

Novan, Inc.

(NOVN: NASDAQ)

NOVN: Counting Down to PDUFA

OUTLOOK

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.

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.

Current Price (5/15/2023) **\$1.16**
Valuation \$14.00

SUMMARY DATA

52-Week High **\$3.33**
 52-Week Low **\$0.79**
 One-Year Return (%) **-54.3**
 Beta **0.2**
 Average Daily Volume (sh) **118,956**

Risk Level **Above Average**
 Type of Stock **Small-Growth**
 Industry **Med-Biomed/Gene**

Shares Outstanding (mil) **28.0**
 Market Capitalization (\$mil) **32.5**
 Short Interest Ratio (days) **3.7**
 Institutional Ownership (%) **6.9**
 Insider Ownership (%) **0.5**

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 2023 Estimate **N/A**
 P/E using 2024 Estimate **7.3**

Zacks Rank **N/A**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2022	\$1.9 A	\$6.2 A	\$5.1 A	\$10.5 A	\$23.7 A
2023	\$3.2 A	\$6.0 E	\$7.0 E	\$6.8 E	\$23.0 E
2024					\$74.0 E
2025					\$104.3 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2022	-\$0.71 A	-\$0.44 A	-\$0.25 A	-\$0.12 A	-\$1.42 A
2023	-\$0.54 A	-\$0.09 E	-\$0.09 E	-\$0.10 E	-\$0.35 E
2024					\$0.16 E
2025					\$0.25 E

WHAT'S NEW

1Q:23 Financial and Operational Results

On May 15th, 2023, Novan Inc. (NASDAQ: NOVN) reported 1Q:23 financial and operational results in a [press release](#) and in 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 has been assigned a target action date of January 25th, 2024. Novan is increasingly focused on potential funding or strategic arrangements and alternatives to address short-term cash needs and access to capital is necessary to progress development of SB206. Since the report of 2022 results in late March, Novan held an analyst and investor day and announced a publication supportive of patient use of Wyzora.

Highlights for 2023 include:

- 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
- Investor KOL [event](#) with Dr. Sugarman on molluscum unmet need – April 2023
- [Publication](#) of survey on patient needs for psoriasis medication – April 2023

With respect to financial performance, Novan generated \$3.2 million in 1Q:23 revenues versus \$1.9 million in 1Q:22, and posted a net loss of (\$14.1) million or (\$0.54) per share compared to a loss of (\$13.4) million or (\$0.71) per share in the prior year period.

For the quarter ending March 31, 2023 and versus the same prior year period:

- Revenues were \$3.2 million, up 64% from \$1.9 million. The increase is predominantly due to revenue contribution from sales of dermatology products Wyzora, Rhofade, Minolira and Cloderm and recognition of a full quarter of sales in 1Q:23 compared with 20 days of sales in 1Q:22. Year over year increases were tempered by Rhofade suffering a manufacturing delay which led to a lack of inventory and loss of sales in 1Q:23; however, management noted that a rebound in orders was experienced in the second quarter as units were restocked. Furthermore, deductible resets for 2023 contributed to the sequential slowdown in scripts and revenues for Novan's three leading products.
- License and collaboration revenues of \$585,000 were down 50% due to the absence of revenues from the distribution and supply agreement for Cloderm. Research and grant revenues were up 370% to \$170,000 from \$36,000 on recognition of multiple federal grants;
- Cost of goods sold was \$1.3 million vs. \$0.2 million;
- Research & development expenses totaled \$4.8 million, essentially flat with prior year levels. Declines in spending on the SB206 program were offset by increases in other research and development expenses related to a \$1 million milestone payment to Ligand;
- Selling, general & administrative expenses were \$10.0 million, also flat with prior year amounts. 1Q:22 expenses related to the EPI acquisition were replaced by greater commercialization spending for the product portfolio in 1Q:23;
- Net loss was (\$14.1) million, or (\$0.54) per basic and diluted share, compared to (\$13.4) million, or (\$0.71) per share.

As of March 31, 2023, cash and equivalents on the balance sheet totaled \$12.5 million. This compares to cash holdings of \$12.3 million at the end of 2022. Cash burn was (\$4.3) million which was partially offset by \$4.1 million of net contributions from financing. \$6.0 million of this amount was from the direct offering which was executed in mid-March. \$5.0 million was also received from Sato related to the license agreement for Rhofade. \$1.25 million of the Sato/Rhofade upfront is owed to a third party tempering the impact from this cash flow. Novan anticipates that there is sufficient liquidity to support operations until late second quarter 2023.

Corporate Updates

Psoriasis Publication

Findings from a National Psoriasis Foundation study were published in the [Journal of Drugs in Dermatology](#) which surveyed more than 400 US patients on patient adherence to topical psoriasis medications. The title of the April 2023 publication is [Patient Preferences in Topical Psoriasis Treatment](#) by *Curcio, et al.*¹ The 17-question survey was administered in March 2022 and queried participants on psoriasis severity, bothersome signs and symptoms, current treatment modalities, frequency of topical therapy use, and vehicle preferences.

84% of the participants reported moderate psoriasis with 72.5% of participants using oral medication and 8% topical treatment alone. 76% used topical therapy at least once weekly and 80% reported that they would wait two weeks after starting a new topical treatment before considering discontinuation. Participants preferred water-based creams (75.7%), followed by oil-based foam (70.8%), gel (48.7%), solution (42.8%), lotion (21.2%), non-oil-based foam (17.5%), ointment (16.5%), and spray (6.3%). Other desirable features were formulas that did not stain, were absorbed quickly, were not sticky and were easy to apply. 75% said they would continue to use a psoriasis medication for a week before stopping if they didn't like its topical formulation.

Novan's press release continued with a summary of Wyzora's features. Novan's product, which is commercialized jointly with MC2 Therapeutics, offers a rapid onset of action with results seen in efficacy, scale and itch as early as one week after application and continued improvement at 8 weeks. Additional detail on Wyzora's profile are included in an analysis by *Han, et al.*² and in the product's [label](#).

A Discussion of Molluscum's Unmet Need

Novan held a stakeholder event on April 25th, 2023 featuring pediatric dermatologist Jeffrey Sugarman, MD, PhD to discuss molluscum's unmet need with investors and analysts. The [presentation](#) began with an introduction by CEO Paula Brown Stafford who summarized the company's pipeline and the status of lead candidate SB-206, which is now being considered for approval by the FDA. She was followed by Chief Commercial Officer Brian Johnson who quantified the unmet need for molluscum patients. Existing options for patients include potentially painful in-office procedures and non-approved approaches that have limited efficacy. Health care providers (HCPs) want to see solutions for MC and are willing to prescribe an effective medicine if available.

To provide the HCP perspective, pediatric dermatologist Dr. Jeffrey Sugarman was featured who also served as the safety monitor for the Phase III clinical trials for SB-206. MC is commonly seen in children from 3 to 8 years of age, but does move outside of this range. Children with MC frequently also experience eczema, which can make the disease uncomfortable in addition to unsightly and contagious. Dr. Sugarman identified some of the features that physicians would like to see in an MC treatment. These include a safe, effective and well-tolerated product that is convenient to use. SB-206 achieves these objectives for patients, including convenience as it is a prescribed product that can be used at home.

Further discussion detailed the manufacturing and commercialization activities that have been taking place and that will take place over the next quarters. Pediatric dermatologists and primary care pediatricians will be the target audience for the anticipated marketing effort. The panel participants brought up the pending target action date for Verica's cantharidin treatment for MC which is in late July. Having two companies commercializing simultaneously could be beneficial for educating providers on the available options.

Direct Offering

In mid-March 2023, 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 re-

¹ Curcio, A., *et al.* [Patient Preferences in Topical Psoriasis Treatment](#). Journal of Drugs in Dermatology, April 2023.

² Han, G., Feldman, S., Bhatia, N., & Præstegaard, M. (2022). Dipropionate (Bdp) Cream (Cal 0.005%/Bdp 0.064% W/W) Improves Plaque Psoriasis At Week One In A Phase 3 Trial. SKIN The Journal of Cutaneous Medicine, 6(4), s42. <https://doi.org/10.25251/skin.6.supp.42>

quired 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.

Corporate Branding

Since the acquisition of EPI Health, Novan maintained two distinct brands. In a March 8th, 2023, Novan [announced](#) that it would be unifying all corporate activities under the Novan name and phase out the use of EPI Health. 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 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.

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.



³ Source: Novan May, 1Q:23 Corporate Presentation. Data is from Syneos Health claims data.

Milestones:

- SB206 NDA-enabling stability testing – 2H:22
- Rhofade arrangement with Sato – 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

Exhibit II - NDA-Track Novan Pipeline⁴

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 DRIVERS²								
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

Novan continues to show growth in its dermatology portfolio; however, a few exogenous hiccups slowed the rate of expansion in the first quarter. SB206 remains front and center for Novan management and investors as it 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. Novan management has highlighted the need for additional capital and with the in-place salesforce and pending response from the FDA regarding SB206, we anticipate there will be investors willing to gain access to anticipated growth and profitability next year. We adjust our price target to recognize the most recent share balance and change it to \$14.00.

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

PROJECTED FINANCIALS

Novan, Inc. - Income Statement⁵

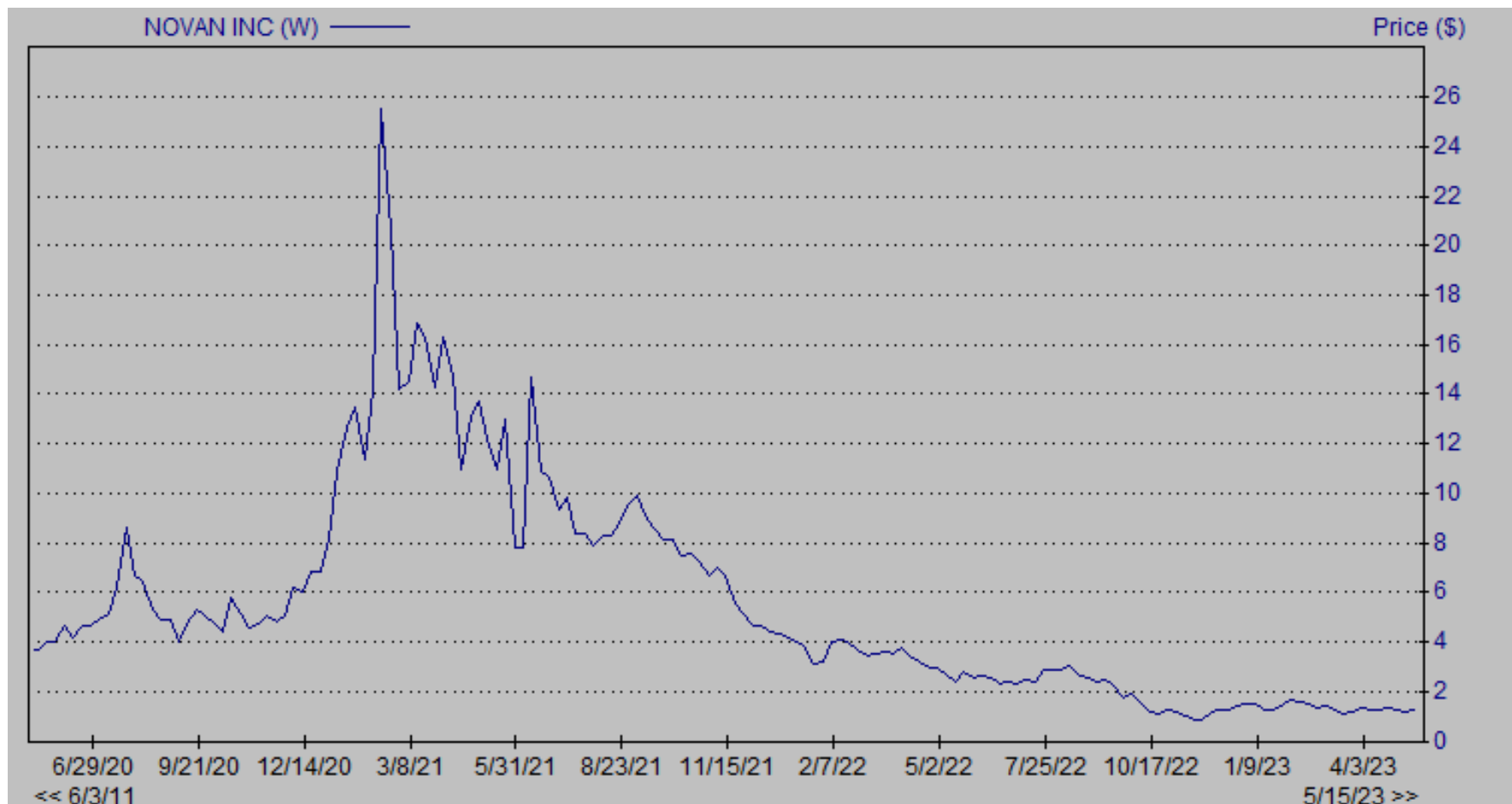
Novan, Inc.	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues (\$US)	\$23,682	\$3,166	\$6,020	\$7,011	\$6,795	\$22,992	\$73,960	\$104,335
YOY Growth	701%	64%	-2%	37%	-35%	-3%		
Product Cost of Goods Sold	\$7,379	\$1,285	\$1,900	\$2,000	\$2,200	\$7,385	\$16,271	\$22,954
Product Gross Margin	53%	47%	60%	60%	60%	58%	78%	
Research & Development	\$15,990	\$4,832	\$3,500	\$3,821	\$3,516	\$15,669	\$8,000	\$10,000
Selling, General & Administrative	\$34,103	\$10,040	\$8,200	\$8,450	\$9,100	\$35,790	\$42,501	\$43,276
Other	\$440	\$842	\$0	\$0	\$0	\$842	\$0	\$0
Income from operations	(\$34,230)	(\$13,833)	(\$7,580)	(\$7,260)	(\$8,021)	(\$36,694)	\$7,188	\$28,105
Operating Margin	-145%	-437%	-126%	-104%	-118%	-160%	10%	27%
Other Income	\$4,318	\$17	\$0	\$0	\$0	\$17	\$0	\$0
Interest Income	(\$1,399)	(\$247)	(\$200)	(\$200)	(\$200)	(\$847)	\$0	\$0
Pre-Tax Income	(\$31,311)	(\$14,063)	(\$7,780)	(\$7,460)	(\$8,221)	(\$37,524)	\$7,188	\$28,105
Provision for Income Tax	\$0	\$56	\$0	\$0	\$0	(\$12,865)	(\$6,323)	\$7,026
Tax Rate	0.0%	-0.4%	0.0%	0.0%	0.0%	34.3%	-88.0%	25.0%
Net Income	(\$31,311)	(\$14,119)	(\$7,780)	(\$7,460)	(\$8,221)	(\$24,660)	\$13,511	\$21,079
Net Margin	-132%	-446%	-129%	-106%	-121%	-107%	18.3%	20.2%
Reported EPS	(\$1.42)	(\$0.54)	(\$0.09)	(\$0.09)	(\$0.10)	(\$0.35)	\$0.16	\$0.25
Basic Shares Outstanding	22,020	26,116	84,250	84,325	84,400	69,773	85,200	85,300

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

⁵ Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

Novan, Inc. – Share Price Chart⁶



⁶ Source: Zacks Research System

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research (“Zacks SCR”), a division of Zacks Investment Research (“ZIR”), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. This research report was prepared under the aforementioned engagement.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business. SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.