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BioLineRx Ltd. (BLRX: NASDAQ)

BLRX: A Series of Fortunate Events

We employ a DCF model and a 15% discount rate to determine our valuation. Regarding ultimate approval and commercialization success, our model applies a 25% probability to motixafortide in PDAC & a 50% probability to SCM in Asia. For AGI-134, we apply a 12% probability to the solid tumor program. Estimates include contributions from the United States, Asia and Rest of World.

Current Price (11/20/2023)	$1.70
Valuation	**$7.60**

OUTLOOK

BioLineRx is a commercial stage biopharmaceutical company with a development portfolio advancing motixafortide, a platform molecule targeting indications in stem cell mobilization 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. FDA approval was granted in 2023 with further approvals expected overseas in the coming years.

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	**2.53**
52-Week Low	**0.55**
One-Year Return (%)	**158**
Beta	**1.1**
Average Daily Volume (sh)	**1,192,053**
Shares Outstanding (mil)	**72.0**
Market Capitalization ($mil)	**122.4**
Short Interest Ratio (days)	**1.0**
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 A	$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	-$0.02 A	-$0.01 E	-$0.06 E
2024					-$0.01 E
2025					$0.00 E

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WHAT'S NEW

3Q:23 Operational and Financial Results

Activity stepped up substantially following BioLineRx Ltd.'s (NASDAQ: BLRX) report of second quarter results. Shortly after the report, the FDA approved Aphexda and BioLineRx announced the closing of the Asia deal with Gloria Biosciences. Data for the collaboration with Columbia University in pancreatic cancer was also in the spotlight with early results shared at AACR. Now as we wind down the year, BioLineRx reports third quarter results and indicates early success with the Aphexda launch in US markets. The National Comprehensive Cancer Network (NCCN) has included Aphexda as part of the guidelines for hematopoietic cell transplantation. Management also noted that the American Society for Transplantation and Cellular Therapy (ASTCT) is updating guidelines to reflect the availability of Aphexda. These changes should accelerate adoption. First revenues are expected in 4Q:23.

BioLineRx exits 2023 in a very strong position with several advantages. A successful start to the Aphexda launch in the United States, formalization of an agreement with a dominant partner in Asia driving development of motixafortide in multiple indications, internal development of a portfolio offering multiple programs and two candidates supported by a healthy, nearly two-year cash position. Successful achievements to date and our positive view support an increase in our valuation to $7.60 per share.

Third quarter results were announced on November 20, 2024 highlighting recent successes related to the APHEXDA launch. A conference call was held with management along with the filing of Form 6-K providing additional information.

Below we summarize financial results for the three-month period ended September 30, 2023, compared to the same prior year period:

- Research and development expenses totaled $2.7 million, down 38% from $4.4 million, on account of lower expenses related to the new drug application (NDA) supporting activities related to Aphexda and lower expenses associated with the completed AGI-134 study;
- Sales and marketing expenses were $8.1 million, up 517% from $1.3 million on account of initiation of pre-commercialization activities related to Aphexda;
- General and administrative (G&A) expenses were $1.5 million, up 8% from $1.4 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 ($3.1) 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 ($0.5) million which was impacted by interest paid on loans partially offset by interest received from cash balances;
- Net loss was ($16.0) million compared with ($6.8) million, or ($0.01) and ($0.01) per share respectively.

Cash, equivalents and short-term bank deposits as of September 30, 2023 totaled $26.0 million, down from the year end 2022 balance of $51.1 million. 3Q:23 cash burn was ($9.9) million and cash flows from financing were $3.5 million related to share capital and warrant exercise. The substantial increase in cash burn year to date reflects the aggressive effort to prepare for the approval of Aphexda and launch the product. 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 Gloria Biosciences in Asia has contributed to cash balances in the amount of almost $30 million, which is expected to fund operations into 2025. We expect year end 2023 cash balances to be around $50 million.

FDA Approval of Aphexda

On September 11th, BioLineRx Ltd. (NASDAQ: BLRX) announced FDA approval of Aphexda, its stem cell mobilization product for autologous transplantation in multiple myeloma. The product was the 36th novel drug approved for 2023. Based on the strong data generated in the Phase III GENESIS trial, we had high expectations for approval and were not disappointed. Management made a considerable effort to prepare for commercialization of Aphexda and has assets in place to build relationships with payors and providers including a medical affairs scientific exchange, preparation for journal publication and medical service liaison (MSL) engagement.

Management provided additional detail on pricing for the product, with a targeted list of $5,900 per vial. The amount of product required is based on weight and, on average, two vials are expected to be required for each patient's collection with an administration of Aphexda sufficient to produce stem cells for a second apheresis session if needed. Now that the label has been finalized, product packaging is taking place. Quality assurance checks will be performed and shipping to a third-party logistics center will occur as Aphexda makes its way to transplant centers.

The commercialization team is in discussions with payors for coverage and reimbursement and BioLineRx is engaging leading physicians in the specialty to educate the community. The team has identified the top centers around the United States which represent more than 85% of autologous transplants. Customer targeting has been even more refined based on local need which could be based on apheresis unit capacity and low yields to identify those most receptive to the product and the benefits it brings. Centers that were involved in the GENESIS trial will be among the first to see the product given their familiarity with it.

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 evaluate 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. This builds on an adaptive single arm study that allows for expansion if data is 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.

Motixafortide at AACR

A poster entitled A phase 2 study with combination chemotherapy (gemcitabine and nab-paclitaxel), chemokine (C-X-C) Motif receptor 4 inhibitor (motixafortide), and immune checkpoint blockade (cemiplimab) in metastatic treatment-naïve pancreas adenocarcinoma was presented at the American Society of Clinical Oncology special conference on pancreatic cancer. The related oral presentation was given on September 28th, 2023 in Boston. The poster and presentation summarized results from the Phase II clinical trial evaluating motixafortide in combination with the PD-1 inhibitor cemiplimab and chemotherapy in first line pancreatic cancer. Columbia University sponsored the trial and recently expanded its scope due to favorable results in the first evaluated patients.

The open label, multicenter, single-arm pilot study evaluated 11 patients. Six achieved a partial response of which four were confirmed partial responses and one resolved the hepatic metastatic lesion. Three patients experienced stable disease. Preliminary results yielded a partial response rate of 55% and disease control rate of 82%, which compares to benchmark rates of 23% and 48% respectively. The study will advance to a Phase II trial with a targeted 108 subjects and a primary endpoint of progression free survival.

Asia License Agreement

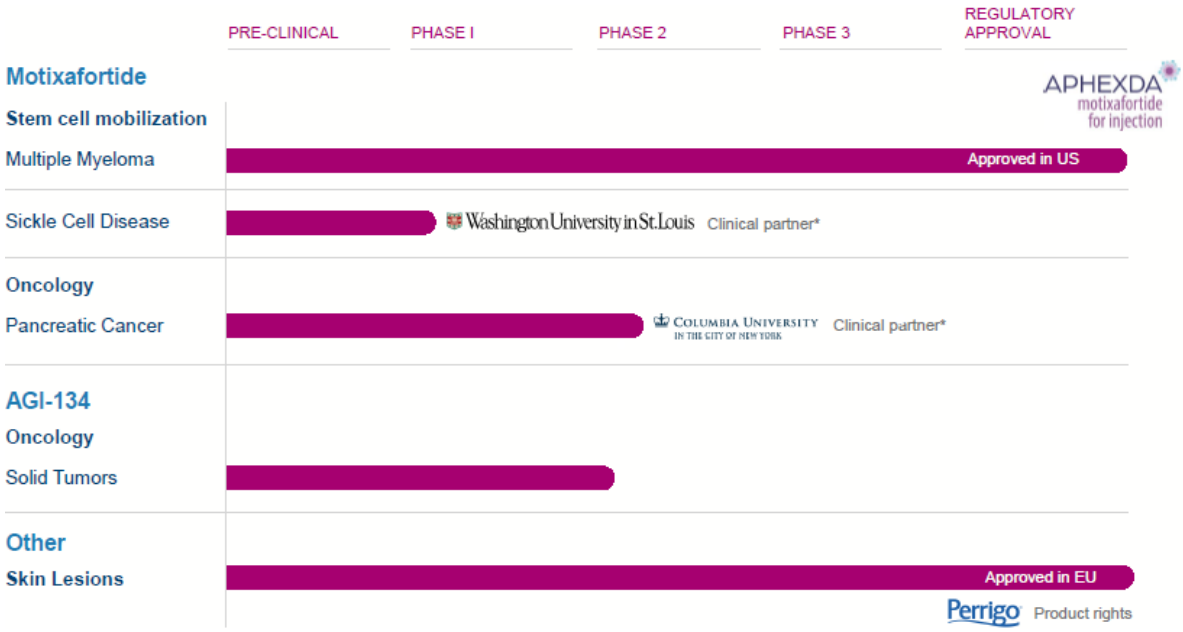
In late August, BioLineRx announced that it had signed an exclusive license agreement to develop and commercialize motixafortide in Asia along with an equity investment from two partners. Features of the arrangement include:

- $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) and did not include warrants. 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, which occurred and was announced on October 12th. While only select financial details were made 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.

Additional details in the Form 6-K filing describe the arrangement more fully, 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. Further discussion of the arrangement is available in the filing.

Exhibit I – BioLineRx Pipeline[1]



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 launch in Sickle Cell Disease – 2H:23
- Motixafortide in SCM target action (PDUFA) date – September 2023
- US launch of motixafortide in SCM – 3Q:23
- Gloria Biosciences strategic equity investment – October 2023
- Approval of Asia Licensing Agreement (Gloria) by Israeli Innovation Authority – 4Q:23
- ASH poster presentation: Aphexda in Transplant Centers – December 10, 2023
- Start of Gloria Biosciences' stem cell mobilization bridge study – 2024
- Start of Gloria Biosciences' 1st line pancreatic cancer study (motixafortide & zimberelimab) - 2024
- Launch motixafortide and anti-PD-1 combination study - 2024
- Potential initiation of randomized Phase 2 study of AGI-134 – 2024
- Sickle Cell Disease Phase I readout – 2H:24

[1] BioLineRx September 2023 Corporate Presentation.

Valuation

The closing of the licensing arrangement with Gloria Biosciences calls for a re-evaluation of our valuation. Our model adds the probability-adjusted development and commercialization of motixafortide in Asia. BioLineRx has already recognized almost $30 million in upfronts and equity investments from the partner and may receive additional milestones and royalties in the future. Development, regulatory and commercial milestones have been quantified up to $250 million while royalties range from 10 to 20% depending upon revenue levels. We anticipate that required studies to obtain approval in China for stem cell mobilization will take place in 2024 and that regulatory submission will take place in 2025. This places Gloria on track to generate first sales in 2026. We assume that the total economic value of future milestones and royalties will total 36% of sales and use this figure to generate the royalty revenues that will be recognized by BioLineRx in our model. We estimate a 50% overall probability of commercial and regulatory success (PoS) for stem cell transplant in China. This increases our overall weighted PoS to 66% and our valuation to $7.60 per share.

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 the best overall response of stable disease. In consultation with its scientific advisory board, BioLine will determine the next steps for the program in the 1H:23.

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 3Q:23 on November 20th. Highlights since our previous update in mid-September include the presentation of data from the Columbia University-sponsored Phase II PDAC trial at AACR and the closing of the licensing arrangement with Gloria Biosciences. Management commentary suggests that the launch of Aphexda is achieving early goals and contact has been made with key transplant centers. The NCCN guidelines recognize Aphexda which should provide a strong impetus for it to be used in transplant work. Development is underway in a number of areas including internal work for motixafortide in pancreatic cancer and partner work with Washington University and its sickle cell disease gene therapy program. BioLine's second development candidate, AGI-134, is in Phase II and next steps for the program will be determined in 2024.

BioLine's approval and finalized partnership are positive catalysts that support our valuation increase. We reflect the development and commercialization of motixafortide in Asia for stem cell mobilization. Additional upside is possible in pancreatic and other cancers depending upon registrational trial success. The recognition of the opportunity in Asia increases our valuation to $7.60 per share.

PROJECTED FINANCIALS

BioLineRx Ltd. - Income Statement[2]

BioLineRx	2022 A	Q1 A	Q2 A	Q3 A	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	$2,727	$2,600	$12,017	$10,000	$12,500
Sales & Marketing Expense	$6,462	$3,874	$5,604	$8,131	$7,000	$24,609	$19,200	$19,650
General & Administrative Expense	$5,066	$1,298	$1,305	$1,499	$898	$5,000	$5,175	$5,356
Income from operations	($29,157)	($8,856)	($9,915)	($12,357)	($9,644)	($40,772)	($12,738)	($4,493)
Non-operating Income, Net	$5,670	($2,916)	($7,733)	($3,141)	$0	($13,790)	$0	$0
Financial Expenses	($2,158)	($927)	($1,337)	($837)	($350)	($3,451)	($1,400)	($1,400)
Financial Income	$694	$537	$440	$312	$380	$1,669	$1,225	$500
Pre-Tax Income	($24,951)	($12,162)	($18,545)	($16,023)	($9,614)	($56,344)	($12,913)	($3,093)
Net Income	**($24,951)**	**($12,162)**	**($18,545)**	**($16,023)**	**($9,614)**	**($56,344)**	**($12,913)**	**($3,093)**
Reported EPS	**($0.03)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.01)**	**($0.06)**	**($0.01)**	**($0.00)**
Basic Shares Outstanding	773,957	922,959	922,959	929,059	1,080,000	963,744	1,100,000	1,150,000

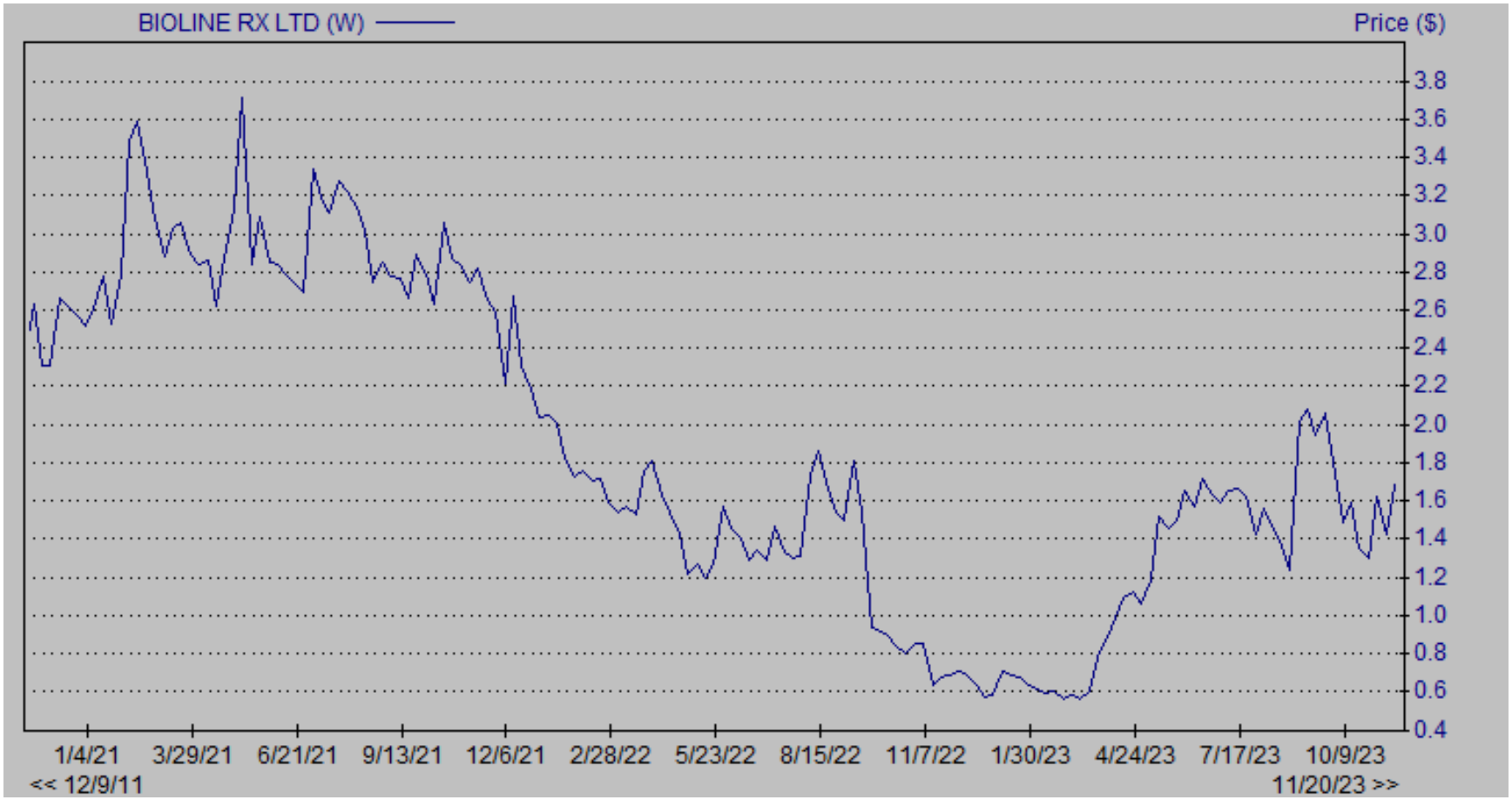
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

BioLineRx Ltd. – Share Price Chart[3]



[3] Source: Zacks Research System

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