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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: Second Quarter 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 programs. The model includes contributions from the United States and rest of world.

Current Price (8/14/2024)	$0.67
Valuation	**$4.50**

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's BT-600 trial has completed the SAD & MAD cohorts & should report results in June. BioJet is on the cusp of a deal & may advance into the clinic through the efforts of pharma 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 dosages 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	**0.58**
One-Year Return (%)	**-78.9**
Beta	**1.2**
Average Daily Volume (sh)	**261,722**
Shares Outstanding (mil)	**43.9**
Market Capitalization ($mil)	**29.4**
Short Interest Ratio (days)	**6.7**
Institutional Ownership (%)	**76.2**
Insider Ownership (%)	**1.0**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.5 A	$0.3 A	$0.0 E	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023	-$1.59 A	-$1.47 A	-$4.89 A	-$0.63 A	-$8.58 A
2024	-$0.14 A	$0.18 A	-$0.35 E	-$0.31 E	-$1.65 E
2025					-$0.93 E
2026					-$0.95 E

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WHAT'S NEW

Biora Therapeutics, Inc. (NASDAQ: BIOR) reported second quarter results representing a period where the company continued refining its capital structure, announced results for its BT-600 trial, progressed with its BioJet partnership discussions and was awarded new patents. In conjunction with the 2Q:24 report, Biora announced a $16 million facility which will give the management team flexibility to negotiate potentially multiple BioJet partnerships.

Second Quarter Financial and Operational Results

Biora reported second quarter 2024 results in a press release and filing of Form 10-Q with the SEC on August 12th. A conference call was held to discuss results with investors following the release. For the quarter ending June 30, 2024 revenues of $318,000 were recognized. Net income for 2Q:24 totaled $6.5 million or $0.18 per share. However, when amounts related to non-cash derivative value changes were removed, net loss was a more representative ($16.4) million. Operational expenses rose 8% to $16.1 million on higher clinical trial expenses related to BT-600. For the second quarter 2024 versus the same prior year period:

- Revenues were $318,000 up from $2,000 the prior year due to an increase in collaboration revenue;
- Research and development expenses totaled $7.7 million, up 29% from $6.0 million on higher clinical trial expenses, salaries and benefits and laboratory supplies, partially offset by a small decrease in consulting and professional fees;
- General & Administrative expenses were $8.4 million, down 6% from $9.0 million due to lower spending on business insurance, salaries and benefits, and facilities costs, partially offset by an increase in consulting and professional fees;
- Interest expense was ($711,000) compared to ($2.7) million with the change attributable to a decrease in the balance of the 7.25% convertible senior notes due 2025 from note exchanges, offset by issuance of 2028 Convertible Notes;
- Other income was $22.9 million vs. ($166,000) with the increase almost entirely related to a gain on warrant liabilities and other derivative instruments resulting from mark to market and equity share price declines;
- Income tax was a benefit of ($67,000) vs. $0;
- Net income was $6.5 million vs. ($17.8) million or $0.18 and ($1.47) per share, respectively. After removing the gains on derivative instruments net loss was ($16.4) million or ($0.46) per share.

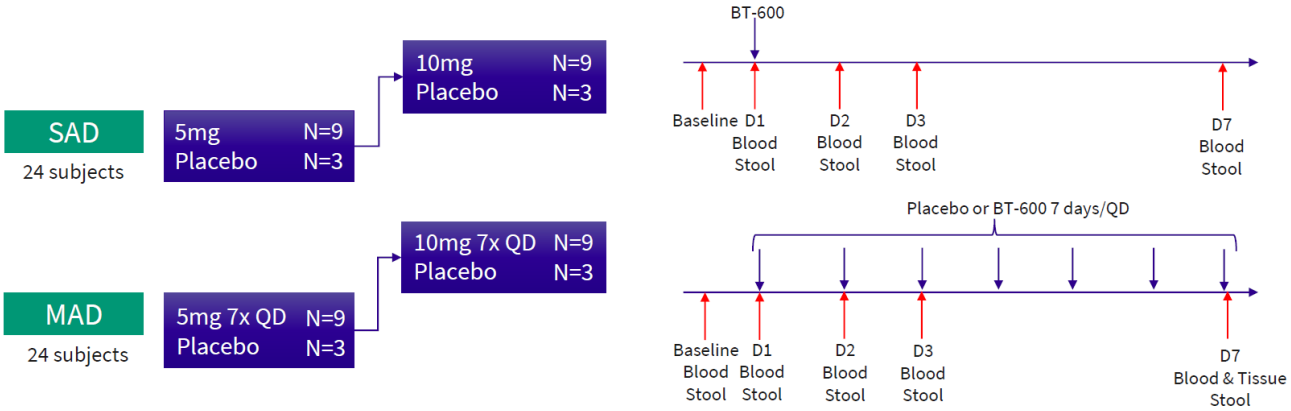
As of June 30, 2024, cash totaled $5.3 million. This amount compares to the $15.2 million cash balance held at the end of 2023. Multiple transactions took place in financing including contributions from issuance of common stock and convertible notes offset by offering costs and finance costs for insurance premiums. Debt is carried on the balance sheet at $45.7 million, which consists of multiple issues of convertible notes. Biora also monetized its interest in Enumera Molecular which contributed an additional $3 million to the cash pile. In August 2024, Biora entered into a note purchase agreement which provides an additional $16 million in funding to the company through the issuance of additional convertible notes. $4 million has been drawn so far and we expect another $4 million will be drawn later in the third quarter.

BT-600 Program

IND Clearance for BT-600
Following an investigational new drug (IND) submission in September 2023 for the NaviCap BT-600 program, the FDA cleared Biora's IND application for BT-600 in November, allowing the study to begin. An announcement of the trial's initiation was made in January. The study produced pharmacokinetic and pharmacodynamic data related to the 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. The MAD portion is designed to enroll 24 participants to receive BT-600 tofacitinib at 5 and 10 mg or placebo. By the end of April 2024, the MAD cohorts had been completed and management guided towards a late June report of full study data. Preliminary data was provided on July 1st in a press release and additional data was given in a key opinion leader (KOL) event on July 17th.

BT-600 Trial Interim Readout – Single Ascending Dose
The BT-600 trial, listed under the NCT06275464 identifier, uses the NaviCap device to deliver a proprietary formulation of tofacitinib in either 5 mg, 10 mg dosages or placebo to healthy patients.

Exhibit I – BT-600 Trial Design



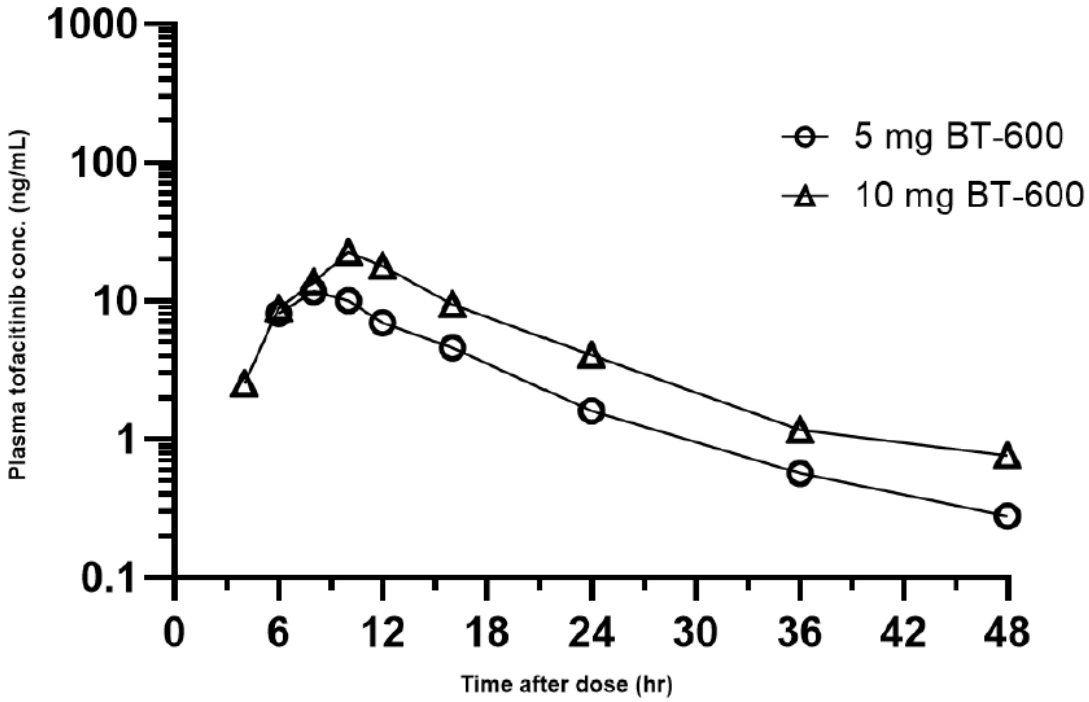
Source: Biora January 2024 Corporate Presentation

The single dose data is consistent with PK and safety data 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 throughout the body compared with conventional administration. Further studies later this year are expected to extract biopsies to confirm tissue concentration.

SAD Interim Results from BT-600

Biora provided additional data for its BT-600 study in an April 4th press release. Clinical data indicated that all pharmacokinetic endpoints were met by all study participants. The drug-device combination was well tolerated with no serious adverse events and all devices performed as intended. All participants showed systemic drug absorption. Six hours after administration, tofacitinib was detected in subject plasma and T_{MAX} was achieved 8-10 hours after first administration of BT-600.[1] Tofacitinib was measured in fecal samples of all subjects, further confirming delivery of drug to the colon.

Exhibit II – Mean Plasma Tofacitinib Concentration Following Oral Dose



Biora August 2024 Presentation

[1] Literature regarding oral administration of tofacitinib shows maximum concentration is achieved at 0.5 to 1.0 hours after administration.

Importantly, delivery of tofacitinib with BT-600 resulted in a 65% to 75% reduction in systemic absorption of the Janus kinase (JAK) inhibitor. Maximum plasma concentration was 26 ng/mL for BT-600 at the 10 mg dose of tofacitinib compared with 88 ng/mL for 10 mg of conventionally administered oral tofacitinib.

Exhibit III – Pharmacokinetics of BT-600

PK Parameters†	BT-600 Multiple Oral Dosing[1] (n=9)				XELJANZ	
	DAY 1		DAY 7			
Dosing Regimen	5 mg Once Daily	10 mg Once Daily	5 mg Once Daily	10 mg Once Daily	5 mg Twice Daily[2]	10 mg Single Dose[3]
T_{first} hours	6 (4–16)	8 (4–10)	N/A	N/A	NR	NR
T_{max} hours	10 (4–10)	8 (4–12)	10 (6–12)	8 (6–10)‡	1.0 (0.5–14.0)	0.5 (0.25–1.0)
C_{max} ng/mL	11.3 (97)	24.2 (27)	11.3 (39)	16.3 (77)	42.7 (26)	88 (10.2)
AUC_{0-24} ng.hr/ml	92.8 (61)	194.0 (21)	115.8 (33)	140.5 (91)	263.4 (15)	283 (80)

† Values for T_{first} and T_{max} represent median (range). Values for C_{max} and AUC_{0-24} represent geometric mean (CV), except Xeljanz single-dose results which represent arithmetic mean (SD).
‡ T_{max} range excludes one device that did not release payload.

Biora August 2024 Presentation

The MAD portion of the study began after the SAD and was conducted to confirm study results. Patients received one daily dose of 5 mg, 10 mg or placebo. The dose was one-half the amount administered as per the drug label for tofacitinib. The MAD portion of the trial evaluated daily doses of BT-600 for seven days at 5 mg and 10 mg tofacitinib or placebo, in healthy adult participants. 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.

Select Results from SAD and MAD Studies
Biora reported select results from its BT-600 trial on July 1st confirming and expanding upon the favorable findings in the interim update provided in April. All pharmacokinetic endpoints were achieved and drug delivery and absorption in the colon, including distal portions, was biopsy confirmed. NaviCap devices performed as intended and were well tolerated, producing no safety signals. The results support the advance of BT-600 into a Phase Ib clinical trial in patients with ulcerative colitis (UC).

BT-600 Phase I trial results reported evidence of systemic absorption of tofacitinib at six hours consistent with NaviCap's expected delivery profile. NaviCap maximum blood serum levels of tofacitinib occurred at eight to ten hours compared to the 30 minutes observed in other conventional oral tofacitinib trials. Systemic drug exposure for BT-600 was from one quarter to one third the levels of those observed with conventional oral tofacitinib.

The clinical trial protocol required biopsy of treated colonic tissue including the distal colon to produce evidence of drug exposure. Biopsy results showed evidence of drug delivery throughout the colon and at common sites of ulcerative colitis-related inflammation and ulcers. In the multiple NaviCap deliveries to the 48 healthy participants in the trial, 100% of the SAD subjects and 98% of the MAD subjects had confirmed NaviCap device delivery.

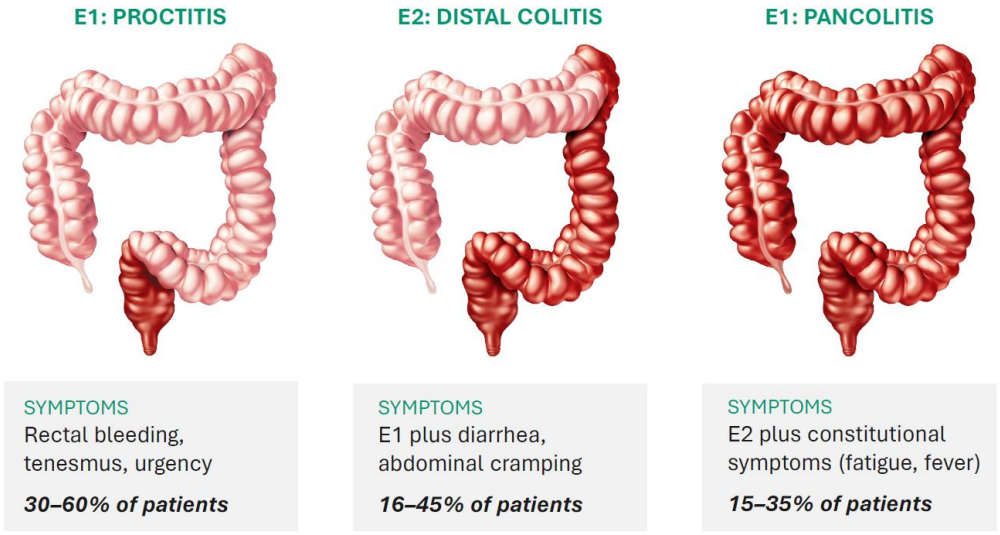
Key Opinion Leader (KOL) Event and Further BT-600 Readout Details

Following the report of BT-600 topline results, Biora held a key opinion leader (KOL) event on July 17th. hosted by LifeSci Events and Biora CEO Adi Mohanty. Experts featured were Bruce Sands, MD, MS, from the Icahn School of Medicine at Mount Sinai, Ariella Kelman, MD the Chief Medical Officer of Biora and Brian Feagan, MD, FRCPC from the University of Western Ontario. The featured guests provided a summary of the unmet needs in ulcerative colitis (UC), reviewed the BT-600 Phase I trial, and addressed the challenges of medicine delivery to the colon.

Dr. Sands began with a review of the clinical presentation of UC noting the relative prevalence of each type of disease and its features. He reviewed the histology of UC, comparing the presentation of a normal colon to inactive chronic colitis to severely active chronic colitis. The impact of UC on patient lives was given, showing evidence that patients felt more impact on their lives from UC than patients with other diseases such as asthma, migraine and rheumatoid arthritis. One of the shortcomings of the most effective class of medicines for UC, the JAK inhibitors, is

the side effect profile that comes from systematic exposure to the drug. Tolerability prevents the optimal therapeutic dose from being used, highlighting a second shortcoming which is difficulty delivering sufficient drug to the site of disease.

Exhibit IV – Clinical Presentation of UC



Source: Biora July 17, 2024 KOL Event Slide Deck

Dr. Kelman summarized the results from the Phase I BT-600 trial evaluating NaviCap and tofacitinib drug delivery in healthy patients. 48 subjects, evenly split between the single ascending dose (SAD) and multiple ascending dose (MAD) cohorts measured the safety, tolerability and pharmacokinetics of BT-600. The randomized, double-blind, placebo-controlled trial achieved all trial objectives with tofacitinib first detected in the blood at 6 hours and maximum blood levels at 1/4th to 1/3rd Xeljanz levels.[2] Tofacitinib was detected throughout the colon with drug tissue levels at or above the estimated IC90 threshold across three biopsy sites in the colon. NaviCap drug delivery was accurate with no early releases and 95% of devices successfully detecting colon entry.

Exhibit V – Pharmacokinetics of BT-600

PK Parameters†	BT-600 Multiple Oral Dosing[1] (n=9)				XELJANZ	
	DAY 1		DAY 7			
Dosing Regimen	5 mg Once Daily	10 mg Once Daily	5 mg Once Daily	10 mg Once Daily	5 mg Twice Daily[2]	10 mg Single Dose[3]
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‡ T_{max} range excludes one device that did not release payload.

Source: Biora July 17, 2024 KOL Event Slide Deck

There was a positive correlation between tissue and plasma levels of drug throughout all measured parts of the colon. Projected tofacitinib levels were estimated to be above IC90 levels for at least 16 hours following administration and above IC50 levels at 24 hours after dosing. The PK study demonstrated that NaviCap can achieve tissue concentrations associated with improved efficacy with lower systemic exposure. Tofacitinib tissue concentrations have been shown to correlate with endoscopic response, with responders having a median tissue concentration above the estimated IC90.

[2] Xeljanz data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

Now that the Phase I is complete, Biora is looking ahead to a Phase Ib which will confirm the PK profile in UC patients. This next step will target the enrollment of 15 UC patients at a single center and evaluate safety and tolerability, PK and pharmacodynamics, and device function. It is scheduled to start in 4Q:24 and last six months. If results continue to be favorable, a Phase II will be launched as a proof-of-concept trial that will enroll 150 UC patients. The trial will be global and evaluate additional endpoints including clinical and endoscopic response, mucosal healing, patient reported outcomes (PROs) and biomarkers. The trial is planned for 4Q:25 with further details forthcoming.

The third featured speaker for the KOL event, Dr. Feagan, provided a review of approved treatments for UC and some of their deficiencies. The speaker highlighted drug toxicity (which constrains administration to subtherapeutic doses) and lack of precise delivery of drug to the site of disease as two of the primary weaknesses. He also noted, in a similar vein to other presenters, that tissue drug exposure and activity correlate with endoscopic outcomes. With respect to NaviCap, Dr. Feagan observed that it achieved a higher tissue to plasma concentration ratio at a lower dose than conventional tofacitinib. In Dr. Feagan's opinion, NaviCap provides consistent PK, precision release and tissue exposure along the length of the colon which have been demonstrated in the Phase I BT-600 study.

The event closed with a summary by the CEO and an opportunity for participants to ask questions. Click on the highlights for a link to the webcast and slide deck.

BioJet Patent

On April 8th, Biora announced that the US Patent and Trademark Office (USPTO) had issued US Patent #11,938,295 titled Ingestible Device for Delivery of Therapeutic Agent to the Gastrointestinal (GI) Tract. The patent makes claims to cover jet parameters for liquid jet delivery of drug to the GI tract, stomach or small intestine. The device described in the application is configured to provide at least three different modes of direct delivery of therapeutic agents to the GI tract of a subject, referred to herein as trans-epithelial, epithelial, and topical delivery. Direct delivery, as used in the patent application, refers to a force-driven delivery mechanism. The patent is anticipated to expire at the end of 2040, unless extensions are granted.

Poster Presentations

Biora participated in two conferences during the second quarter including Digestive Disease Week (DDW) on May 19th in Washington D.C. and the Next Gen Peptide Formulation and Delivery Summit on June 19th in Boston.

Digestive Disease Week
The poster presentation at DDW was entitled Results of Human Device Function Studies for the NaviCap Targeted Oral Delivery Platform in healthy volunteers and patients with UC. The associated press release summarized the functionality and safety of NaviCap as explained in four clinical studies. Biora's Chief Medical Officer Ariella Kelman, MD, noted that the NaviCap device was well-tolerated in 81 administrations to 47 participants, releasing its payload in the colon, regardless of variable GI transit time, the level of inflammation, or the presence of blood in stool. Biora asserts that NaviCap's ability to function across variable GI conditions and eating schedules illustrates its potential to deliver therapeutics locally to the colon of patients with UC.

Conclusions from the poster noted that the NaviCap platform's ability to function across variable GI pH, motility, and eating schedules illustrates the device's potential capability to deliver therapeutics locally to the colon of patients with UC and that localized delivery could potentially improve efficacy while minimizing systemic exposure and toxicity that is associated with systemic drug delivery.

Next Gen Peptide Formulation and Delivery Summit
The Peptide Summit, which took place from June 18 to 20 in Boston included a presentation by Biora entitled Empowering Peptide Self Administration with Needle-Free Smart Capsules. It was presented in the afternoon of June 19 by Sharat Singh, PhD, Head of Research, Biora Therapeutics. Dr. Singh also joined a panel presentation at the event titled "Uncovering Innovations in Peptide Drug Delivery & Formulation for Improved Bioavailability," alongside representatives from Eli Lilly, Merck, and Novo Nordisk. A press release detailing Biora's participation in the event was published on June 11.

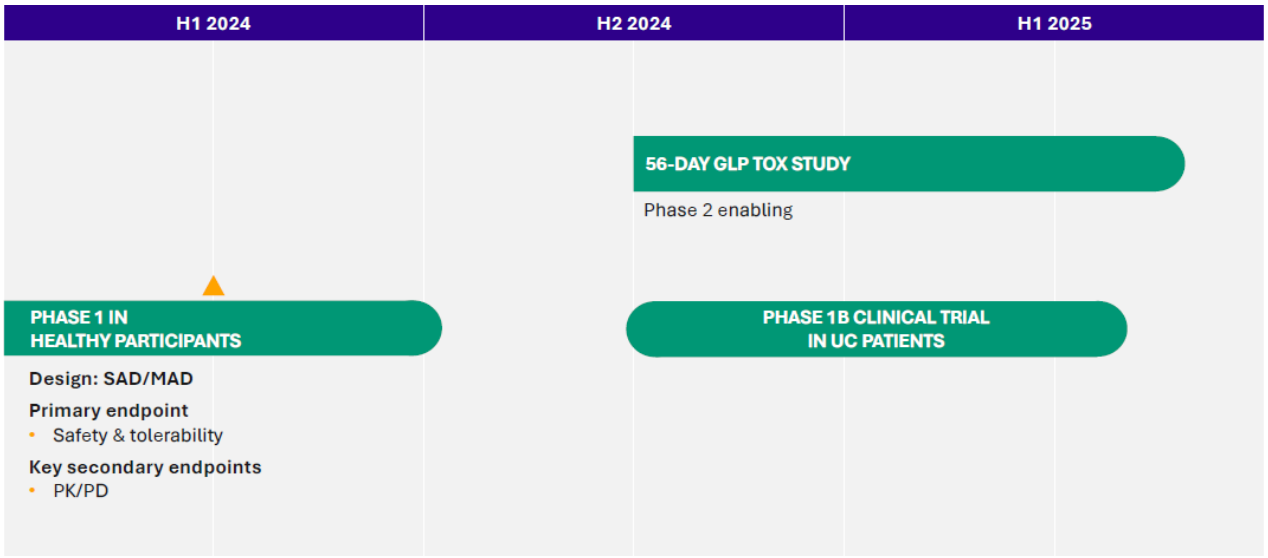
$16 Million Note Purchase Agreement

On August 12th, 2024, Biora announced a funding agreement with existing investors that will provide near-term flexibility to negotiate an arrangement with partners interested in further development of the BioJet system. The financing agreement will provide a maximum amount of $16 million accessible in up to four $4 million monthly distributions. The principal will add to the existing balance of the company's 11/13% convertible senior secured notes due in 2028. As incentive for the cash access, 6,677,794 warrants will be issued along with each $4 million tranche. Details of the purchase agreement are contained in a Form 8-K filing. The first $4 million closed on August 14th. Investors that contributed to the note purchase agreement will be allowed to exchange their notes to receive payment priority, which improves their seniority in the capital structure.

Milestones

- Settlement of IPO litigation – March 2024
- Nasdaq notification letter indication bid price below compliance level – May 2024
- NaviCap Clinical Data presentation at Digestive Disease Week – May 2024
- BT-600 Phase I final data assessment – 2Q:24
- Animal study data for BioJet presented at the Next Gen Peptide Summit – June 2024
- Report of topline data for SAD and MAD portions of BT-600 – July 2024
- KOL event to discuss UC and BT-600 results – July 17, 2024
- BT-600 Phase I data presentation at American College of Gastroenterology – October 2024
- Sign partnership agreement with one or more BioJet partners – 2H:24
- Begin BT-600 Phase Ib in Active UC for NaviCap – 4Q:24
- Launch of Phase Ib study for tofacitinib in UC patients – 4Q:24

Exhibit VI – Clinical Development Plan



Source: Biora April 2024 Corporate Presentation

Valuation

We adjust our per share valuation to reflect additional claims on equity which arose through recent financings; however, our enterprise value does not change from our last update. Compared with our post-first quarter report, Biora gained 585,000 equity shares, 7.2 million warrants and an estimated $8.0 million of convertible debt. The incremental increase in debt assumes that Biora draws two, $4 million tranches in the thrid quarter from its facility. Reflecting these claims on the company generates a per share valuation of $4.50 per share.

Exhibit VII – Biora Therapeutic Pipeline

NAVICAP™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
NaviCap™ Targeted Oral Delivery Platform	--			
BT-600 in ulcerative colitis	tofacitinib*			
BT-001 in ulcerative colitis	adalimumab variant*			

BIOJET™ PROGRAMS	DRUG	DESIGN/FEASIBILITY	PRECLINICAL	CLINICAL
BioJet™ Systemic Oral Delivery Platform	--			
AstraZeneca collaboration	undisclosed			
Ionis collaboration	antisense oligonucleotide			
Multiple pharma collaborations	undisclosed			

Source: Biora August 2024 Corporate Presentation

Summary

Biora has demonstrated NaviCap's accurate drug delivery of tofacitinib to the colon with low systemic exposure. This may allow therapeutic levels of the drug to be administered while avoiding common side effects of the JAK inhibitor, such as infections. Using biopsy, drug delivery was measured throughout the colon in the BT-600 Phase I trial with systematic exposure at one-third to one-quarter the level associated with conventional oral tofacitinib. Literature on the subject shows that there is a correlation between the presence of tofacitinib in the colonic tissue and alleviation of UC symptoms, stimulating keen interest in advancing NaviCap further along the regulatory route to approval. The next step is to conduct a Phase Ib study in UC patients which will be continue to evaluate if this relationship holds true. The Phase Ib study is expected to start towards the end of 2024.

Animal studies for Biora's other product, BioJet, have been completed and several of the company's collaborators are now considering whether or not to move forward. Management has indicated that we are close to executing a deal with one or more of the big pharmas. In support of this effort, Biora entered into a note purchase agreement with existing investors to provide the financial flexibility necessary to get the best deal possible. We think an upfront amount will be part of a partnership deal which can help alleviate some of the capital needs that we see related to launching the Phase Ib later this year. The claims on equity and debt balance have increased since the financial update for the first quarter, so we adjust our model to reflect this. While our enterprise value for Biora remains the same, we reduce our per share valuation to $4.50 per share.

PROJECTED FINANCIALS

Biora Therapeutics, Inc. - Income Statement

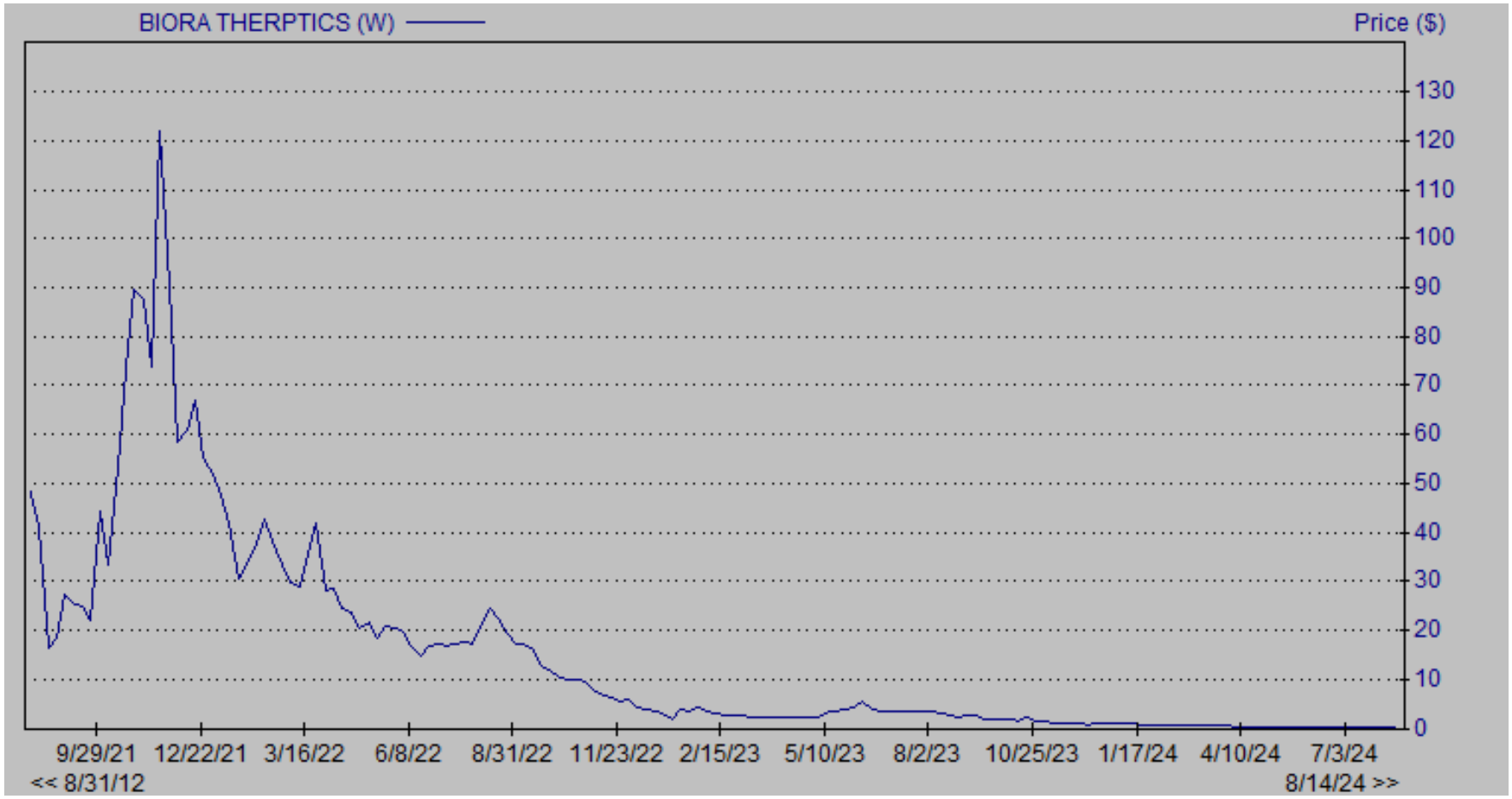
Biora Therapeutics, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Revenues	**$4**	**$542**	**$318**	**$0**	**$0**	**$860**	**$5**	**$25**
Research & Development	$29,838	$7,005	$7,704	$6,125	$6,044	$26,878	$24,720	$28,520
Selling, General & Administrative	$37,309	$9,053	$8,400	$7,850	$7,725	$33,028	$34,210	$34,100
Operating Income	($67,143)	($15,516)	($15,786)	($13,975)	($13,769)	($59,046)	($58,925)	($62,595)
Interest Expense, net	($9,815)	($2,757)	($711)	$0	($3,075)	($6,543)	($6,150)	($6,150)
Other Income (Loss)	($47,466)	$14,132	$22,895	$0	$0	$0	$0	$0
Loss Before Income Taxes	($124,424)	($4,141)	$6,398	($13,975)	($16,844)	($65,589)	($65,075)	($68,745)
Income Tax	($90)	$48	($67)	$0	$0	$0	$0	$0
Net Loss	**($124,334)**	**($4,189)**	**$6,465**	**($13,975)**	**($16,844)**	**($65,589)**	**($65,075)**	**($68,745)**
Net Loss Per Share	**($8.58)**	**($0.14)**	**$0.18**	**($0.35)**	**($0.31)**	**($1.63)**	**($0.93)**	**($0.95)**
Weighted Average Shares	15,773	29,297	35,720	40,500	55,000	40,129	70,000	72,000

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

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HISTORICAL STOCK PRICE

Biora Therapeutics, Inc. – Share Price Chart



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