# Zacks Small-Cap Research

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## Biora Therapeutics, Inc. (BIOR: NASDAQ)

### *BIOR: 3Q:23 Results*

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 (11/13/2023) | $1.37 |
| **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 three 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** | **7.68** |
| **52-Week Low** | **1.32** |
| **One-Year Return (%)** | **-80.5** |
| **Beta** | **1.2** |
| **Average Daily Volume (sh)** | **144,550** |
| **Shares Outstanding (mil)** | **23.7** |
| **Market Capitalization ($mil)** | **32.5** |
| **Short Interest Ratio (days)** | **3.3** |
| **Institutional Ownership (%)** | **18.6** |
| **Insider Ownership (%)** | **3.6** |
| **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 E | $0.0 E |
| 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 | -$0.45 E | -$8.39 E |
| 2024 | | | | | -$1.00 E |
| 2025 | | | | | -$0.93 E |


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## WHAT'S NEW

**3Q:23 Financial and Operational Results**

Since our October 18th initiation of Biora Therapeutics, Inc. (NASDAQ: BIOR), management attention has centered on the investigational new drug (IND) application and the start of the BT-600 Phase I clinical trial. Following interaction with the FDA regarding the application and sharing requested clarifying information, the company distributed a press release on October 30th reporting that the IND had been resubmitted and that the trial is expected to begin before year end.

During the third quarter and to date, Biora has been deeply involved in advancing its NaviCap and BioJet programs. Data for BioJet has been presented at multiple conferences as the company prepares to move from the research collaboration stage to partnerships with the next generation BioJet 2 device. One highlight in particular emphasized the liver-targeted delivery of large molecules, such as RNA-based candidates, where BioJet delivers the molecule to the small intestine and the hepatic portal system transports it to the liver. Presentations and patents were also part of the news flow as results from the semaglutide BioJet study were presented at the American Diabetes Association and a group of US and EU patents were granted for multiple therapeutic targets on the NaviCap platform as well as other patents for the BioJet liquid jet injection technology.

During the reporting period, Biora's Head of Research, Dr. Sharat Singh, shared study results for NaviCap which demonstrated accurate deployment in 100% of subjects using radioisotopes. An IND application was submitted in September for the NaviCap BT-600 program which will deliver tofacitinib to the small intestine for treatment of ulcerative colitis (UC). Following a request for additional information from the regulatory agency, Biora resubmitted the application with the responses and expects to hear positive news before the end of November.

There was substantial movement on the balance sheet since the beginning of the third quarter as the diagnostic business was sold, a registered direct offering was completed and the company's largest shareholder exchanged its convertible notes for equity shares. Furthermore, the company interacted with investors at the Canaccord Genuity's Growth and HC Wainwright's Global Investment conferences.

Most recently, Biora reported 3Q:23 results in a press release and Form 10-Q filing with the SEC on November 13th. A conference call was also held to discuss results with investors. For the third quarter of 2023 ending September 30, 2023 and versus the prior year's third quarter, no revenues were recognized. Net loss for the third quarter totaled ($73.5) million or ($4.89) per share. Operational expenses rose 67% over 3Q:23 levels 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 nil down from $80,000 the prior year;
- Research and development expenses totaled $10.5 million, up 81% from $5.8 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;
- General & Administrative expenses were $12.8 million, up 57% from $8.1 million on account of an increase in salaries and benefits attributable to the accelerated vesting of unvested RSU awards, an increase in consulting and professional fees, offset by a decrease in business insurance, facilities and software costs;
- Interest expense was ($2.6) million compared to ($2.8) million;
- Other income was ($47.5) million vs. $1.9 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 ($73.5) million vs. ($14.9) million or ($4.89) and ($1.99) per share, respectively.

As of September 30, 2023, cash totaled $12.6 million. This amount compares to the $30.5 million cash balance held at the end of 2022. Convertible notes were carried on the balance sheet at $80.4 million. For the first nine months of the year, cash used in operations was ($34.8) million in 2023 versus ($56.0) million for the same period in 2022.

During 3Q:23, Biora reduced the principal amount of its senior convertible debt by $50 million. The convertible notes were exchanged for 9.2 million shares of common stock and 7.4 million pre-funded warrants and warrants to buy 16.6 million shares. Other cash items contributing to the balance sheet post quarter include a net $2.5 million from

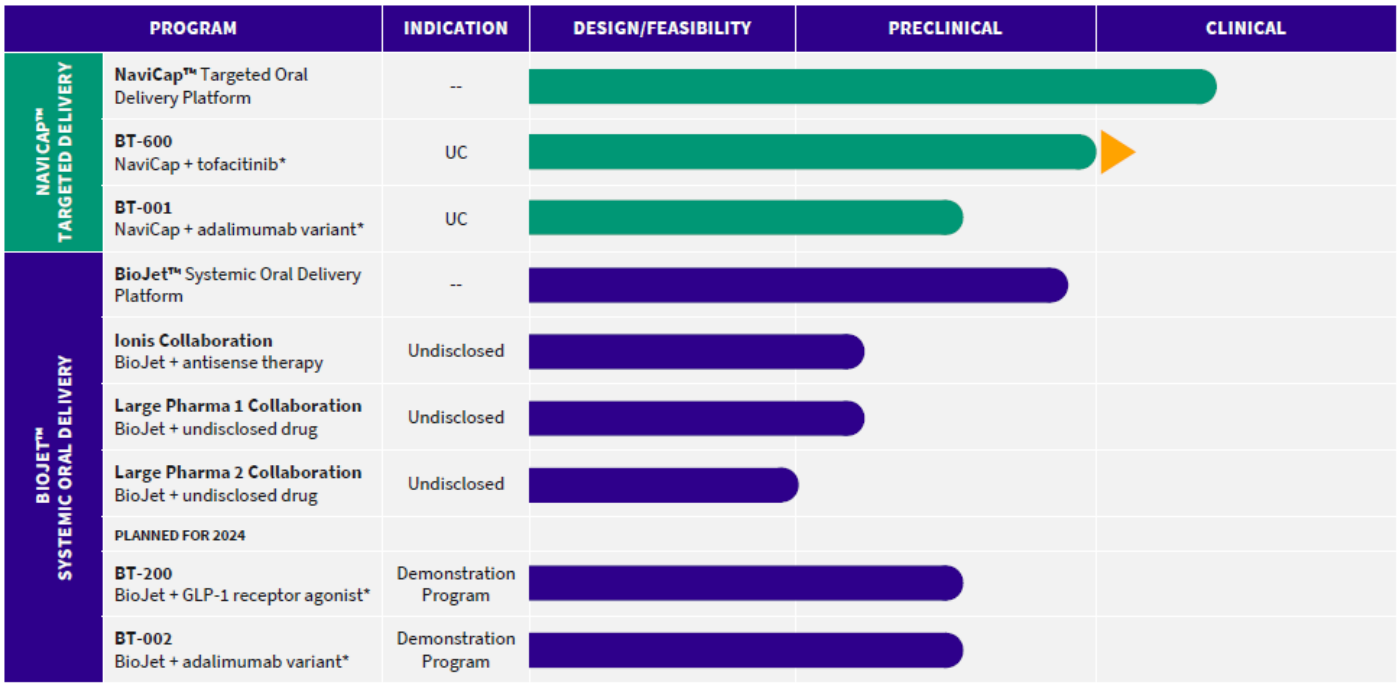
the sale of the Ann Arbor laboratory as well as other arrangements with investors bringing total post-Q3 cash raised to approximately $6 million.

## Milestones

- NaviCap toxicity study – 1H:23
- IND filing for NaviCap (BT-600) – September 2023
- Submit NaviCap toxicity study to FDA – 3Q:23
- Balance sheet clean up – 2H:23
- Sale of Ann Arbor facility – October 2023
- Resubmit NaviCap IND to FDA – October 2023
- FDA clearance of IND – November 2023
- Begin Phase I trial for NaviCap – December 2023
- BT-600 Phase I final data assessment – 2Q:24
- Begin Phase Ib in Active UC for NaviCap – 2H:24
- Partnership identity announcement if favorable data – 2024

## Therapeutic Pipeline

**Exhibit I – Biora Therapeutic Pipeline[1]**




## Summary

Biora is developing two promising candidates to more effectively deliver drugs and biologics to the GI tract and circulatory system. The pipeline consists of NaviCap and BioJet with the former able to precisely deliver drug to specific sites in the GI tract and the latter providing an oral option for biologics, most recently with a focus on liver delivery which is relevant to RNA-based molecules. Biora's lead program, BT-600, recognizes the unmet need in ulcerative colitis and can deliver an effective drug directly to the diseased tissue. This should provide better remission rates and reduce side effects, potentially moving the product to first-line therapy. BioJet offers broader applications as it may allow biologics to be delivered orally, improving administration and convenience as well as providing access to an immense market.

[1] Biora Corporate Presentation November 2023

Biora has completed preclinical research for NaviCap and has resubmitted its IND to the FDA, which may be cleared shortly. We anticipate a Phase I study to begin before year-end and a Phase Ib to commence in 2024. We see Phase II and pivotal trials taking place in time for a 2026 regulatory submission and first sales in 2027. BioJet is undergoing preclinical investigation by Biora and its research collaborators. Our sense is that these associates are close to signing a deal with Biora for further development in an arrangement that will likely include upfront payments.

Ulcerative colitis is a serious inflammatory disease that offers several lines of therapy that are either weakly effective or are associated with severe side effects. It is a chronic inflammatory bowel disease that affects the colon and rectum. It causes inflammation and ulcers in the lining of the colon, which can lead to a variety of symptoms, including abdominal pain, diarrhea, and rectal bleeding. There are almost one million cases of UC in the United States and more than five million around the globe. Existing therapies for UC are either intended for temporary relief or have limited efficacy and present severe side effects opening the door for a better alternative.

Biora has raised capital this summer and has been consistently addressing the convertible debt that is held on its balance sheet. While we forecast a capital raise in the near term, partners working on the BioJet project may elect to move forward with their programs and sign a deal that could include upfront payments. The upfronts may more than cover cash burn for the next few years and address the outstanding convertible debt. Recent activity including the sale of the Ann Arbor lab has provided a small pool of funds that will help offset near-term capital needs. Cash burn is estimated to be about $48 million per year, which is expected to hold steady as spending increases for clinical work for NaviCap and support of BioJet programs moves exclusively to partners.

Key reasons to own Biora shares:

- **Developing multiple smart capsules to improve drug delivery to the GI tract**
  - **NaviCap (Targeted Oral Delivery)**
    - **Able to deliver to specific site in the colon**
    - **Can be modified to release in multiple GI tract treatment sites**
  - **BioJet (Systemic Oral Delivery)**
    - **Delivering biologics orally**
    - **Compared with infusion, BioJet offers**
      - **Convenience**
      - **Steady blood plasma levels**
      - **Low cost**
- **Targeting drugs for indications with poor bioavailability**
- **Targeting indications with substantial revenue opportunity**
  - **Ulcerative Colitis**
  - **Oral delivery of biologics**
    - **Improved convenience**
    - **Stable pharmacokinetics vs. weekly infusion**
    - **Better adherence**
- **Global rights to intellectual property**

Biora offers two compelling devices that may dramatically improve drug delivery for a variety of medicines and indications. NaviCap has the potential for improved therapeutic results and improved side effect profile in UC while BioJet allows biologics to be delivered orally. Our valuation work forecasts the commercialization of the devices around the globe, assuming a 20% and 10% probability of success respectively. As NaviCap and BioJet generate additional data, we will refine our indications and timeline accordingly. We maintain our valuation of $5.60 per share.

## PROJECTED FINANCIALS

**Bluejay Diagnostics, Inc. - Income Statement**

| Biora Therapeutics, Inc. | 2022 A | Q1 A | Q2 A | Q3 A | Q4 E | 2023 E | 2024 E | 2025 E |
|---|---|---|---|---|---|---|---|---|
| **Revenues** | **$305** | **$2** | **$2** | **$0** | **$1** | **$5** | **$6** | **$5** |
| Research & Development | $24,049 | $7,190 | $5,983 | $10,547 | $6,020 | $29,740 | $24,950 | $24,720 |
| Selling, General & Administrative | $38,037 | $8,356 | $8,953 | $12,774 | $8,103 | $38,186 | $33,750 | $34,210 |
| Operating Income | ($61,781) | ($15,544) | ($14,934) | ($23,321) | ($14,122) | ($67,921) | ($58,694) | ($58,925) |
| Interest Expense, net | ($10,990) | ($2,680) | ($2,703) | ($2,592) | ($1,538) | ($9,513) | ($6,150) | ($6,150) |
| Other Income (Loss) | $23,521 | $783 | ($166) | ($47,540) | $0 | ($46,923) | $0 | $0 |
| Loss Before Income Taxes | ($49,250) | ($17,441) | ($17,803) | ($73,453) | ($15,660) | ($124,357) | ($64,844) | ($65,075) |
| Income Tax | ($420) | $0 | $4 | $1 | $0 | $5 | $0 | $0 |
| **Net Loss** | **($48,830)** | **($17,441)** | **($17,807)** | **($73,454)** | **($15,660)** | **($124,362)** | **($64,844)** | **($65,075)** |
| **Net Loss Per Share** | **($6.40)** | **($1.59)** | **($1.47)** | **($4.89)** | **($0.45)** | **($8.39)** | **($1.00)** | **($0.93)** |
| Weighted Average Shares | 7,635 | 10,971 | 12,143 | 15,025 | 34,943 | 18,270 | 65,000 | 70,000 |

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

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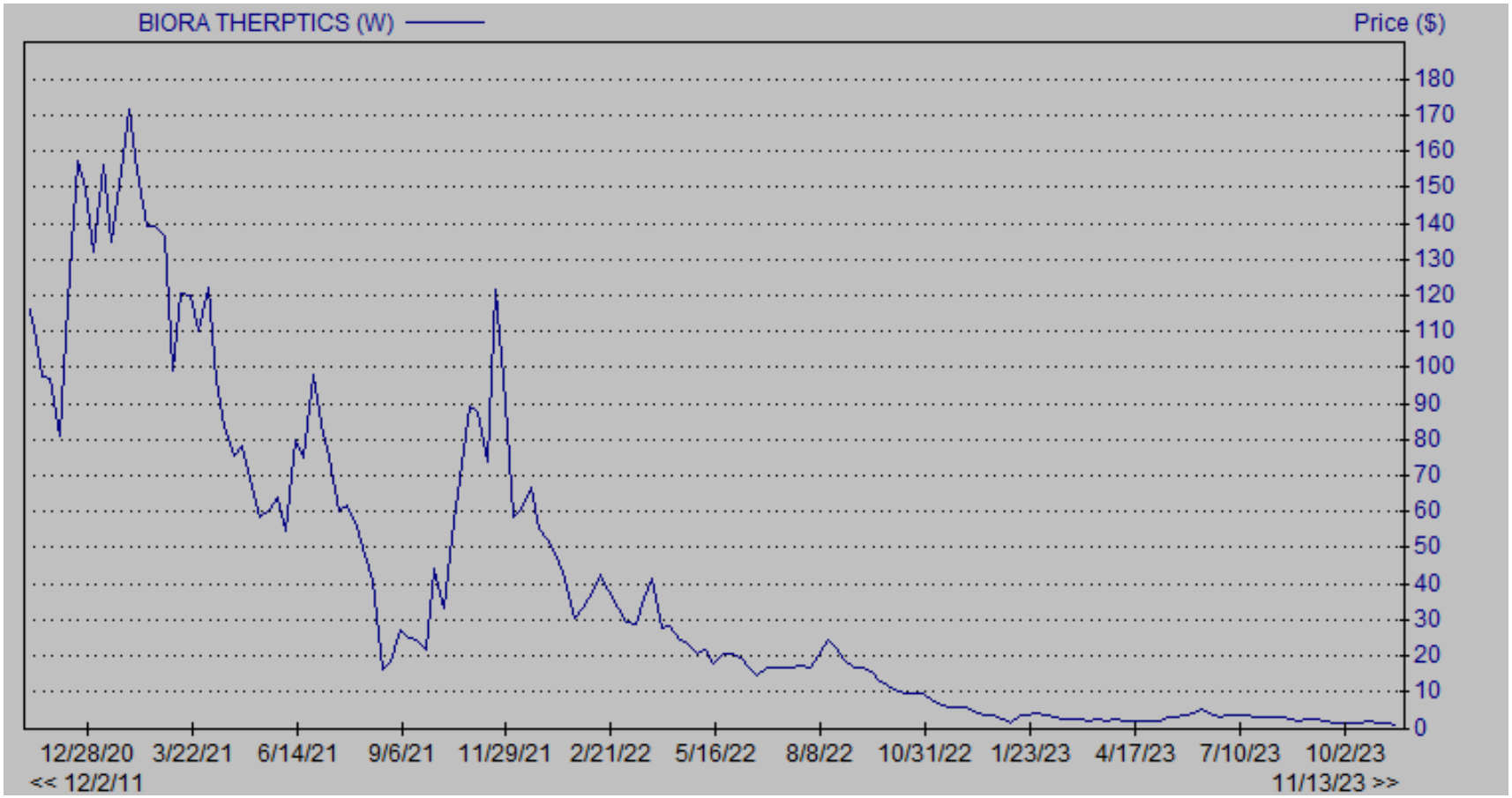
## HISTORICAL STOCK PRICE

**Bluejay Diagnostics, Inc. – Share Price Chart**



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