 to 1H:22
- Development of NDA – 1H:22
- Submission of NDA for SB206 – no later than 3Q:22
- Cash runway – 1Q:23

[10] Source: Novan May 2021 Corporate Overview Slide Deck

Summary

Novan published a flurry of news during the second quarter. Multiple study readouts, including the impressive B-SIMPLE4 results, a reverse stock split, capital raise and addition to the Russell indices were all highlights of 2Q:21. This was followed by the completion of the safety portion of the B-SIMPLE4 study in late July. Now Novan continues to have a full plate with stability studies, regulatory meetings and new drug application (NDA) preparation work underway. Management will also be meeting with prospective partners to help develop their commercialization strategy which is still being refined. We expect to hear an update before the end of the third quarter on the company's future strategy and the prioritization of in-development products as the company changes to a commercial enterprise.

Novan has guided towards an NDA submission no later than 3Q:22 and in the meantime, we expect to see continued work on drug stability, NDA development and consultation with regulatory agencies and partners. After an NDA filing, we expect the standard 10 month analysis period after acceptance. This suggests that SB206 may begin commercialization by 3Q:23, assuming there are no delays and the product is approved.

Other work underway on COVID and animal health initiatives is expected to advance. A COVID Phase I study may be launched before the end of the year for SB019 after GLP repeat dose intranasal study in canines is completed. After reporting favorable *in vitro* proof of concept work for NVN4100, additional studies and formulation work are planned for this compound to build a data set sufficiently compelling to attract a partner to move forward.

PROJECTED FINANCIALS

Novan, Inc. - Income Statement[11]

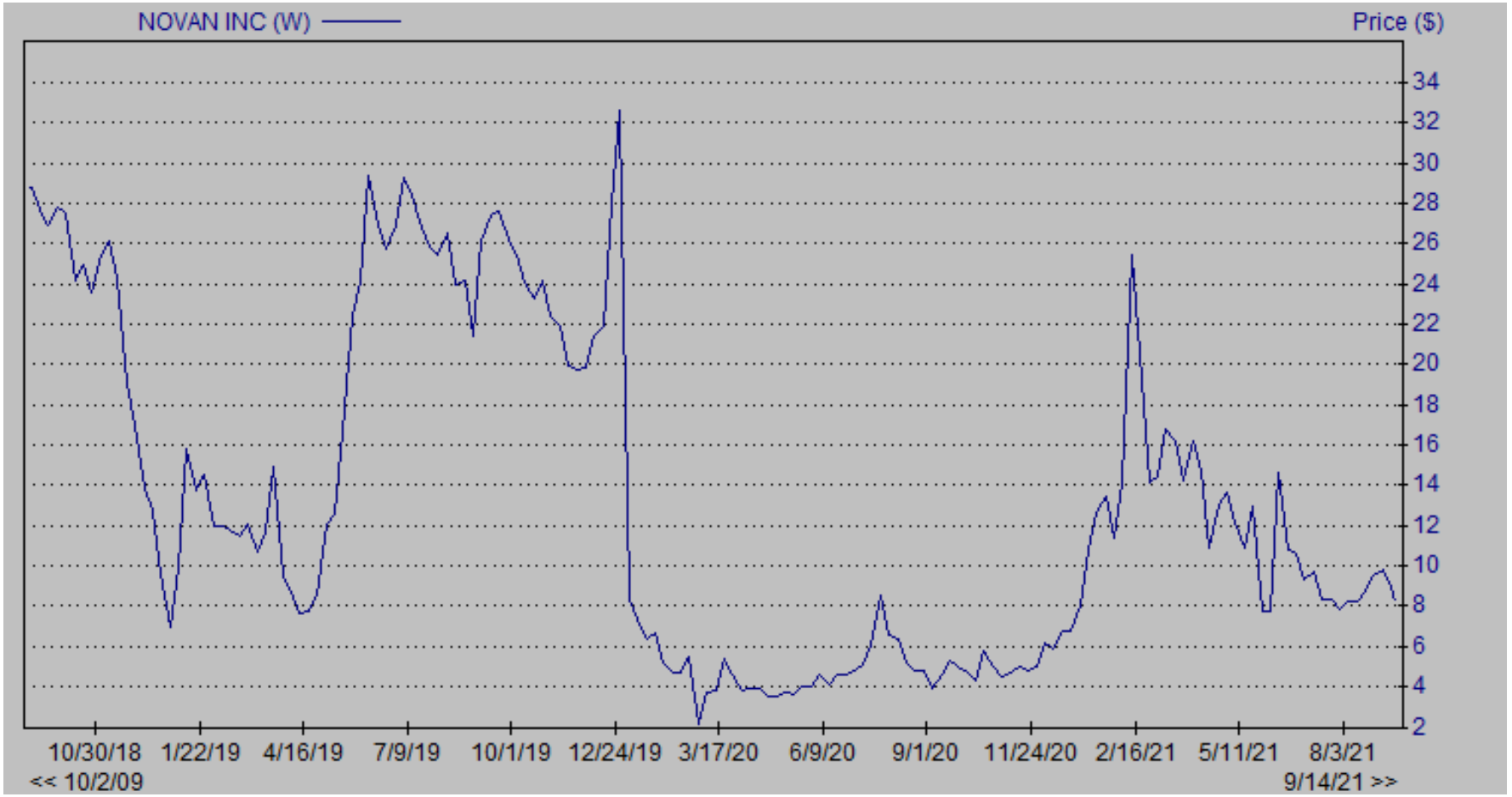
Novan, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US)	**$4,920**	**$819**	**$747**	**$840**	**$840**	**$2,599**	**$3,550**	**$172,105**
YOY Growth	*0%*	*-32%*	*-43%*	*-36%*	*-21%*	*-47%*		
Research & Development	$19,814	$6,418	$5,257	$5,800	$5,600	$23,075	$10,000	$5,000
Selling,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

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

HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart[12]



[12] Source: Zacks Research System

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