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BioLineRx Ltd. (BLRX: NASDAQ)

BLRX: On Your Marks, Get Set…

We employ a DCF model and a 15% discount rate to determine our valuation. Regarding ultimate approval and commercialization success, our model applies an 85% probability to motixafortide in HSC mobilization, an 18% probability to motixafortide in PDAC and a 12% probability to AGI-134 in solid tumors. It includes contributions from the United States and Rest of World.

Current Price (9/1/2023)	$2.02
Valuation	**$6.00**

OUTLOOK

BioLineRx is a late clinical-stage biopharmaceutical company advancing lead candidate Motixafortide (BL-8040), a platform molecule targeting indications in stem cell mobilization for multiple myeloma (MM) and in the treatment of advanced pancreatic cancer. The second candidate in the portfolio, AGI-134, is being evaluated in a Ph1/2a study in solid tumors.

Motixafortide, a CXCR4 chemokine antagonist, is able to mobilize hematopoietic stem cells (HSCs) for successful transplantation in fewer apheresis sessions vs primary therapy, G-CSF. Many transplant-eligible patients have trouble achieving collection targets using SoC G-CSF alone & require additional agents to facilitate success. Motixafortide and G-CSF together achieved targeted collection in 88.3% of patients after only one apheresis session compared to 9.5% using G-CSF alone. Top-line results from the related Ph3 study, GENESIS, were recently published. An NDA has been submitted & PDUFA date of 9SEP23 assigned.

The second pipeline candidate, AGI-134, is a synthetic α-Gal glycolipid that is pursuing an indication in cancer immunotherapy for solid tumors and recently announced results demonstrating safety and tolerability.

SUMMARY DATA

52-Week High	**2.10**
52-Week Low	**0.55**
One-Year Return (%)	**35.6**
Beta	**1.8**
Average Daily Volume (sh)	**501,274**
Shares Outstanding (mil)	**61.5**
Market Capitalization ($mil)	**124.2**
Short Interest Ratio (days)	**6.2**
Institutional Ownership (%)	**5.2**
Insider Ownership (%)	**0.0**
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 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-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 E	$1.1 E	$1.1 E
2024					$22.6 E
2025					$34.3 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 A
2023	-$0.01 A	-$0.02 A	-$0.01 E	-$0.01 E	-$0.05 E
2024					-$0.01 E
2025					$0.00 E

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WHAT'S NEW

2Q:23 Operational and Financial Results

It had been relatively quiet between the first and second quarter report with only the start of the Phase II metastatic pancreatic cancer trial evaluating motixafortide announced in July. However, along with the second quarter report, BioLineRx Ltd. (NASDAQ: BLRX) revealed an exclusive agreement for development and commercialization in Asia. The arrangement includes an upfront payment and investment in BioLineRx that will materially extend the company's cash runway and allow for sales throughout China, Japan and other Far East territories.

Second quarter earnings were announced on August 30, 2024 concurrent with intense background work to prepare for the anticipated FDA approval of motixafortide for stem cell mobilization in multiple myeloma patients. A conference call was held with management along with the filing of Form 6-K providing additional information. First and foremost in investors' minds is the target action date of September 9, 2023 for motixafortide, or Aphexda as it is branded, for stem cell mobilization in multiple myeloma patients.

In this report, we will review the latest news reported as well as 2Q:23 operational and financial results. Since our previous update, BioLineRx has oriented its efforts towards pre-commercialization activities. A discussion of BioLineRx' plans to commercialize Aphexda can be found in a previous report entitled BLRX: Self-Commercialization in the US. It discusses the company's plans, reviews Aphexda's mechanism of action and addresses the real-world benefits of an improved approach to stem cell mobilization.

Below we summarize financial results for the three-month period ended June 30, 2023, compared to the same period ending June 30, 2022:

- Research and development expenses totaled $3.0 million, down 44% from $5.4 million, on account of lower expenses related to the new drug application (NDA) supporting activities related to motixafortide and lower expenses associated with the completed AGI-134 study;
- Sales and marketing expenses were $5.6 million, up 384% from $1.2 million on account of initiation of pre-commercialization activities related to motixafortide;
- General and administrative (G&A) expenses were $1.3 million, up 24% from $1.0 million due to a rise in payroll and related expenses due to an increase in headcount and share-based compensation, as well as small increases in a number of G&A expense categories;
- Non-operating expense was ($7.7) million reflecting changes in fair-value adjustments of warrant liabilities on the balance sheet as the company's share price rose;
- Net financial expenses amounted to ($0.9) million which was impacted by interest paid on loans partially offset by interest received from cash balances;
- Net loss was ($18.5) million compared with ($4.9) million, or ($0.01) and ($0.01) per share respectively.

Cash, equivalents and short-term bank deposits as of June 30, 2023 totaled $32.8 million, down from the year end 2022 balance of $51.1 million. Cash burn during 2Q:23 amounted to ($9.8) million and cash used in financing was ($134,000) related to repayment of lease liabilities. The substantial increase in cash burn year to date reflects the aggressive effort to prepare for the approval of motixafortide which is anticipated in a few days. In September 2022, BioLineRx entered into a $40 million loan agreement with Kreos Capital, and $10 million was drawn. The remaining $30 million will be available in two additional tranches upon the achievement of unspecified milestones. BioLineRx' deal granting rights to two entities in Asia will also contribute to cash balances in the amount of almost $30 million, which is expected to extend the need for more capital by several quarters.

Asia License Agreement

Along with its second quarter earnings release, BioLineRx announced that it had signed an exclusive license agreement to develop and commercialize motixafortide in Asia along with an equity investment from two partners. Features of the arrangement include:

- $15 million upfront payment
- Potential development, regulatory and sales milestones
- Tiered double-digit royalties
- Initiation of a registrational study in stem-cell mobilization in China
- Initiation of a randomized Phase II/III study in first line pancreatic cancer
- Equity investment of $14.6 million

The equity investment was made at $2.136 per American Depository Share (ADS) with no warrants attached. This represents 6,829,137 shares. Other closing conditions of the transaction include the requirement that it be approved by the Israeli Innovation Authority within four months. While only select financial details are public, this appears to be a standard agreement for a strong candidate and if successful will open up one of the largest markets in the world to motixafortide in multiple indications. We expect to update our valuation model to reflect this following FDA approval and launch of motixafortide in the United States.

The license agreement has been made between BioLineRx and two separate entities. The first is Guangzhou Gloria Biosciences Co., Ltd., a company organized under the laws of the People's Republic of China. The second company is Hong Seng Technology Limited, a company organized under the laws of the Special Administrative Region of Hong Kong.

Additional detail in the Form 6-K filing show more specific detail including that BioLineRx is further entitled to $49 million based on reaching development and regulatory milestones in China and Japan and up to $197 million in sales milestones based upon defined sales targets. Royalties will range from 10-20% of revenues. A caveat is that if FDA approval for motixafortide does not occur by the end of 2023, the development and regulatory milestones will only be partially payable and royalty rates drop to single digits. Further discussion of the arrangement is available in the filing.

Motixafortide Pancreatic Trial

BioLineRx began a Phase II clinical trial in first line metastatic pancreatic cancer as announced in a July 17th press release. The investigator-initiated effort will be evaluating motixafortide based on the success of earlier work done in a single arm pilot study. A clinicaltrials.gov entry (NCT04543071) details the design and endpoints among other pieces of information.

The study, sponsored by Columbia University, will compare treatment with motixafortide combined with a PD-1 inhibitor (cemiplimab) and chemotherapy to chemotherapy alone in 102 subjects. This builds on an adaptive single arm study that allowed for expansion if data was supportive. We anticipate that BioLineRx' primary development activities will shift to pancreatic ductal adenocarcinoma (PDAC) following approval of motixafortide for stem cell mobilization.

The company provides a description of the agent's mechanism of action explaining that motixafortide takes advantage of the expression of the CXCR4 receptor on different immune cells and orients the immune system against the tumor. Among CXCR4-expressing immune cells, some exhibit anti-tumoral activity, such as effector T cells and some exhibit pro-tumoral activity and support tumor growth. By blocking the CXCR4 receptor, motixafortide was shown in a Phase II study in pancreatic cancer patients to enhance anti-tumoral activity and inhibit the pro-tumoral activities by modulating the effector/suppressor cell ratio towards a proinflammatory profile.

Publication in Nature Medicine

BioLineRx announced that a journal article discussing the Phase III GENESIS trial was published in the April issue of Nature Medicine. The article, entitled Motixafortide and G-CSF to mobilize hematopoietic stem cells for autolo-

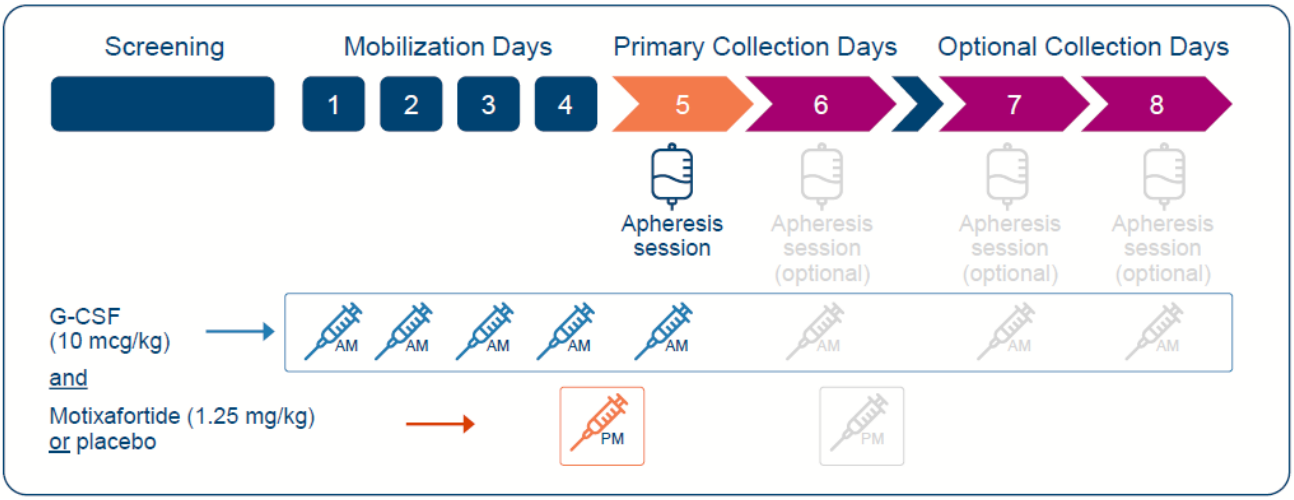
gous transplantation in multiple myeloma: a randomized phase 3 trial,[1] examines motixafortide + G-CSF's ability to produce sufficient $CD34^+$ hematopoietic stem and progenitor cells to conduct stem cell transplantation in multiple myeloma patients. Most patients under approved approaches are unable to collect the target number of cells for stem cell transplantation; however, by adding motixafortide, almost 90% of patients were able to collect sufficient cells in one apheresis session.

The primary endpoint for the trial was to collect greater than 6 x 10^6 $CD34^+$ cells per kilogram within two apheresis sessions. The secondary endpoint was to achieve the goal in one apheresis session. 122 subjects were enrolled across 18 sites and randomized 2:1 comparing motixafortide + G-CSF or placebo + G-CSF. Motixafortide + G-CSF enabled 92.5% of the subjects to successfully meet the primary endpoint versus 26.2% with placebo + G-CSF. The odds ratio was 53.3, with a 95% confidence interval of 14.12–201.33 and a p-value of less than 0.0001. Motixafortide + G-CSF also enabled 88.8% of subjects to meet the secondary endpoint versus 9.5% with placebo + G-CSF. The odds ratio for the secondary endpoint was 118.0 with a 95% confidence interval of 25.36–549.35 and a p-value of less than 0.0001.

Treatment emergent adverse events (TEAEs) occurred in 93.8% of the motixafortide patients compared with 83.3% of the placebo patients and consisted of pain (local injection site, bone and back), flushing, pruritus, erythema, nausea and hypokalemia. Grade 3 TEAEs were reported in 27.5% of motixafortide patients compared with 4.8% in placebo subjects.

Another important observation from the trial was the improvement in healthcare resource utilization, as fewer apheresis days and procedures were required. Based on these data reported in the article, a single injection of motixafortide added to G-CSF substantially improves upon approved mobilization regimens. Favorable aspects include the rapidity, robustness and reliability of hematopoietic stem and progenitor cell mobilization for autologous hematopoietic stem cell transplantation in patients newly diagnosed with multiple myeloma following modern induction therapy.

Exhibit I – GENESIS Study Design[2]

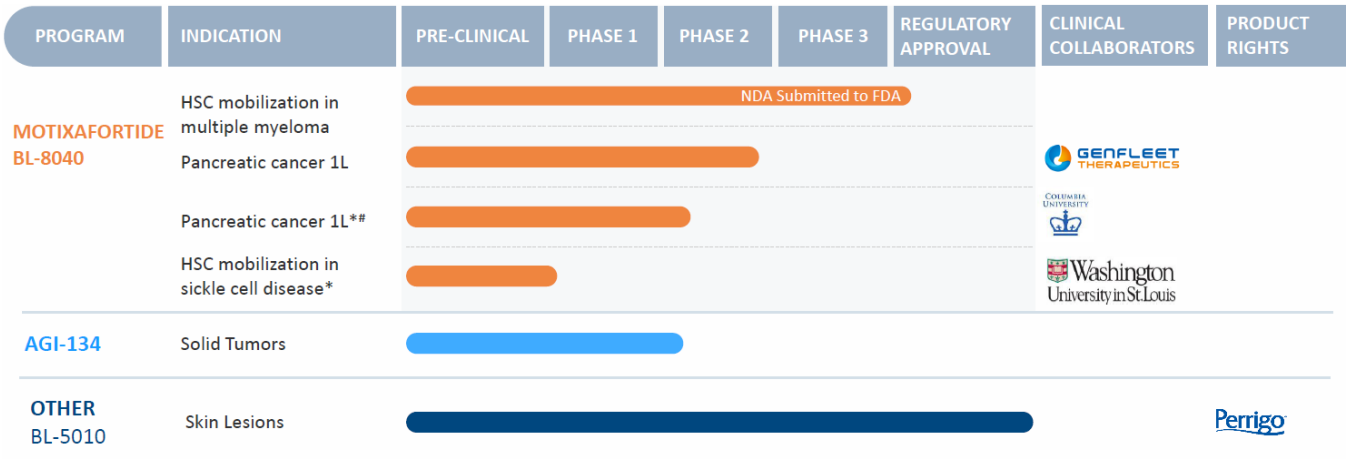


AGI-134

In January 2022, the AGI-134 trial completed enrollment and by year end, results were announced. The study met its primary safety and tolerability endpoint. An immune response and markers of clinical efficacy were assessed as secondary endpoints. Most patients analyzed showed an increase in Alpha-Gal antibodies, indicating increased overall immune activity. Additionally, increases in antigen presenting cells were observed in most tissue samples analyzed. T cell and macrophage tumor infiltration was seen in approximately one-third of evaluable patients' injected tumors and in approximately half of evaluable patients' lesions not injected. Radiological assessments found that 29% (11/38) of patients in the trial achieved best overall response of stable disease. BioLineRx plans to seek publication of the data at a medical congress in 2023, and in consultation with its scientific advisory board, it will determine the next steps for the program in the 1H:23.

[1] Crees, Z.D., Rettig, M.P., Jayasinghe, R.G. et al. Motixafortide and G-CSF to mobilize hematopoietic stem cells for autologous transplantation in multiple myeloma: a randomized phase 3 trial. Nat Med 29, 869–879 (2023).
[2] BioLineRx July 2023 Corporate Presentation.

Exhibit II – BioLineRx Pipeline[3]



Upcoming Milestones

- Motixafortide, Phase II (Columbia) PDAC study data release – 2023
- Presentation of GENESIS data at medical meetings & conferences – 2023
- Data published for Phase II PDAC trial – 2H:23
- Motixafortide, Phase I in Sickle Cell Disease – 2H:23
- Motixafortide in SCM target action (PDUFA) date – September 2023
- US launch of motixafortide in SCM – 3Q:23
- Approval of Asia Licensing Agreement (Gloria) by Israeli Innovation Authority – 4Q:23
- Potential initiation of randomized Phase 2 study of AGI-134 – 2023

Summary

BioLineRx reported financial and operational results for 2Q:23 on August 30th. Highlights since our previous update include the start of the Columbia University-sponsored Phase II PDAC trial and the signing of an agreement for development and commercialization of motixafortide in Asia. All eyes remain focused on the upcoming PDUFA date, when we expect to hear from the FDA regarding Aphexda's approval. The US commercialization team is hard at work preparing for a launch and is ahead of the game, ready to leap out of the gate once FDA approval is granted. Other ongoing work includes programs with its partners including Washington University School of Medicine, and Columbia University for the advancement in its gene therapy and pancreatic oncology programs respectively.

The market for Aphexda is sizable with approximately 23,000 stem cell transplants taking place per year in the United States. About 59% of these are autologous and 90% are in multiple myeloma (MM) and lymphomas with about 65% of the autologous MM and lymphoma patients appropriate for the therapy. BioLineRx' second indication for motixafortide is in pancreatic cancer which is being developed in Phase II trials. There is also a substantial opportunity to support collection of stem cells for gene therapy. We maintain a valuation of $6.00 per share.

[3] BioLineRx May 2023 Corporate Presentation.

PROJECTED FINANCIALS

BioLineRx Ltd. - Income Statement[4]

BioLineRx	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US '000)	**$0**	**$0**	**$0**	**$0**	**$1,149**	**$1,149**	**$22,575**	**$34,340**
YOY Growth							1865%	52%
Cost of Revenues	$0	$0	$0	$0	$295	$295	$938	$1,327
Product Gross Margin					74%	74%	95%	96%
Research & Development	$17,629	$3,684	$3,006	$2,600	$2,600	$11,890	$10,000	$12,500
Sales & Marketing Expense	$6,462	$3,874	$5,604	$4,500	$5,000	$18,978	$19,200	$19,650
General & Administrative Expense	$5,066	$1,298	$1,305	$1,905	$492	$5,000	$5,175	$5,356
Income from operations	($29,157)	($8,856)	($9,915)	($9,005)	($7,238)	($35,014)	($12,738)	($4,493)
Non-operating Income, Net	$5,670	($2,916)	($7,733)	$0	$0	($10,649)	$0	$0
Financial Expenses	($2,158)	($927)	($1,337)	($350)	($350)	($2,964)	($1,400)	($1,400)
Financial Income	$694	$537	$440	$400	$380	$1,757	$1,225	$500
Pre-Tax Income	($24,951)	($12,162)	($18,545)	($8,955)	($7,208)	($46,870)	($12,913)	($3,093)
Net Income	**($24,951)**	**($12,162)**	**($18,545)**	**($8,955)**	**($7,208)**	**($46,870)**	**($12,913)**	**($3,093)**
Net Margin								
Reported EPS	**($0.03)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.01)**	**($0.00)**
Basic Shares Outstanding	773,957	922,959	922,959	926,485	928,882	925,321	927,450	930,000

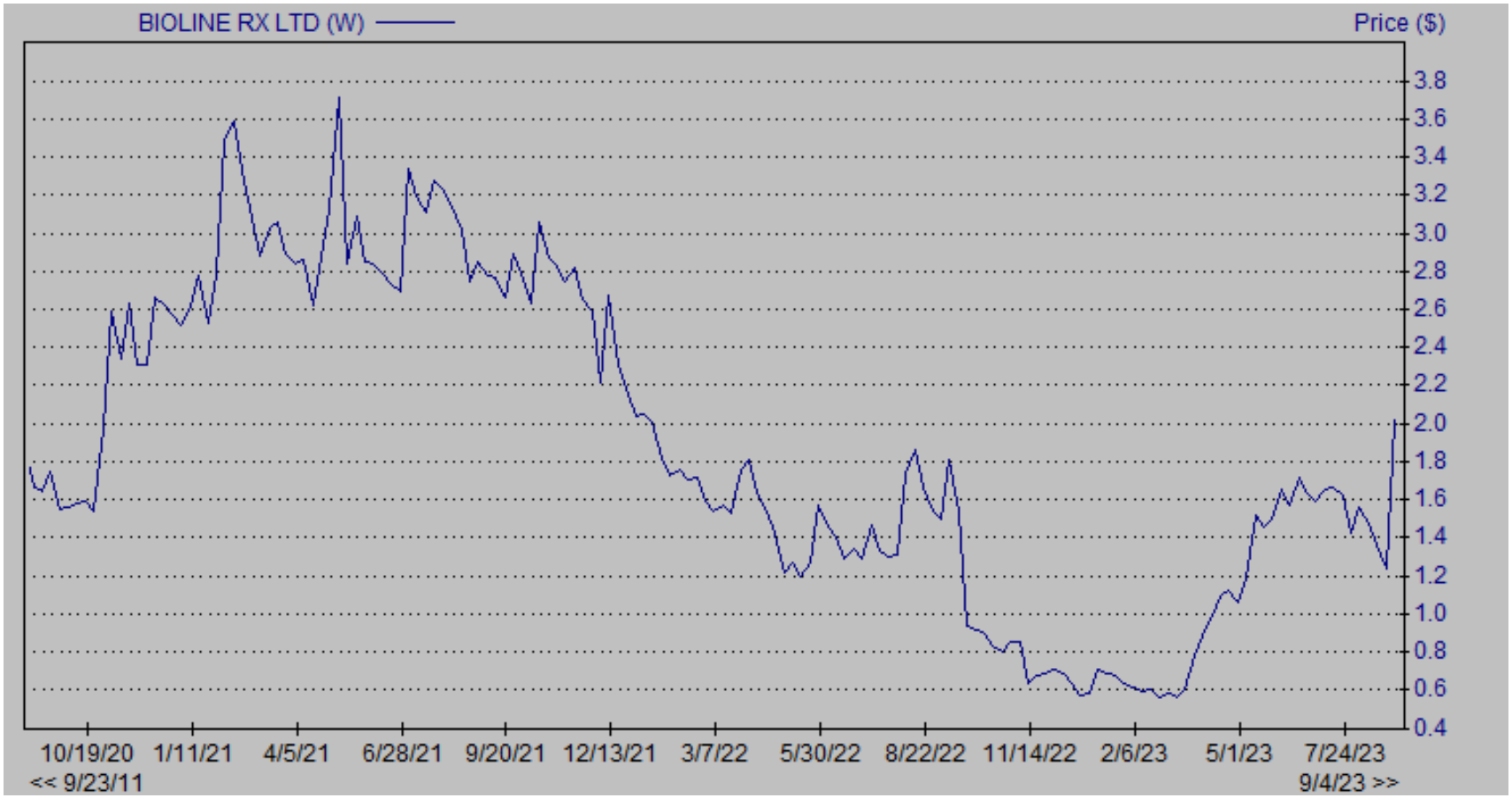
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

BioLineRx Ltd. – Share Price Chart[5]



[5] Source: Zacks Research System

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