# Zacks Small-Cap Research

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## Novan, Inc. (NOVN: NASDAQ)

***3Q:22 Results***

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 (11/16/2022) | $0.89 |
| **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** | **$6.00** |
| **52-Week Low** | **$0.79** |
| **One-Year Return (%)** | **-85.4** |
| **Beta** | **0.3** |
| **Average Daily Volume (sh)** | **182,610** |
| **Shares Outstanding (mil)** | **24.5** |
| **Market Capitalization ($mil)** | **21.8** |
| **Short Interest Ratio (days)** | **3.1** |
| **Institutional Ownership (%)** | **21.0** |
| **Insider Ownership (%)** | **5.2** |
| **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 |

## WHAT'S NEW

**Third Quarter 2022 Results**

On November 14, 2022, Novan Inc. (NASDAQ: NOVN) reported third quarter financial and operational results in a press release and the filing of Form 10-Q. 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 is expected to be submitted to the FDA around year-end. A memorandum of understanding with partner Sato was recently signed and may yield a licensing arrangement and potential upfront payments for EPI's Rhofade if negotiations are successful.

Highlights for the third quarter ending September 30, 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

With respect to financial performance, Novan generated $5.1 million in revenue in 3Q:22 versus $0.7 million in 3Q:21, and posted a net loss of ($6.0) million or ($0.25) per share compared to a loss of ($6.5) million or ($0.34) per share in the prior year period.

For the third quarter ending September 30, 2022 and versus the same prior year quarter:

- Revenues were $5.1 million, up nearly sixfold 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 $492,000 were primarily associated with the Sato R&D upfront and the Prasco agreement for Cloderm. There was also a small contribution from research and grant revenue;
- Cost of goods sold was $1.4 million vs. nil representing a 69% gross margin on product revenues. This is a sequential improvement from second quarter product gross margin of 55%;
- Research & development expenses totaled $4.3 million, essentially flat with prior year levels. A reduction in spending on the SB206 program were offset by increases in other research and development expenses;
- Selling, general & administrative expenses were $8.6 million, up 190% from $3.0 million with the increase attributable to $4.4 million of EPI Health commercial sales operations, $0.4 million of SB206 prelaunch and commercial preparation, $562,000 of personnel and related benefits and small increases in other miscellaneous costs;
- Net loss was ($6.0) million, or ($0.25) per basic and diluted share, compared to ($6.5) million, or ($0.34) per share.

As of September 30, 2022, cash and equivalents on the balance sheet totaled $14.9 million. This compares to cash holdings of $47.1 million at the end of 2021. Over the first nine months of the year, cash burn was ($22.5) million and Novan expended ($12.0) million for its acquisition of EPI Health. This was partially offset by contributions from financing related to the $15 million direct offering in June 2022 and a small contribution from the at-the-market (ATM) facility. During the third quarter Novan repaid the $16.5 million note related to the EPI acquisition for $10 million.

**Rhofade and Cash Position**

On November 11th, Novan entered into a nonbinding memorandum of understanding with Sato for a proposed licensing arrangement. If the deal is executed, Sato would gain the right to develop, manufacture and market Rhofade for rosacea in Japan. Sato would also be granted to option to negotiate rights for other Asia-Pacific countries. If consummated, this agreement would add on to the other arrangements with Sato for SB206 (molluscum contagiosum) and SB204 (acne vulgaris). The deal could potentially provide upfront funds[1] to Novan, which would

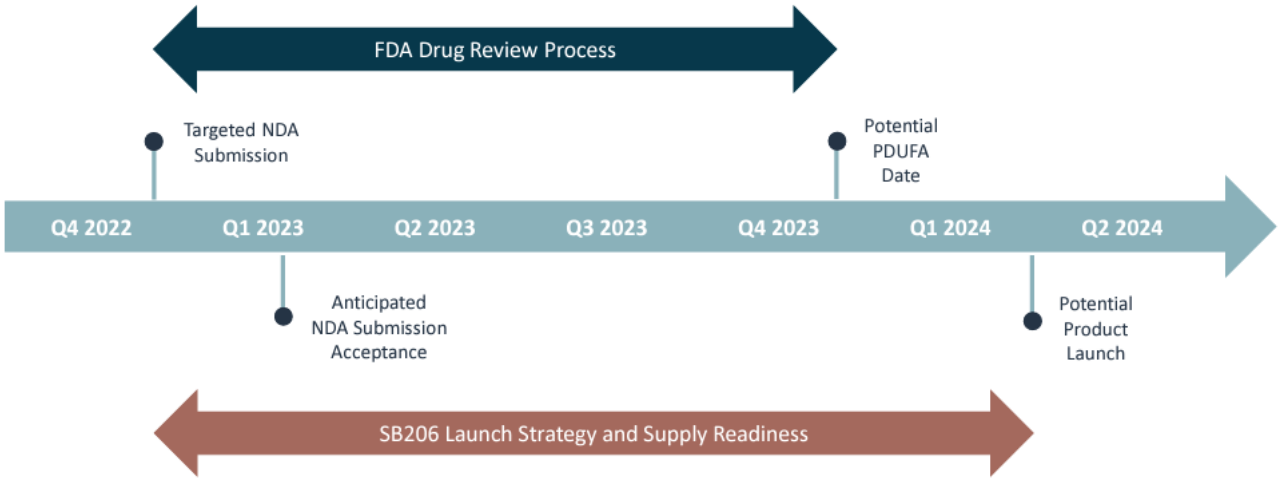
[1] EPI Health is required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

help offset the cash burn from the other EPI assets. Novan may seek other sources of non-dilutive capital including debt or credit. It may also issue equity or convertible securities to address future cash needs.

**SB206**

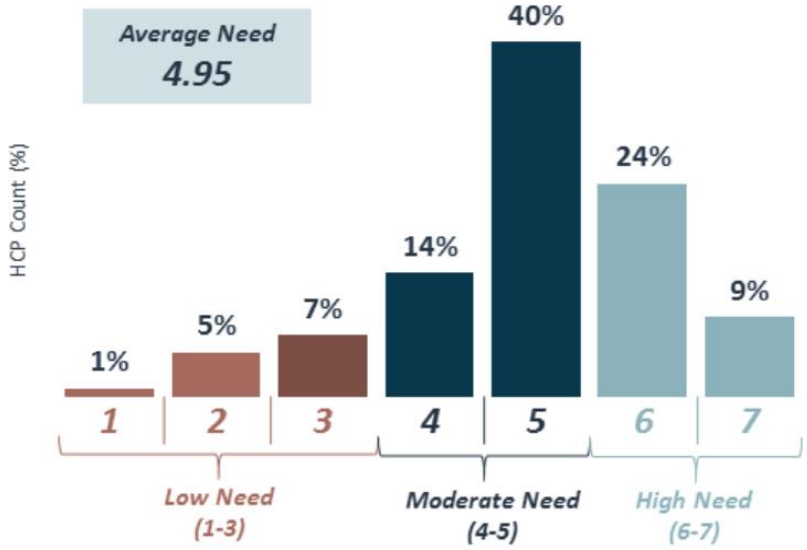
Novan is on track to submit its new drug application (NDA) to the FDA for SB206 in late December or early January 2022. The timing is dependent on stability and other analytical testing conducted on SB206 that is required as part of the submission. The stability of registration batches has been completed 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.

**Exhibit I – Berdazimer Gel, 10.3% Anticipated Regulatory Timeline[2]**




Novan sponsored a survey in August 2022, the details of which were shared on the 3Q:22 investor call, to measure the unmet need for molluscum contagiosum treatment. Syneos Health conducted the survey with 142 health care providers and polled them on the topic. The survey posed the question: "How would you rate the level of need for new drug therapy options for molluscum, on a scale of 1 – 7." One represented a low need and seven a high need. A third of respondents identified a high need and 87% identified a moderate need or greater in the survey. As expected, since it is mostly a childhood disease, pediatricians and pediatrician dermatologists identified the highest need of the specialties polled.

**Exhibit II – Need for New MC Treatment[3]**




[2] Source: Novan 3Q:22 Earnings Call Corporate Presentation
[3] Source: Novan 3Q:22 Earnings Call Corporate Presentation

The survey also found that there was a high degree of willingness to prescribe berdazimer gel, 10.3% by all providers polled. 43% voiced a high willingness and 49% indicated a moderate willingness to do so. Nurse practitioners and pediatric dermatologists were the most willing to prescribe of the four provider types polled.

Additional work investigating the likely behavior of payors towards pricing and reimbursement for SB206 suggests that the payors may be more favorably disposed to providing SB206 access to pediatric patients as opposed to a treatment that is for adults. While MC does resolve for most patients after a period of time, the condition does lack other treatments and payors gave an average rating of 5.1 (on a scale of 1 – 7) regarding willingness to provide coverage. The six payors polled in the survey cited being first to market as one of SB206's primary advantages to be given coverage if approved. The survey further concluded that step edits and non-coverage were unlikely outcomes for managed care and health plan offerings.

**Presentations**

Novan and its subsidiary EPI Health have developed several posters and abstracts that have been presented at a variety of conferences recently. The topics were predominantly centered on Wynzora with a secondary focus on Kinsolus (SB206). Eight of the company's abstracts were accepted for the 42nd Annual Fall Clinical Dermatology Conference in Las Vegas, Nevada that took place in late October. The posters addressed the results of the B-SIMPLE4 study, adherence to psoriasis treatment, polyaphron dispersion (PAD)[4] drug delivery technology as used in Wynzora and the safety and efficacy of Wynzora in a variety of populations. The results of a survey conducted by the National Psoriasis Foundation and sponsored by Novan were also presented which examined the attributes that patients value in topical medications. A majority of patients said they want to see improvement from a topical treatment in a week or two before discontinuing treatment. Those surveyed identified application feel, topical treatments that are non-staining, quick absorption and non-sticky texture among other attributes as being most important.

*Poster Presentation at Skin of Color Update 2022 Conference*
In mid-September, Novan subsidiary, EPI Health, presented a poster entitled Calcipotriene (CAL) and betamethasone dipropionate (BDP) cream demonstrates high efficacy and convenience in skin of color patients with plaque psoriasis at the Skin of Color conference in New York. The poster evaluated the efficacy and convenience factors for skin of color patients using Wynzora cream and the benefit observed upon plaque psoriasis. 784 subjects comprised the modified intent-to-treat population. Approximately 8% of the subjects were African American and 36% fell into the Fitzpatrick grade IV-VI, which is classified as skin of color. The analysis showed that skin of color patients treated with Wynzora have similar efficacy to the overall evaluated population. Patient convenience and satisfaction scores for those using Wynzora cream for patients with skin of color were similar to or higher than they were for the total population. Despite the favorable results, the small number of African American patients (64) was too small to calculate statistical significance.

JAMA Dermatology published "Efficacy and Safety of Topical Nitric Oxide−Releasing Berdazimer Gel in Patients With Molluscum Contagiosum: A Phase 3 Randomized Clinical Trial" in its July 2022 online issue. The paper summarized the design, measures and results for the B-SIMPLE4 trial that was conducted in 2020 and 2021. It concluded that use of berdazimer gel, 10.3%, for molluscum contagiosum appears to demonstrate favorable efficacy and safety with low adverse event rates.

Upcoming milestones include:

- SB206 NDA-enabling stability testing – 2H:22
- Potential deal with Sato for Rhofade – Year-end 2022
- SB206 NDA submission – Year-end 2022
- 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] PAD Technology is a proprietary topical formulation and drug delivery system that allows the components of Wynzora cream to co-exist in an aqueous environment. These active ingredients are stable at different pH levels, and without the unique properties of PAD Technology could not co-exist in a water-based formulation.

**Exhibit III - NDA-Track Novan Pipeline[5]**

| 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 |

## Valuation Adjustment

Novan is close to needing capital and we see a chance for some non-dilutive funds coming from an agreement with Sato and licensing of Rhofade; however, the amount will likely be insufficient to support the next year of operations. Since the first quarter, we have estimated that Novan will need to raise approximately $50 million in funds by year end and maintain this view. Since the share price has declined materially from our initial estimate, we mark it to market using recent closing price and update our target accordingly. After increasing our estimated shares outstanding to reflect reasonable raise levels, we adjust our target price to $15.00.

## Summary

Novan reported third quarter 2022 financial and operational results, showing year over year improvements in scripts for Rhofade, Wynzora and Minolira. We are also very close to the anticipated submission of the NDA for SB206, which should occur around year end. While the trends in sales for EPI are not yet fully clear, we anticipate as the following several quarters are reported, the financial contribution from the unit will crystallize.

With SB206 soon to be submitted to 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. 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, is readying its manufacturing capabilities and is conducting stability testing, expected to be completed in the next few weeks. Meanwhile, Novan's SB204 in acne is slated to begin its pivotal trial in 2023, targeting NDA submission in 2024. We adjust our target price to $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]**

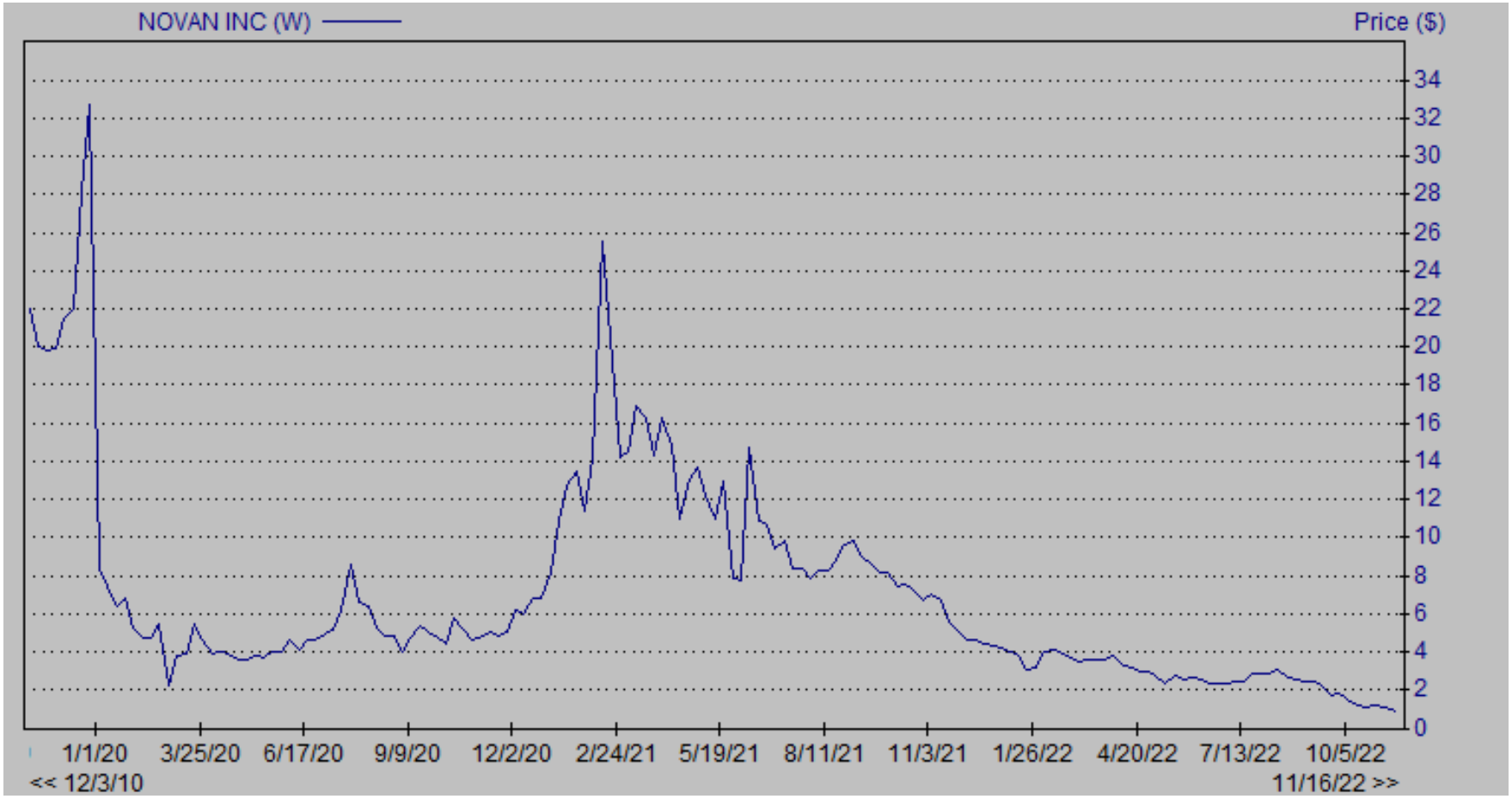
| Novan, Inc. | 2021 A | Q1 A | Q2 A | Q3 A | Q4 E | 2022 E | 2023 E | 2024 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues ($US)** | **$2,958** | **$1,928** | **$6,158** | **$5,115** | **$4,700** | **$17,901** | **$25,220** | **$109,413** |
| YOY Growth | -40% | 135% | 724% | 594% | 618% | 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*

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

## HISTORICAL STOCK PRICE

**Novan, Inc. – Share Price Chart[7]**




[7] Source: Zacks Research System

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