Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
December 3, 2024
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

BioLineRx Ltd. (BLRX: NASDAQ)

BLRX: Ayrmid Assumes Commercialization Efforts

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. AGI-134 has been discontinued. Estimates include contributions from the United States, Asia and Rest of World.

Current Price (12/3/2024)	$0.28
Valuation	**$2.70**

OUTLOOK

BioLineRx is a commercial stage biopharmaceutical company with a development portfolio advancing motixafortide, a platform molecule targeting indications in stem cell mobilization (SCM) & in the treatment of advanced pancreatic cancer. The candidate is approved in the US for SCM and is undergoing studies for use in gene therapy and in pancreatic cancer. Partner Gloria Biosciences is developing motixafortide in Asia & is expected to be conducting bridging studies in the near term for SCM & longer-term studies for other indications. In Asian jurisdictions where FDA approval is recognized, first sales may be recognized in 2024. Ayrmid has assumed commercialization activities in the US.

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. Commercialization is underway in the United States.

SUMMARY DATA

52-Week High	**1.89**
52-Week Low	**0.25**
One-Year Return (%)	**-81.3**
Beta	**0.9**
Average Daily Volume (sh)	**761,247**
Shares Outstanding (mil)	**96.5**
Market Capitalization ($mil)	**27.0**
Short Interest Ratio (days)	**2.4**
Institutional Ownership (%)	**3.1**
Insider Ownership (%)	**8.5**
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-Biomed/Gene**

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	$4.8 A	$4.8 A
2024	$6.9 A	$5.4 A	$4.9 A	$6.9 E	$24.1 E
2025					$2.3 E
2026					$7.7 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.01 A	-$0.02 A	-$0.02 A	-$0.01 A	-$0.06 A
2024	-$0.00 A	$0.00 A	-$0.00 A	-$0.01 E	-$0.01 E
2025					-$0.01 E
2026					-$0.01 E

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

WHAT'S NEW

A few days prior to its third quarter earnings report, BioLineRx Ltd. (NASDAQ: BLRX) announced a commercialization agreement with Ayrmid Ltd. and its subsidiary Gamida Cell Ltd. BioLineRx will grant Ayrmid rights to commercialize Aphexda (motixafortide) across all indications except in solid tumors and in all territories except Asia. The arrangement will provide a $10 million upfront payment to BioLineRx, royalties ranging from 18% to 23% and the potential for $87 million in commercial milestones. After a transition period, BioLineRx' expenses are expected to decline by about 70% as the company reverts to a research and development firm.

The announcement of the arrangement with Ayrmid was followed by the third quarter earnings report where total revenues reached $4.9 million and net loss was ($5.8) million. Aphexda revenues were down sequentially to $1.7 million and lower than expected expenses across the board, especially sales and marketing led to the less severe-than-expected loss which was about 60% of what we had forecast.

Other achievements of note since our last update include BioLine's launch of the "Mobilization Matters" digital resource for multiple myeloma patients, a new US Patent Office allowance for a motixafortide patent and announcement an oral presentation at the American Society of Hematology (ASH) Annual Meeting in December.

3Q:24 Operational and Financial Results

BioLineRx achieved third quarter 2024 sales of $4.9 million producing a net loss of ($5.8) million or ($0.00) per share. Ignoring non-operating income, net loss was ($5.4) million. The results were announced in a press release on November 25, 2024 followed by a conference call with management and the filing of Form 6-K providing additional information.

Below we summarize financial results for the three-month period ended September 30, 2024, compared to the same prior year period:

- Revenues were $4.9 million representing a portion of the upfront and milestone payment from Gloria Biosciences of $3.2 million and Aphexda product revenues of $1.7 million versus $0. Aphexda reached 10% market share of total CXCR4 inhibitor usage in the United States. Institutions ordering the drug increased by 40% in the third quarter;
- Cost of revenues was $0.8 million which largely represents a pass through to license-holder Biokine as a royalty on motixafortide revenues. Amortization of intangible assets is also included in cost of revenues. Product gross margin relating to Aphexda sales was 95.2%;
- Research and development expenses totaled $2.6 million, down 6% from $2.7 million, on account of lower expenses related to the termination of the AGI-134 program and a decrease in payroll and share-based compensation;
- Sales and marketing expenses were $5.5 million, down 32% from $8.1 million as a result of commercialization activities related to Aphexda including the addition of new sales personnel and a fully hired field team;
- General and administrative (G&A) expenses were $1.4 million, down 7% from $1.5 million due to small decreases in a number of expense categories;
- Non-operating expense was $756,000 million reflecting changes in fair-value adjustments of warrant liabilities on the balance sheet;
- Net financial expenses amounted to ($1.2) million as financial expenses of ($1.6) million related to the BlackRock loan were partially offset by financial income of $0.4 million from bank deposit interest;
- Net loss was ($5.8) million compared with ($16.0) million, or ($0.00) and ($0.02) per share respectively.

Cash, equivalents and short-term bank deposits as of September 30, 2024 totaled $29.2 million, down from the year end 2023 balance of $43.0 million. Cash burn for the first nine months was ($35.3) million and net cash from financing was $21.8 million. Financing cash contributions came from issuance of share capital and warrants as well as net proceeds from the loan agreement with BlackRock. After the end of the quarter and in conjunction with the commercialization deal with Ayrmid, BioLineRx received a $9 million equity investment and used these proceeds along with the $10 million milestone from Ayrmid to reduce the BlackRock debt by $16.5 million. Following the announced transactions as of the report of third quarter results, estimated cash and equivalents are $20 million, which is seen to be sufficient to support operations into 2026.

Commercialization Agreement with Ayrmid Pharma

On November 21st, BioLineRx announced an exclusive license agreement with Ayrmid Pharma Ltd., the parent company of Gamida Cell, where Ayrmid will assume commercialization rights for Aphexda in stem cell mobilization. The deal provides a $10 million upfront payment, commercial milestones for sales and additional regulatory approvals totaling $87 million and royalties ranging from 18% to 23%. Ayrmid gains rights in all geographies excluding Asia[1] in all indications excluding solid tumor indications.[2] Along with the Ayrmid agreement, BioLineRx raised an additional $9 million equity investment with Highbridge Capital that will be used to reduce debt.[3]

Ayrmid's subsidiary, Gamida Cell, will execute the commercialization effort. Gamida Cell is now marketing Omisirge, a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood. The product is indicated for use in patients with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. BioLineRx is taking advantage of the substantial overlap between the target market for Aphexda and Omisirge. BioLineRx will separate its US commercialization subsidiary headed by President Holly May and transfer about a third of the team to Gamida Cell to continue its activities. The transition of the Aphexda commercialization activities from BioLineRx to Gamida Cell is expected to take place over the next month or so with the changeover complete by early 2025.

We see the integration into the Gamida Cell sales team as a beneficial change as the group will now have more products to offer as well as a broader reach, thereby increasing the efficiency of the marketing effort. We further see the merit in layering on a new product to an existing sales team which has developed relationships and established territories. We identify synergies in multiple product offerings as it allows representatives to frequently interact with the providers and professionals who use their products. Additionally, the incremental cost of adding one new product to the mix is minimal. BioLineRx has noted that while it has cost about $25 million to sustain the sales team to support Aphexda inside of BioLineRx, there is only a $3 to $5 million incremental cost anticipated to market Aphexda using the Gamida Cell sales force.

2H:24 Financings

On November 20, 2024, BioLineRx issued 16,471,449 ADSs or pre-funded warrants for ADSs along with 0.5 warrants for every ADS or pre-funded ADS. The units were sold at $0.5464 per ADS (or $0.5463 per pre-funded ADS warrant). The 8,235,724 regular ADS warrants have an exercise price of $0.59. The financing raised $9.0 million in gross proceeds.

Along with the Ayrmid agreement and the ADS sale, BioLineRx also amended its loan agreement with BlackRock. The loan was carried on the balance sheet at $27.8 million as of September 30, 2024. The company will pay $16.5 million of the loan with recent proceeds and future revenue-based payments will be cancelled. Other modifications as a result of the loan modification include a reduction in the required minimum cash balance to $4.0 million. The remaining debt balance will carry a fixed annual interest rate of 9.5%

Motixafortide Trials

Since December of 2023, BioLineRx partners have started dosing patients in multiple trials for motixafortide in gene therapy and PDAC. Both partners are associated with US-based universities, but the end indications are quite different. The first trial is sponsored by the Washington University School of Medicine and is evaluating motixafortide and natalizumab to mobilize CD34+ HSCs for gene therapy in sickle cell disease. The second trial is sponsored by Columbia University and is examining motixafortide treatment in combination with a checkpoint inhibitor and first line chemotherapies in PDAC. Another study was announced in May with St. Jude Children's Hospital which will evaluate motixafortide in stem cell mobilization for gene therapy in sickle cell disease.

[1] Rights to motixafortide have already been granted to Gloria Biosciences in Asia.
[2] BioLineRx will retain rights to solid tumor indications for motixafortide.
[3] Highbridge Capital is also an investor in Gamida Cell.

Washington University School of Medicine Sickle Cell Disease
In late December 2023, BioLineRx partner Washington University School of Medicine (WashU) in Saint Louis, Missouri dosed its first patient. WashU is conducting a proof-of-concept study to identify a more efficient CD34+ HSC mobilization regimen for patients with sickle cell disease (SCD). The study, registered under the NCT05618301 identifier, initially planned to enroll five patients diagnosed with SCD to assess the safety and tolerability of motixafortide alone and with natalizumab to produce HSCs for use in gene therapy. This was later increased to ten patients who will be followed for eight weeks for adverse event monitoring. The trial seeks to evaluate the safety of stem cell mobilization in sickle cell patients; however, it will not be followed by gene therapy treatment which may take place at a later time under another investigational new drug (IND) application. Data from the trial will be presented at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition taking place December 7-10, 2024 in San Diego, California. Zachary Crees, MD, from the Washington University School of Medicine will give an oral presentation entitled *Motixafortide (CXCR4 Inhibition) Alone and in Combination with Natalizumab (VLA-4 Inhibition) As a Novel Regimen to Mobilize Hematopoietic Stem Cells for Gene Therapies in Sickle Cell Disease: A First-in-Human, Proof-of-Principle Safety and Feasibility Study* on Saturday, December 7th at 12:00 pm.

Columbia University Pancreatic Adenocarcinoma
The investigator-initiated trial is a multi-center, randomized Phase IIb study evaluating motixafortide with cemiplimab, gemcitabine and nab-paclitaxel for effectiveness in treating pancreatic ductal adenocarcinoma. It combines the might of Regeneron and BioLineRx along with Columbia University in this combination drug trial. On February 28th, BioLineRx announced that the first patient had been enrolled in the CheMo4METPANC Phase II combination study. While checkpoint inhibitors have been effective in a number of cancers such as melanoma, this has not been the case for PDAC prompting investigators to examine the use of combination therapies to improve prognosis. Early pilot data was supportive of this proof-of-concept study where 64% of patients experienced a partial response and 27% experienced stable disease. Listed under NCT04543071 in the clinical trials database, the study first enrolled 11 participants to measure response rate and safety. Study objectives were met with the first group, and it is now expanding into a randomized Phase IIb study enrolling 108 participants in two arms.

Early pilot phase data were presented at the Immuno-oncology 360° Summit on February 29, 2024. Data was later presented at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting held on June 1. New analyses of paired pre- and on-treatment biopsy samples demonstrated a statistically significant increase in CD8+ T-cell density in tumors from all 11 patients treated with the combination therapy approach with a p-value of 0.007. Enrollment in the randomized trial continues with full enrollment anticipated in 2027. A prespecified interim futility analysis is planned when 40% of progression free survival (PFS) events are observed.

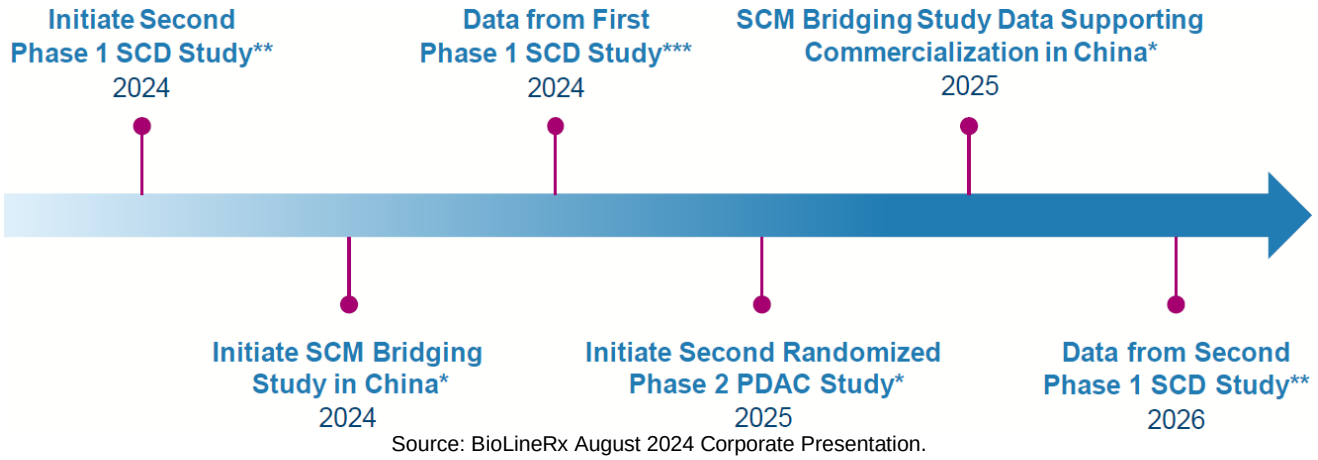
St. Jude Children's Research Hospital
On May 30th, 2024 BioLine announced that it had entered into an agreement with St. Jude Children's Research Hospital to expand clinical research of motixafortide into stem cell mobilization for sickle cell disease (SCD). The investigator-initiated study will enroll SCD patients at three clinical sites. Enrollment in the trial is expected in September with results to be shared in 2025.

The trial is designated SCDSTEMM (Sickle Cell Disease Stem Cell Mobilization and Apheresis Using Motixafortide). It will be an open-label, multi-center Phase I clinical trial evaluating the safety, tolerability and feasibility of single-agent motixafortide for the mobilization and collection of CD34+ HSCs in 12 adult patients with SCD. The trial's primary objective is to assess the safety and tolerability of motixafortide in SCD patients, as determined by the incidence of adverse events. Secondary objectives include understanding CD34+ kinetics after motixafortide administration in patients with SCD and determining the number of CD34+ HSCs collected via leukapheresis. The study is designed in two parts with equal enrollment in each arm. The first, Part A, will evaluate single dose motixafortide mobilization followed by one apheresis session. The second, Part B, will evaluate daily motixafortide administration over a two-day mobilization and apheresis regimen. Additional goals include phenotype and cell function characterization as well as assessment of the gene modifying potential and senescence of CD34+ cells.

Milestones

- IND filing for bridging study for Aphexda in China – February 2024
- Motixafortide PDAC trial first patient dosed – February 2024
- USPTO Notice of Allowance: Process for Manufacturing Peptide – March 2024
- Response to IND filing for Aphexda bridging study in China – May 2024
- Nasdaq notification of non-compliance with bid price minimum – May 2024
- Sickle Cell trial with St. Jude announced – May 2024
- Gloria Biosciences' IND submission for PDAC study – 2024
- Preliminary results from investigator initiated COVID trial (Israel) - 2024
- Start of Gloria Biosciences' stem cell mobilization bridging study – 2H:24
- St. Jude first sickle cell patient anticipated dosing – September 2024
- Launch of Mobilization Matters digital resource – September 2024
- Annual meeting of shareholders – October 2024
- Ayrmid commercialization agreement – November 2024
- Participation in ASH on motixafortide in sickle cell disease – December 2024
- Gloria Biosciences' PDAC study launch – 1H:25
- Gloria Biosciences' bridging study launch – 1H:25
- Gloria Biosciences' bridging study data report – 2025
- St. Jude sickle cell initial data – 2025
- Data from St. Jude Phase I sickle cell study - 2026
- Full enrollment for Columbia University PDAC - 2027

Exhibit I – Milestones



Source: BioLineRx August 2024 Corporate Presentation.

Valuation

We update our valuation for BioLineRx to reflect the commercialization agreement with Ayrmid, the elimination of the internal sales and marketing team as well as related expenses and changes in capital structure. By early 2025, we expect the majority of commercialization activities will have transitioned to Ayrmid. As outlined in recent press releases and 6-K filings, BioLineRx will receive up to $87 million in commercial milestones and a tiered royalty ranging from 18% to 23%. We modify our model to reflect the change from an in-house commercialization effort to a royalty revenue model for US-based sales of motixafortide. Other regions were already modeled using royalty-based structures for revenue generation of motixafortide. Neither the break points for the higher tiers of royalties nor the sales targets needed to earn the anticipated milestones were disclosed. Therefore, we assume a percentage of sales at the lowest royalty tier plus 200 basis points to reflect milestone values less the 10 percentage points owed to Biokine as a pass through. This produces a 10% net royalty to BioLineRx. While this may understate the profile of the arrangement, we will adjust as more information becomes available.

Aphexda sales in the United States are expected to reach $22.6 million in 2025 and rise to $37.3 million by 2027. We expect continued market penetration in subsequent years. Company management has guided towards a 70% reduction in operating expenses following the wind down of the BioLineRx USA commercialization arm. We remove all sales and marketing expenses and reduce general and administrative expenses, reflecting the company's anticipated structure as a research and development company. Other contributors to royalty revenues include motixafortide sales in China for both pancreatic cancer and stem cell mobilization. We also forecast royalty revenues for the same indications in the EU and broader Europe including the UK. The net result of our adjustments generates a valuation of $2.70 per share.

Summary

BioLineRx made a surprise announcement prior to its third quarter report announcing that it had signed a licensing agreement with Ayrmid to commercialize Aphexda in all indications except solid tumors worldwide except for Asia. The deal takes advantage of Gamida Cell's salesforce, which has established itself commercializing Omisirge, a product with a near 90% marketing overlap with Aphexda. BioLineRx will maintain rights to developing motixafortide in solid tumors, specifically PDAC, for which it has several trials with partners underway. The agreement frees up BioLineRx to return to its research and development roots and seek new products to advance. The BioLineRx team is now stronger and more experienced in the realm of research, development and regulatory process and brings this asset to the table as it seeks new candidates. With a competency in oncology and early-stage clinical trials, we anticipate that the company will find a Phase I or Phase II ready asset in the solid tumor space to add to its pipeline. With milestones and royalty revenues expected from multiple sources over the next years, the company has improved its profile and will be less reliant on capital markets to fund its R&D activities. We update our valuation to reflect the company's new financial and revenue generation profile. Our valuation is $2.70 per share, representing approximately 9x upside.

PROJECTED FINANCIALS

BioLineRx Ltd. - Income Statement[4]

BioLineRx	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US '000)	**$4,800**	**$6,855**	**$5,393**	**$4,943**	**$6,920**	**$24,111**	**$2,256**	**$7,689**
YOY Growth						402%	-91%	
Cost of Revenues	$3,692	$1,455	$897	$822	$1,301	$4,475	$0	$0
Product Gross Margin						46%	100%	100%
Research & Development	$12,519	$2,494	$2,225	$2,565	$3,020	$10,304	$8,250	$9,940
Sales & Marketing Expense	$25,270	$6,342	$6,415	$5,553	$8,691	$27,001	$0	$0
General & Administrative Expense	$6,310	$1,386	$1,629	$1,390	$1,725	$6,130	$5,217	$5,400
Other	$6,703	$0	$0	$0	$0	$0	$0	$0
Income from operations	($49,694)	($4,822)	($5,773)	($5,387)	($7,817)	($23,799)	($11,211)	($7,650)
Non-operating Income, Net	($10,819)	$4,490	$7,807	$756	$0	$13,053	$0	$0
Financial Expenses	($2,169)	($929)	($2,085)	($1,625)	($1,141)	($5,780)	($3,913)	($5,000)
Financial Income	$2,068	$565	$535	$434	$275	$1,809	$500	$0
Pre-Tax Income	($60,614)	($696)	$484	($5,822)	($8,683)	($14,717)	($15,124)	($12,650)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($60,614)**	**($696)**	**$484**	**($5,822)**	**($8,683)**	**($14,717)**	**($15,124)**	**($12,650)**
Reported EPS	**($0.06)**	**($0.00)**	**$0.00**	**($0.00)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**
Basic Shares Outstanding	963,366	1,086,586	1,197,583	1,199,486	1,206,421	1,172,519	1,250,000	1,300,000

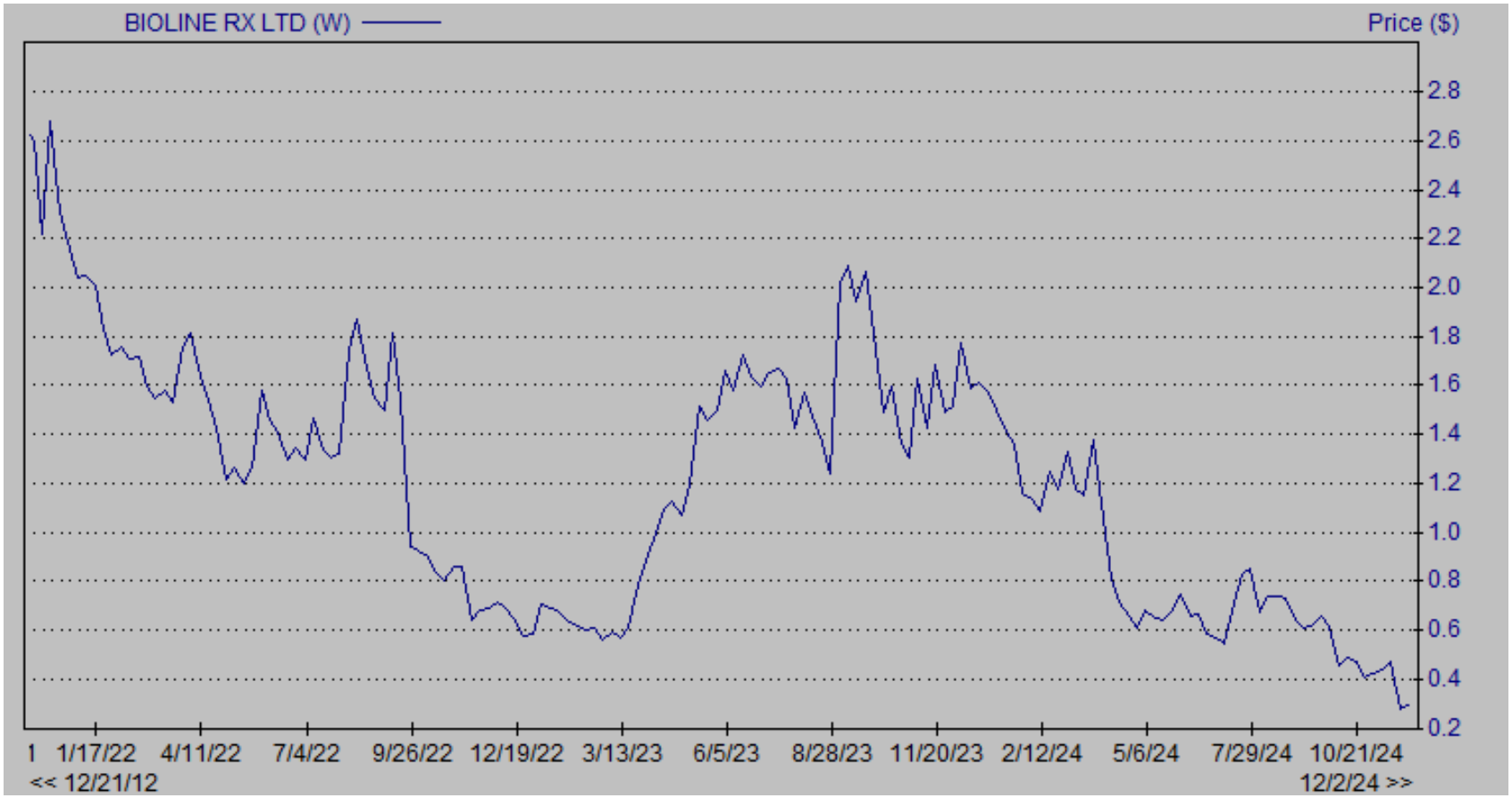
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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

HISTORICAL STOCK PRICE

BioLineRx Ltd. – Share Price Chart[5]



[5] Source: Zacks Research System

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, from an investment manager 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. Fees typically range between ten thousand and fifty thousand dollars per annum. This research report was prepared under the aforementioned engagement.

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.

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