Zacks Small-Cap Research
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BioLineRx Ltd. (BLRX: NASDAQ)

September NDA

Based on our DCF model and a 15% discount rate, BioLineRx is valued at approximately $6.00 per share. 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. The model includes contributions from the United States and Rest of World.

Current Price (11/1/2022)	$0.85
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. A pre-NDA meeting with the FDA was held, to be followed by a mid-2022 NDA submission and commercialization in 2023, if approved.

The second pipeline candidate, AGI-134, is a synthetic α-Gal glycolipid that is pursuing an indication in cancer immunotherapy for solid tumors and is currently in an open-label study in the UK and Israel with results expected in 2H:22.

SUMMARY DATA

52-Week High	**3.02**
52-Week Low	**0.76**
One-Year Return (%)	**-70.0**
Beta	**1.54**
Average Daily Volume (sh)	**264,395**
Shares Outstanding (mil)	**61.5**
Market Capitalization ($mil)	**52.3**
Short Interest Ratio (days)	**0.46**
Institutional Ownership (%)	**3.0**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2023					$3.8 E
2024					$14.6 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.02 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2022	-$0.01 A	-$0.01 A	-$0.01 E	-$0.01 E	-$0.03 E
2023					-$0.02 E
2024					-$0.01 E

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WHAT'S NEW

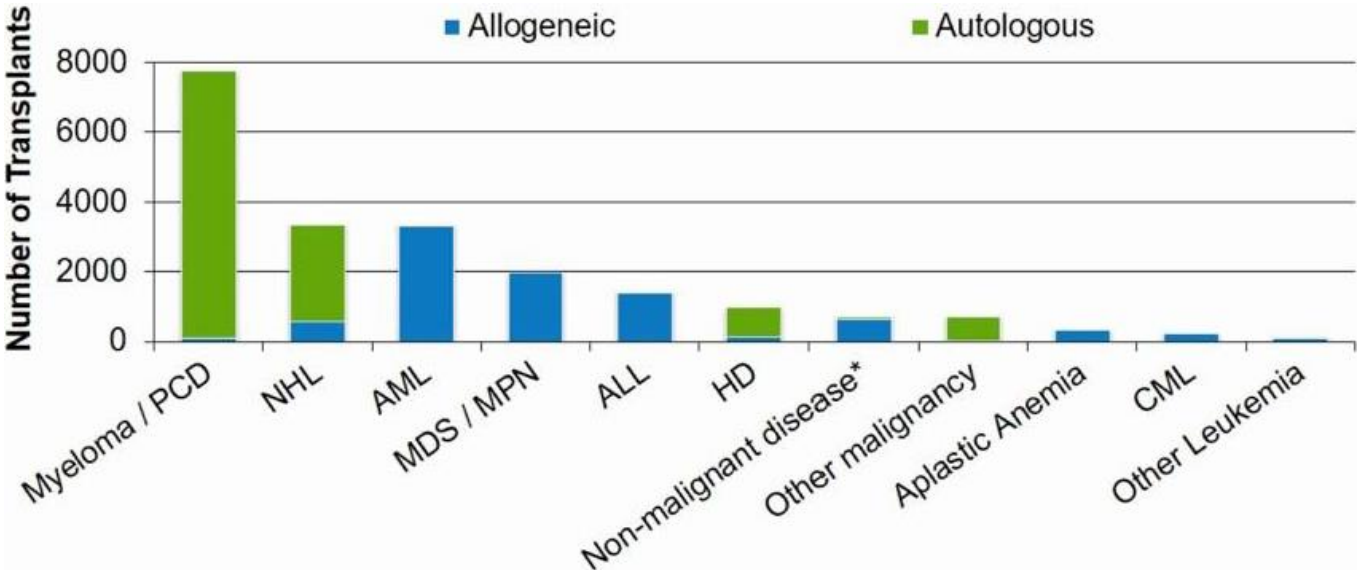
Commercialization Plans for Motixafortide (APHEXDA®)

BioLineRx Ltd. (NASDAQ: BLRX) submitted its New Drug Application (NDA) to the FDA on September 9, 2022 for Motixafortide (now branded Aphexda) in stem cell mobilization for multiple myeloma patients undergoing autologous bone marrow transplantation. Since then, BioLineRx has undertaken significant pre-commercialization activities and presented a plan to advance commercialization of Aphexda in the United States. On September 27, BioLineRx held a webinar to explain Aphexda's position in stem cell mobilization, shared details of the apheresis process with a specialized nurse and a patient/caregiver who underwent the procedure and provided a review of the anticipated commercialization plan for Aphexda.

The webinar began with an introduction by CEO Phil Serlin who introduced the participants including the KOL, Dr. John DiPersio. He is Chief of the Division of Oncology, Washington University School of Medicine, St. Louis and was the principal investigator for the GENESIS trial. Dr. DiPersio began his presentation with an explanation of hematopoietic stem cell (HSC) transplantation. HSC transplantation requires stem cell mobilization from the bone marrow into the blood circulation where the stem cells can be collected and set aside for use after treatment for blood cancer in a process called apheresis. Following chemotherapy treatment, the stem cells are returned to the bloodstream where they home in to the bone marrow and repopulate, providing the basis for the patient's post-treatment immune system. One of the difficulties of this procedure is that five to eight days are required to collect sufficient stem cells using the standard agent, granulocyte colony stimulating factor (G-CSF). Other shortcomings related to G-CSF include bone pain and inability to use in all disease types.

Dr. DiPersio continued his presentation and quantified the number of HSC transplantations conducted per year, which exceeded 14,000 autologous and reached almost 10,000 allogeneic transplants in the United States for 2020. There are other opportunities to use SCM, including those in gene therapy that may increase demand to an even greater extent. The leading indications for HSC transplantation include multiple myeloma, non-Hodgkins lymphoma and acute myeloid leukemia among others.

Exhibit I – Indications for HSC Transplantation (United States)[1]

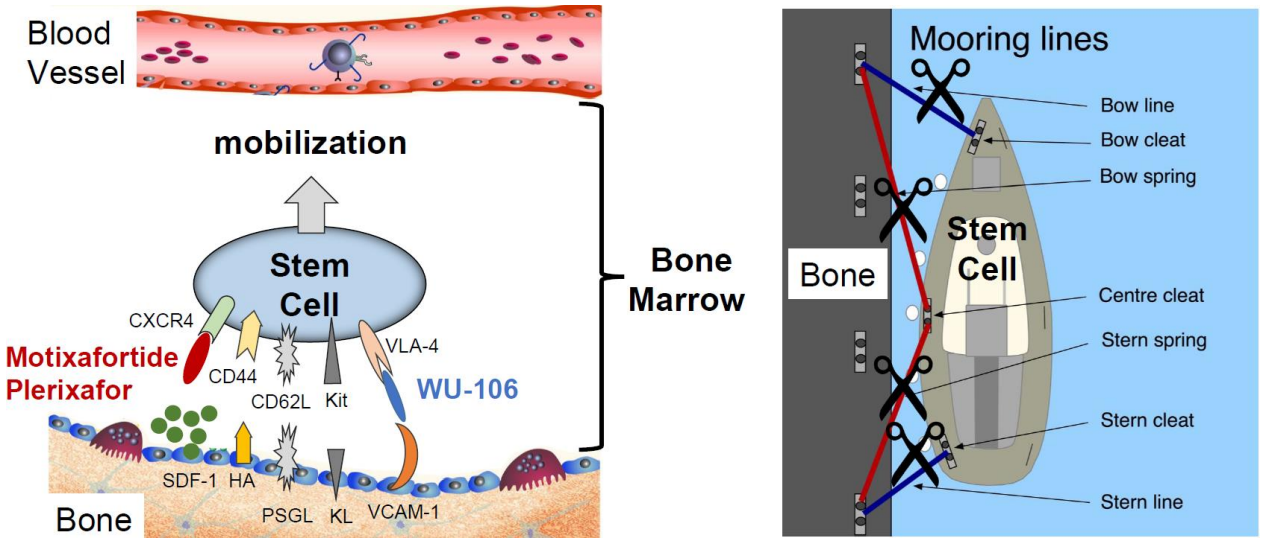


The most engaging part of Dr. DiPersio's presentation was his explanation of the mechanism of action for stem cell mobilization agents. There are numerous ligand-receptor interactions between stem cells and the perivascular niche which hold stem cells in place. For the stem cell to be mobilized into the bloodstream, the connection between the two must be broken. Several of these ligand-receptor pairs are illustrated in the following illustration. They are similar to mooring lines used to secure a boat to the pier, which must be released before the vessel can

[1] Source: BioLineRx Corporate Presentation, September 2022 KOL Event.

depart. Motixafortide is able to break the bonds or mooring lines, allowing the stem cells to drift away from the bone marrow and into circulation, where they later can be collected via apheresis.

Exhibit II – Stem Cells and Mooring Lines[2]



Commercialization Plans

With the approval of Motixafortide (now branded Aphexda) on the horizon, BioLineRx is undergoing a significant effort to prepare for commercialization. BioLineRx had initially considered two commercialization models: out-license to a commercial partner and self-commercialization. In many cases when a large salesforce is needed for a non-differentiated product, using a partner is an attractive route. However, for Aphexda, which is substantially more effective than existing standard of care and targets a limited number of transplant centers that will be the predominant users of the product, self-commercialization has many elements in its favor. BioLineRx will be able to maintain a higher percentage of the profits, maintain control over market development, field a small and effective sales team and make a compelling economic case to physicians and health systems for the product. Other favorable factors include the established manufacturing and distribution partners that will support the commercialization effort.

Holly May, President and Chief Commercial Officer, highlighted several of the activities that are already underway in preparation for first sales. Efforts that require a long lead time including manufacturing, distribution, licensing, pricing and stakeholder relationships are being developed. Presence of BioLineRx USA in the Boston area provides access to a talent pool for managing the sales process and finding medical affairs specialists.

At this point it is unknown if the FDA will consider Aphexda's New Drug Application (NDA) under Priority Review or a standard review. A Priority designation is associated with a six month rather than a ten-month review and if granted would produce a target action date that is expected to be in 2Q:23.

BioLineRx is putting all of its efforts forward to be able to launch within a couple weeks of an FDA approval. In preparation for this, there are relationship building programs which include a medical affairs scientific exchange, preparation for journal publication and medical service liaison (MSL) engagement.

Management is relying on the strong efficacy and economic case for Aphexda. Using the product can improve efficiencies for apheresis unit scheduling and increase throughput. This is addition to the quality-of-life benefit for a patient who will likely be able to complete their procedure in one day rather than three or four. The obstacles faced by multiple myeloma patients were made clear in the webinar segment that interviewed patient and caregiver Mary and Albert Quarterman where transportation, lodging, separation from family and additional responsibilities make each successive day incrementally harder. Aphexda's ability to obtain sufficient cells in one day for 90% of patients can dramatically reduce the burden on all stakeholders.

Over the long term there are opportunities to expand into peripheral indications such as autologous stem cell-based gene therapies, allogeneic transplants and other blood cancers and conditions. BioLineRx will not initially pursue these indications; however, physicians may elect to use the product anyway.

[2] Source: BioLineRx Corporate Presentation, September 2022 KOL Event.

Upcoming Milestones

- BL-8040 NDA submission for stem cell mobilization (SCM) – September 2022
- AGI-134 Phase I/IIa initial results - 2H:22
- Presentation of GENESIS data at medical meetings & conferences – 2022/2023
- Phase II combination study of motixafortide with GenFleet - 2023
- Potential FDA approval of motixafortide (priority review) – 2Q:23
- Potential FDA approval of motixafortide (standard review) – 3Q:23
- US launch of motixafortide in SCM – 2023
- Potential initiation of randomized Phase 2 study of AGI-134 – 2023

Valuation

BioLineRx announced a $40 million debt agreement with Kreos Capital in September and immediately drew down the facility by $10 million. Additional tranches may be drawn upon the achievement of pre-specified milestones. The company also issued $15 million in shares in a registered direct offering for 13.6 million American Depositary Shares (ADSs) and 13.6 million ADS warrants with an exercise price of $1.15. The share and warrant combination was issued at $1.10. Net proceeds from the issuance will be used for the commercial launch of motixafortide (Aphexda) and for working capital. We adjust our per share valuation to reflect the change in capital structure noting that our enterprise value for the company remains the same. Adding the new shares and debt to our valuation model generates a target price of $6.00 per share.

Summary

BioLineRx participated in a KOL and commercialization plan investor meeting which featured Dr. John DiPersio, the principal investigator for the GENESIS trial. The event also included BioLineRx' Patient Advocacy Lead, Lissa Gray and President and Chief Operating Officer, Holly May. These individuals reviewed the hematopoietic stem cell mobilization ecosystem, the mechanism of action for motixafortide, real world patient experience in an apheresis unit and the company's commercialization plans.

Following a September NDA submission, BioLineRx expects to receive approval from the FDA in either 2Q:23 or 3Q:23 depending on whether the agency considers the application under expedited or regular submission standards. We see BioLineRx' motixafortide, now branded Aphexda, as a substantial improvement over existing approaches for stem cell mobilization for multiple myeloma patients. The potential market for Aphexda is much broader than autologous mobilization for multiple myeloma patients, however, and can expand into other blood cancers, allogeneic treatments and gene therapy to name a few. Additional opportunity also exists overseas, especially in Europe, which is expected to be developed by a partner.

The market for motixafortide 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 and lymphomas with about 65% of the autologous multiple myeloma and lymphoma patients appropriate for the therapy. BioLineRx' second indication for motixafortide is in pancreatic cancer which is being developed in Phase II trials. We calculate a valuation of $6.00 for BioLineRx' shares.

PROJECTED FINANCIALS

BioLineRx Ltd. - Income Statement[3]

BioLineRx	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US '000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$3,820**	**$14,619**
Research & Development	$19,466	$4,435	$5,395	$3,800	$3,200	$15,400	$18,250	$19,500
Sales & Marketing Expense	$1,003	$637	$1,158	$225	$225	$2,245	$880	$880
General & Administrative Expense	$4,308	$1,007	$1,049	$1,170	$1,203	$4,429	$5,000	$5,175
Income from operations	($24,777)	($6,079)	($7,602)	($5,195)	($4,628)	($22,074)	($20,310)	($10,936)
Non-operating Income, Net	($1,830)	$1,268	$458	$0	$0	$1,726	$420	$425
Financial Expenses	($1,006)	($186)	($379)	($120)	($100)	($785)	$0	$0
Financial Income	$559	$67	$80	$50	$50	$247	$100	$0
Pre-Tax Income	($27,054)	($4,930)	($7,443)	($5,265)	($4,678)	($20,886)	($19,790)	($10,511)
Net Income	**($27,054)**	**($4,930)**	**($7,443)**	**($5,265)**	**($4,678)**	**($20,886)**	**($19,790)**	**($10,511)**
Net Margin								
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.02)**	**($0.01)**
Basic Shares Outstanding	662,934	715,156	715,366	825,250	925,000	795,193	926,300	927,450

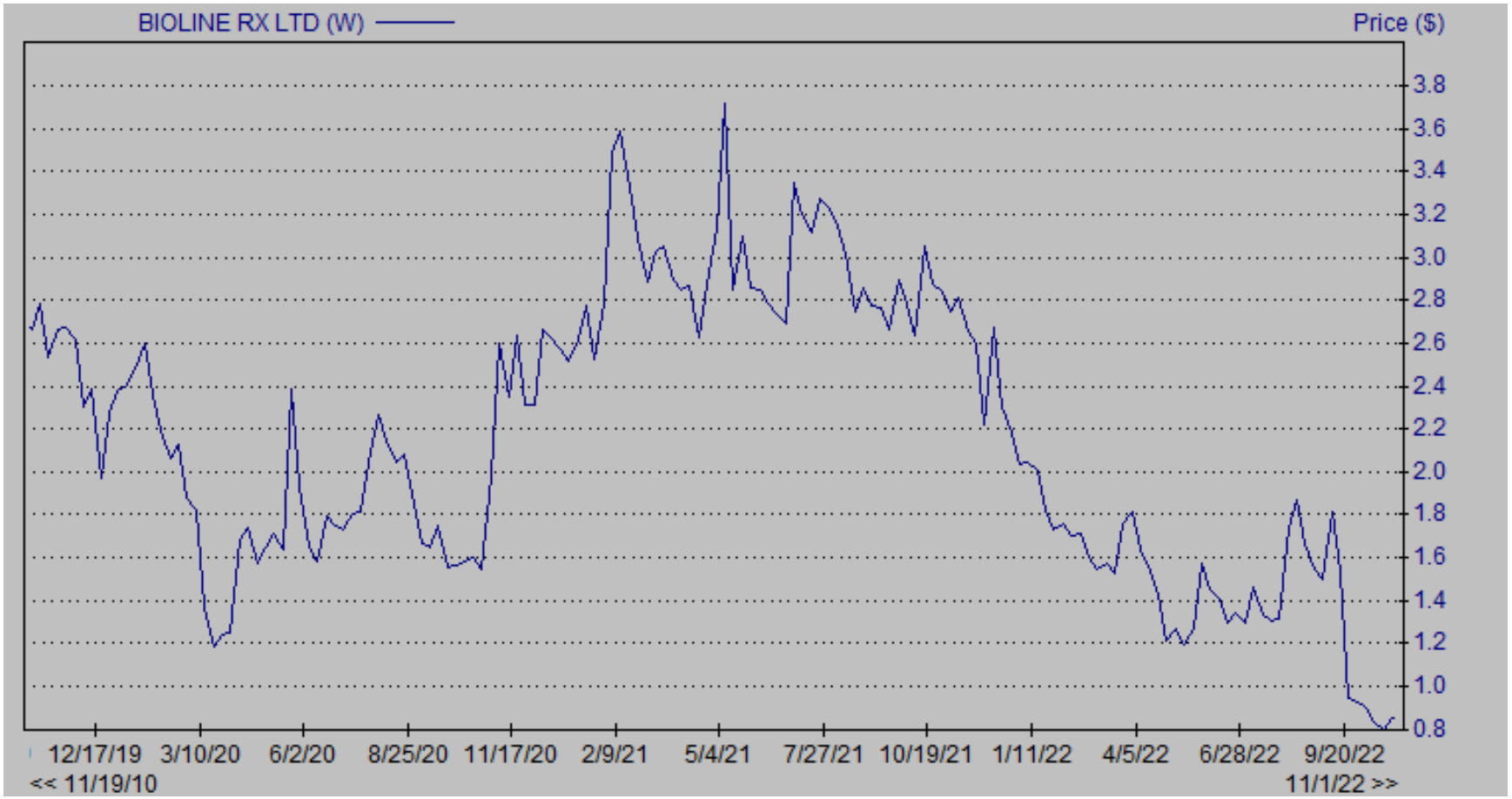
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

BioLineRx Ltd. – Share Price Chart[4]



[4] Source: Zacks Research System

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