Zacks Small-Cap Research
*Sponsored – Impartial – Comprehensive*

March 27, 2024
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

# Biora Therapeutics, Inc. (BIOR: NASDAQ)

## *BIOR: Negotiations Accelerating*

Biora's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. We apply a success probability of 20% for the NaviCap program in ulcerative colitis and 10% for the BioJet diabetes program. The model includes contributions from the United States and rest of world.

| | |
|---|---|
| Current Price (3/26/2024) | $1.18 |
| **Valuation** | **$5.60** |

## OUTLOOK

Biora is a drug-device company developing smart pills for GI diseases and enabling oral delivery of biologics. Its pipeline features two assets: NaviCap, for targeted drug delivery in GI diseases & BioJet, for oral delivery of biologics. NaviCap is poised for IND clearance and BioJet may advance into the clinic through the efforts of pharmaceutical partners.

Animal work has shown effective and accurate delivery of both small and large-molecule drugs using the NaviCap device and biologics in BioJet. Next steps are for the start of Phase I for NaviCap and completion of preclinical work for BioJet. BioJet is also the subject of four outside partnerships with pharmaceutical companies.

NaviCap's accurate delivery of drug to the site where it is needed may create a new therapeutic class for the lead BT-600 program by providing improved efficacy with a better side effect profile.

We expect clinical trials will be completed and approval granted for the NaviCap program in 2027 in UC and for partner efforts with the BioJet program in 2028. The accurate delivery of drug allows lower dosage to be used which may improve overall response and reduce side effects with potentially better outcomes.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **6.70** |
| **52-Week Low** | **0.76** |
| **One-Year Return (%)** | **-55.8** |
| **Beta** | **1.1** |
| **Average Daily Volume (sh)** | **388,391** |
| **Shares Outstanding (mil)** | **31.8** |
| **Market Capitalization ($mil)** | **37.4** |
| **Short Interest Ratio (days)** | **2.9** |
| **Institutional Ownership (%)** | **54.8** |
| **Insider Ownership (%)** | **11.1** |
| **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** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Tech Devices** |

## ZACKS ESTIMATES

### Revenue

(In millions of USD)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2022 | $0.1 A | $0.1 A | $0.1 A | $0.0 A | $0.3 A |
| 2023 | $0.0 A | $0.0 A | $0.0 A | $0.0 A | $0.0 A |
| 2024 | | | | | $0.0 E |
| 2025 | | | | | $0.0 E |

### Earnings per Share

| | Q1 | Q2 | Q3 | Q4 | Year |
|---|---|---|---|---|---|
| 2022 | -$1.88 A | -$0.81 A | -$1.99 A | -$1.69 A | -$6.40 A |
| 2023 | -$1.59 A | -$1.47 A | -$4.89 A | -$0.63 A | -$8.58 A |
| 2024 | | | | | -$1.00 E |
| 2025 | | | | | -$0.93 E |

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

Since our previous update in December, Biora Therapeutics, Inc. (NASDAQ: BIOR) has generated compelling data from its BioJet collaborations, initiated its BT-600 Phase I study, completed several cohorts of the study and made beneficial changes to its capital structure. On March 26th, 2024, the company reported full year 2023 results highlighting both the progress that it has made in its clinical program and collaborations. The company has also substantially reduced its debt, dramatically improving the capital structure. Based on the preclinical work that has been completed so far, management is optimistic that they will see a partnership emerge this year.

**2023 Financial and Operational Results**

Biora reported full year 2023 results in a press release and Form 8-K filing with the SEC on March 26th. A conference call was held to discuss results with investors following the release. For the financial year ending December 31, 2023 and versus the prior year, insignificant revenues were recognized. Net loss for 2023 totaled ($124.3) million or ($8.58) per share. Operational expenses rose 8% to $67.1 million as increases related to vesting of non-cash compensation were recognized in both research and development (R&D) and general and administrative (G&A) expense lines.

- Revenues were $4,000 down from $305,000 the prior year;
- Research and development expenses totaled $29.8 million, up 24% from $24.0 million due to an increase in salaries and benefits attributable to the accelerated vesting of unvested restricted stock unit (RSU) awards and an increase in consulting and professional fees. Higher expenses related to the launch of the BT-600 program also contributed;
- General & Administrative expenses were $37.3 million, down 2% from $38.0 million in part due to a decrease in business insurance, facilities and software costs;
- Interest expense was ($9.8) million compared to ($11.0) million;
- Other income was ($47.5) million vs. $23.5 million as a result of the inducement loss on the convertible notes, offset by an increase in income related to the sale of preeclampsia assets and intellectual property;
- Net loss was ($124.3) million vs. ($48.8) million or ($8.58) and ($6.40) per share, respectively.

As of December 31, 2023, cash totaled $15.2 million. This amount compares to the $30.5 million cash balance held at the end of 2022. A variety of notes are carried on the balance sheet at $45.7 million which is a substantial decline from the $127.8 million at the end of 2022. Biora debt instruments underwent a number of conversions and refinancings that reduced debt and added to the share balance and warrant count. These efforts also improved the company's capital structure and added cash to the balance sheet. Following the end of the quarter, Biora monetized a non-core asset generating an additional $3 million.

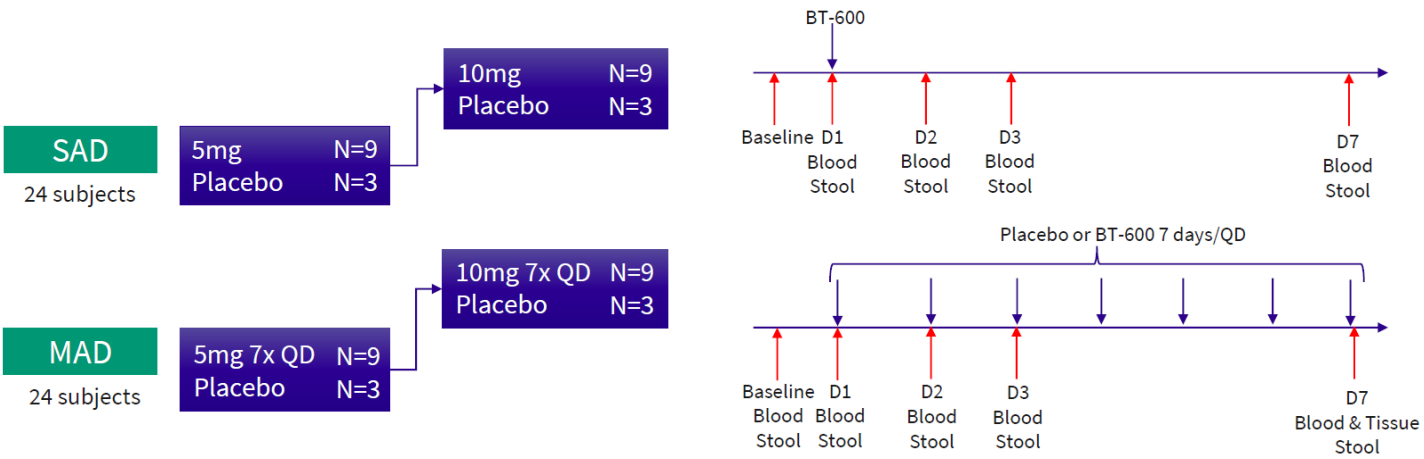
During 2023, Biora reduced its outstanding notes by more than $80 million and most recently came to an agreement with investor Context Capital to exchange $5.6 million in 2025 convertible notes for $3.8 million in 2028 convertible senior secured notes. Context will also purchase $2.8 million in 2028 notes which include common stock warrants. Other cash items contributing to the balance sheet in 2023 include a net $2.5 million from the sale of the Ann Arbor laboratory as well as other arrangements.

**Update on Programs**

*IND Clearance for BT-600*
Following an investigational new drug (IND) submission in September for the NaviCap BT-600 program, the FDA responded with questions in late October. The data the agency sought for the clinical trial evaluating the safety of tofacitinib delivery to the small intestine for ulcerative colitis (UC) was readily available and resubmitted to the agency a week later. On November 30, the FDA cleared Biora's IND application for BT-600, allowing the study to begin. An announcement of the trial's initiation was made in January. The Phase I will directly deliver tofacitinib to the colon for the treatment of moderate to severe UC. Data from the study is expected to produce data related to the pharmacokinetic and pharmacodynamic effects of BT-600. In late February, Biora announced that the single ascending dose (SAD) cohorts had been completed and that the multiple ascending dose (MAD) cohorts would begin promptly. The MAD portion is designed to enroll 24 participants to receive BT-600 tofacitinib at 5 and 10 mg or placebo. During the full year earnings conference call on March 26th, Dr. Ariella Kelman provided a summary of the SAD study findings.

*BT-600 Trial Interim Readout – Single Ascending Dose*
The BT-600 trial, carried under the NCT06275464 identifier, was launched in January as a randomized, double-blind, placebo-controlled Phase I study to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of BT-600 when administered in single and multiple ascending doses to healthy participants. The NaviCap device used a proprietary formulation of tofacitinib to deliver either 5 mg, 10 mg or placebo to healthy patients. Data from the trial will be presented in future publications and scientific events.

**Exhibit I – BT-600 Trial Design**




Source: Biora January 2024 Corporate Presentation

The single dose data is consistent with PK and safety generated in previous studies. The product was deemed to be well tolerated and functioned as intended and designed with drug release as predicted. Devices carrying drug demonstrated corresponding systemic absorption and delivery to the colonic tissue. Measurable tofacitinib in the blood was observed at approximately 6 hours and maximum concentration at 8 hours. This is in contrast to the conventionally orally delivered tofacitinib which reaches its maximum concentration within the first hour. Based on measurements taken during the study, delivery to the colon vs. the upper gastrointestinal tract was confirmed. Dose proportional PK was observed between the 5 mg and 10 mg doses. NaviCap's goal is to achieve higher concentrations of drug in the target tissue and lower levels systemically compared with conventional administration. Further studies later this year are expected to extract biopsies to confirm tissue concentration.

The MAD portion of the study is underway and will be conducted to confirm the results already produced. Patients will receive one daily dose of 5 mg, 10 mg or placebo. The dose will be one-half the amount administered as per the drug label for tofacitinib. Results are expected to be shared with stakeholders before the end of 2Q:24.

In the second half of the year, another study is planned that will evaluate the use of NaviCap tofacitinib in UC patients to further confirm plasma and tissue PK and PD and to further inform subsequent trials.

*BioJet Collaboration Update*
Biora announced a new collaboration for its BioJet Systemic Oral Delivery platform last December. The new agreement provides funding to test the BioJet platform's ability to achieve bioavailability through oral delivery of the collaborator's molecules to the small intestine in animal models. Based on our conversations with management, we believe that several of the company's other large pharma relationships are nearing the end of their collaborations and possibly close to securing a partnership which may include upfront payments. BioJet allows for large molecule drugs to be delivered orally, bringing a number of benefits including administration convenience and daily dosing which contrast with the more frequently used infusion method.

A January 2nd press release announced that BioJet has achieved an important bioavailability hurdle in a collaboration with AstraZeneca, mentioning the collaborator's name for the first time. The preclinical study generated greater than 25% bioavailability compared to subcutaneous delivery with a less than 50% coefficient of variation. In this study, the BioJet device was administered to a porcine model in comparison with subcutaneous administration. BioJet devices were delivered endoscopically and released for autonomous activation. These results build upon other preclinical work evaluating a variety of molecules in animal models.

**Debt Reduction and Capital Raise**

Biora has been burdened with convertible debt that it incurred as part of its 2020 financing. In 2023, the company and its investors made a concerted effort to reduce this burden and increase the proportion of equity in its capital structure which is more appropriate for a non-revenue generating research and development company. At the end of 2022, the convertible debt was held on the balance sheet at approximately $128 million. In a series of transactions, this balance sits at approximately $51 million as of 1Q:24. We discuss the details of the transactions that took place in our previous report which are current up to year end 2023 and align with the recently reported 2023 financial results.

Following the end of the year, Biora made further progress improving its capital structure, monetizing a legacy asset for $3 million and conducting a convertible note exchange for another $2.8 million in new capital. Management notes that as of the March 11th transaction Biora's debt had been reduced by more than $80 million while also raising $19.8 million in new capital. As we discuss above, Biora agreed with Context Capital to exchange $5.6 million of 2025 convertible notes for $3.8 million of 2028 convertible notes. Along with this transaction, Context also purchased $2.8 million of 2028 notes and common stock purchase warrants. The 2.0 million warrants have an exercise price of $2.75 per share and are exercisable until March 12, 2029

**New Patent Issue Notification**

The US Patent and Trademark Office (USPTO) provided an issue notification for a new NaviCap patent to deliver a Janus kinase (JAK) inhibitor to the gastrointestinal tract. As reported, US Patent Application 17/313,339, entitled "Treatment of a Disease of the Gastrointestinal Tract with a JAK Inhibitor and Devices," will issue as US Patent #11,857,669 on January 2, 2024 following payment of fees. JAK inhibitors such as tofacitinib present a variety of potential side effects such as infections, liver damage, blood cell count changes, blood clots, and pregnancy risks. Patients taking these medications require close monitoring. Direct delivery to the diseased tissue may allow for improved efficacy compared with systemic delivery and reduced side effects through the use of a lower dose.

**Milestones**

- NaviCap toxicity study – 1H:23
- IND filing for NaviCap (BT-600) – September 2023
- Sale of Ann Arbor facility – October 2023
- Resubmit NaviCap IND to FDA – October 2023
- FDA clearance of IND – November 2023
- Convertible debt conversion and reduction – December 2023
- Begin Phase I trial for NaviCap – December 2023
- Achieve >25% bioavailability in AstraZeneca collaboration – January 2024
- Settlement of IPO litigation – March 2024
- BT-600 Phase I final data assessment – 2Q:24
- Begin Phase Ib in Active UC for NaviCap – 2H:24

## Therapeutic Pipeline

**Exhibit II – Biora Therapeutic Pipeline**

| | PROGRAM | INDICATION | DESIGN/FEASIBILITY | PRECLINICAL | CLINICAL |
|---|---|---|---|---|---|
| NAVICAP™ TARGETED DELIVERY | **NaviCap™** Targeted Oral Delivery Platform | -- | | | |
| | **BT-600** NaviCap + tofacitinib* | UC | | | |
| | **BT-001** NaviCap + adalimumab variant* | UC | | | |
| BIOJET™ SYSTEMIC ORAL DELIVERY | **BioJet™** Systemic Oral Delivery Platform | -- | | | |
| | **AstraZeneca Collaboration** BioJet + undisclosed drug | Undisclosed | | | |
| | **Ionis Collaboration** BioJet + antisense therapy | Undisclosed | | | |
| | **Large Pharma 2 Collaboration** BioJet + undisclosed drug | Undisclosed | | | |
| | **Large Pharma 3 Collaboration** BioJet + undisclosed drug | Undisclosed | | | |
| | **PLANNED FOR 2024** | | | | |
| | **BT-200** BioJet + GLP-1 receptor agonist* | Demonstration Program | | | |
| | **BT-002** BioJet + adalimumab variant* | Demonstration Program | | | |

Source: Biora January 2024 Corporate Presentation

## Summary

Biora makes continued progress with NaviCap, BioJet and its capital structure since our previous report in December. The company provided a first look at the BT-600 trial showing continued evidence of targeted delivery and low systemic concentration using the NaviCap device in UC. Data from a BioJet collaboration was made public with the preclinical study showing greater than 25% bioavailability compared with subcutaneous injection. The identity of the partner was also shared along with greater confidence that Biora may see a partnership emerge this year. On the financing front, debt continues to decline. Existing investors add more cash to the company's balance sheet and non-core assets have been monetized. We anticipate that there will be movement with BioJet collaborators this year and could see something in the near term which may include upfront capital that will help support Biora's internal programs and fund BioJet research and development. Our valuation remains at $5.60 per share.

## PROJECTED FINANCIALS

**Biora Therapeutics, Inc. - Income Statement**

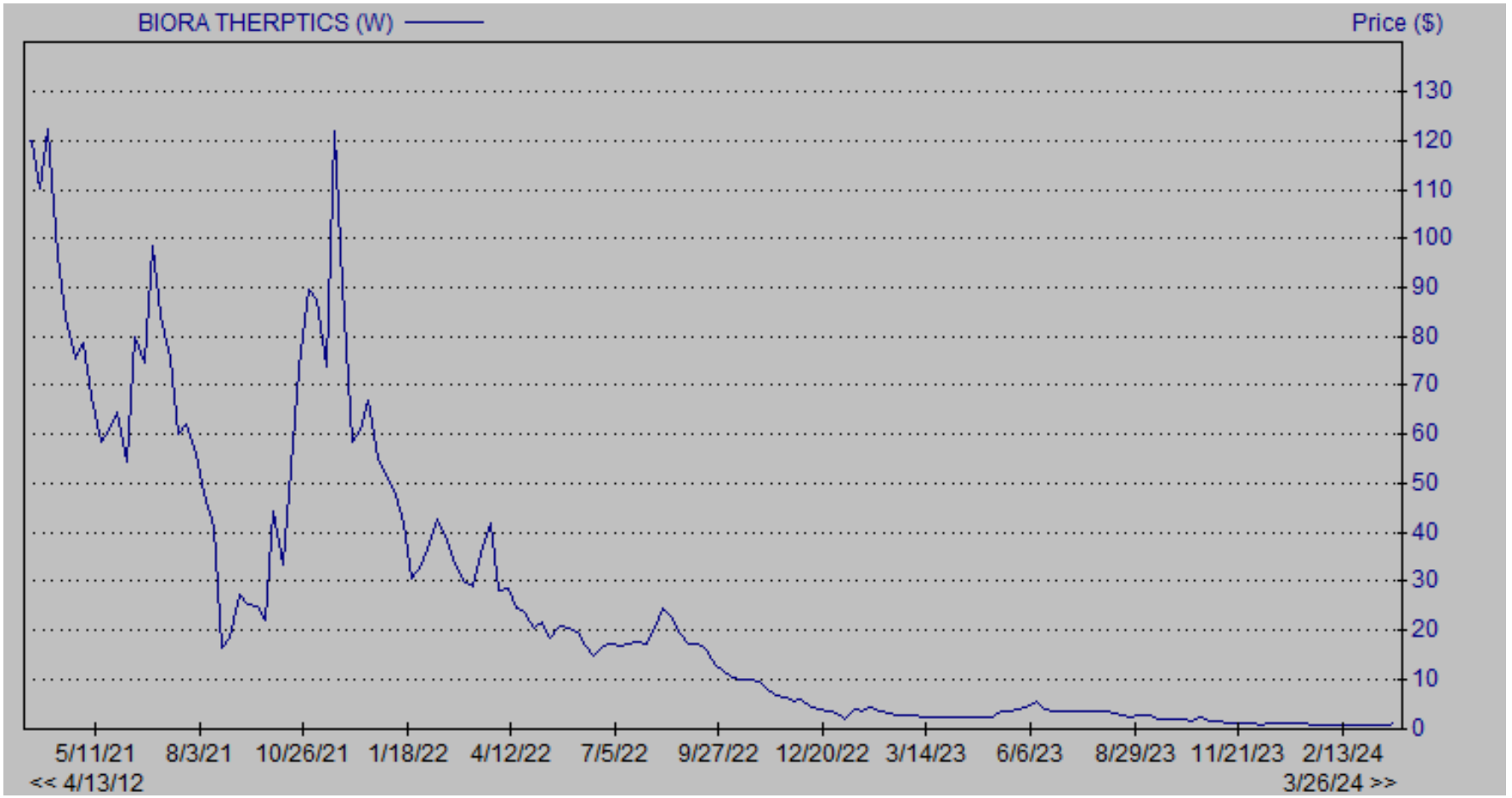
| Biora Therapeutics, Inc. | 2022 A | Q1 A | Q2 A | Q3 A | Q4 A | 2023 A | 2024 E | 2025 E |
|---|---|---|---|---|---|---|---|---|
| **Revenues** | **$305** | **$2** | **$2** | **$0** | **$0** | **$4** | **$6** | **$5** |
| Research & Development | $24,049 | $7,190 | $5,983 | $10,547 | $6,118 | $29,838 | $24,950 | $24,720 |
| Selling, General & Administrative | $38,037 | $8,356 | $8,953 | $12,774 | $7,226 | $37,309 | $33,750 | $34,210 |
| Operating Income | ($61,781) | ($15,544) | ($14,934) | ($23,321) | ($13,344) | ($67,143) | ($58,694) | ($58,925) |
| Interest Expense, net | ($10,990) | ($2,680) | ($2,703) | ($2,592) | ($1,840) | ($9,815) | ($6,150) | ($6,150) |
| Other Income (Loss) | $23,521 | $783 | ($166) | ($47,540) | ($543) | ($47,466) | $0 | $0 |
| Loss Before Income Taxes | ($49,250) | ($17,441) | ($17,803) | ($73,453) | ($15,727) | ($124,424) | ($64,844) | ($65,075) |
| Income Tax | ($420) | $0 | $4 | $1 | ($95) | ($90) | $0 | $0 |
| **Net Loss** | **($48,830)** | **($17,441)** | **($17,807)** | **($73,454)** | **($15,632)** | **($124,334)** | **($64,844)** | **($65,075)** |
| **Net Loss Per Share** | **($6.40)** | **($1.59)** | **($1.47)** | **($4.89)** | **($0.63)** | **($8.58)** | **($1.00)** | **($0.93)** |
| Weighted Average Shares | 7,635 | 10,971 | 12,143 | 15,025 | 24,811 | 15,773 | 65,000 | 70,000 |

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

© Copyright 2024, Zacks Investment Research. All Rights Reserved.

## HISTORICAL STOCK PRICE

**Biora Therapeutics, Inc. – Share Price Chart**



## 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 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.

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.

CANADIAN DISCLAIMER

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada and is not an associated person of any Canadian registered adviser and/or dealer and, therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.

© Copyright 2024, Zacks Investment Research. All Rights Reserved.