Zacks Small-Cap Research
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September 14, 2023
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BioLineRx Ltd. (BLRX: NASDAQ)

BLRX: …Go!

We employ a DCF model and a 15% discount rate to determine our valuation. Regarding ultimate approval and commercialization success, our model recognizes US approval of Aphexda and applies an 85% probability of success in the EU, an 18% probability of motixafortide success 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 (9/13/2023)	$1.66
Valuation	**$7.00**

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 and FDA approval was granted in September 2023. A commercialization agreement for motixafortide has been signed with entities in Asia pending IIA clearance.

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 (%)	**-1.2**
Beta	**1.3**
Average Daily Volume (sh)	**985,845**
Shares Outstanding (mil)	**61.5**
Market Capitalization ($mil)	**102.1**
Short Interest Ratio (days)	**3.7**
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					$19.4 E
2025					$29.4 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

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 also be among the first to see the product given their familiarity with it.

Valuation

Upon FDA approval of Aphexda, we increase our probability of success of Aphexda commercialization in the United States to 100% from 85%. Pricing is adjusted to reflect management's guidance of $5,900 per vial and the use of an average of ~2 vials per treatment. We maintain our probabilities in the EU until approval in that region and will add contributions from Asia after approval for the deal is granted by the Israeli Innovation Authority (IIA). We maintain our values for the motixafortide PDAC and AGI-134 programs. The result of our adjustment supports an increase in the valuation to $7.00 per share.

We are keeping our eye on the next valuation-driving catalyst, which is the approval of the license agreement with Guangzhou Gloria Biosciences Co., Ltd., which we discuss in further detail below. As approval for Aphexda was granted before year-end 2023, BioLineRx remains eligible for the higher royalty rates. There are also several jurisdictions in the licensed regions where commercialization may begin when FDA approval is granted, requiring only a minor bridging study and administrating filings. This suggests that first foreign revenues could begin flowing over the next few 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

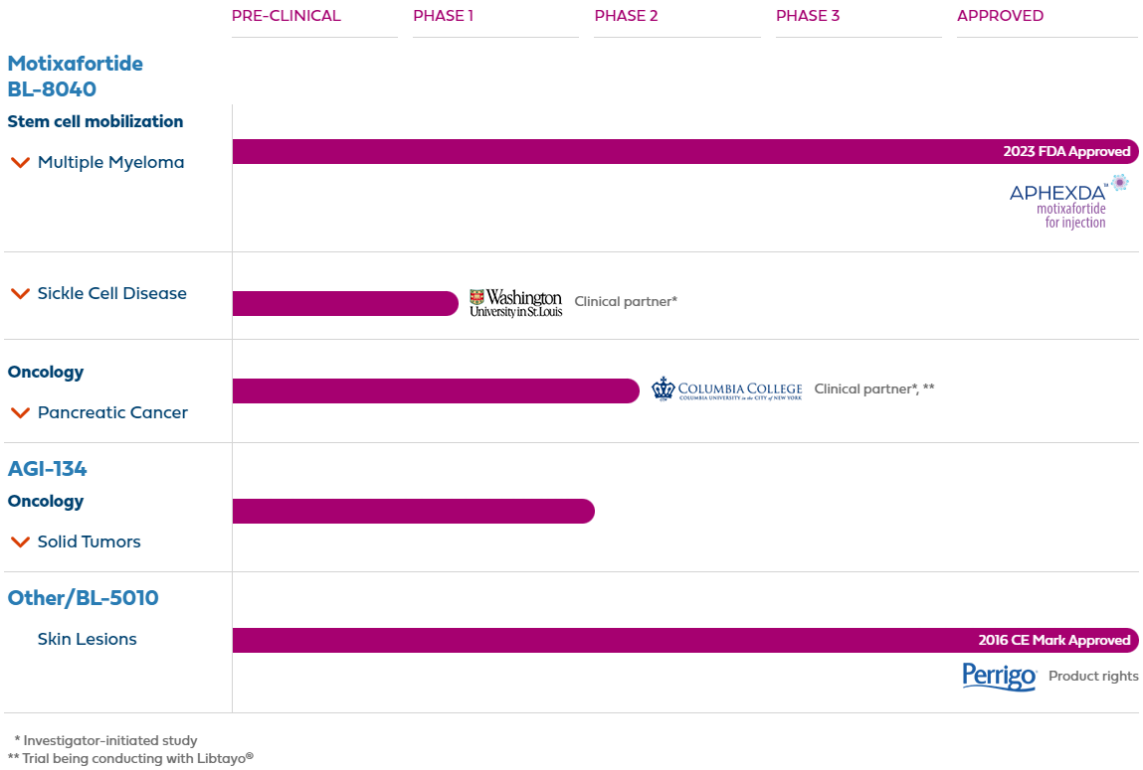
The equity investment was made at $2.136 per American Depository Share (ADS) and did not include warrants. This represents 6,829,137 shares. Other closing conditions of the transaction include the requirement that it be approved by the Israeli Innovation Authority within four months. While only select 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. 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. Further discussion of the arrangement is available in the filing.

Exhibit I – BioLineRx Pipeline[1]



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

[1] BioLineRx Corporate Website, Accessed September 2023.

Summary

BioLineRx reported its second piece of material good news in as many weeks with FDA approval of Aphexda for stem cell mobilization in multiple myeloma patients. The approval of the drug delivers additional credibility to BioLineRx' other motixafortide programs and provides a tailwind to commercialization efforts in Asia. We expect to see IIA approval for the Asia deal in the next few months and could see first ex-US revenues shortly after. Other highlights for the company include the start of the Columbia University-sponsored Phase II PDAC trial, Washington University's work on sickle cell disease and efforts advancing AGI-134 in solid tumors. The US commercialization team has been hard at work preparing for Aphexda's approval and could have first sales in the next few weeks. Based on the approval of Aphexda, we increase our valuation to $7.00 per share reflecting an increase in the probability of regulatory success to 100%.

PROJECTED FINANCIALS

BioLineRx Ltd. - Income Statement[2]

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**	**$19,350**	**$29,435**
YOY Growth							1584%	52%
Cost of Revenues	$0	$0	$0	$0	$295	$295	$804	$1,137
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)	($15,829)	($9,209)
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)	($16,004)	($7,809)
Net Income	**($24,951)**	**($12,162)**	**($18,545)**	**($8,955)**	**($7,208)**	**($46,870)**	**($16,004)**	**($7,809)**
Net Margin								
Reported EPS	**($0.03)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.02)**	**($0.01)**
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

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

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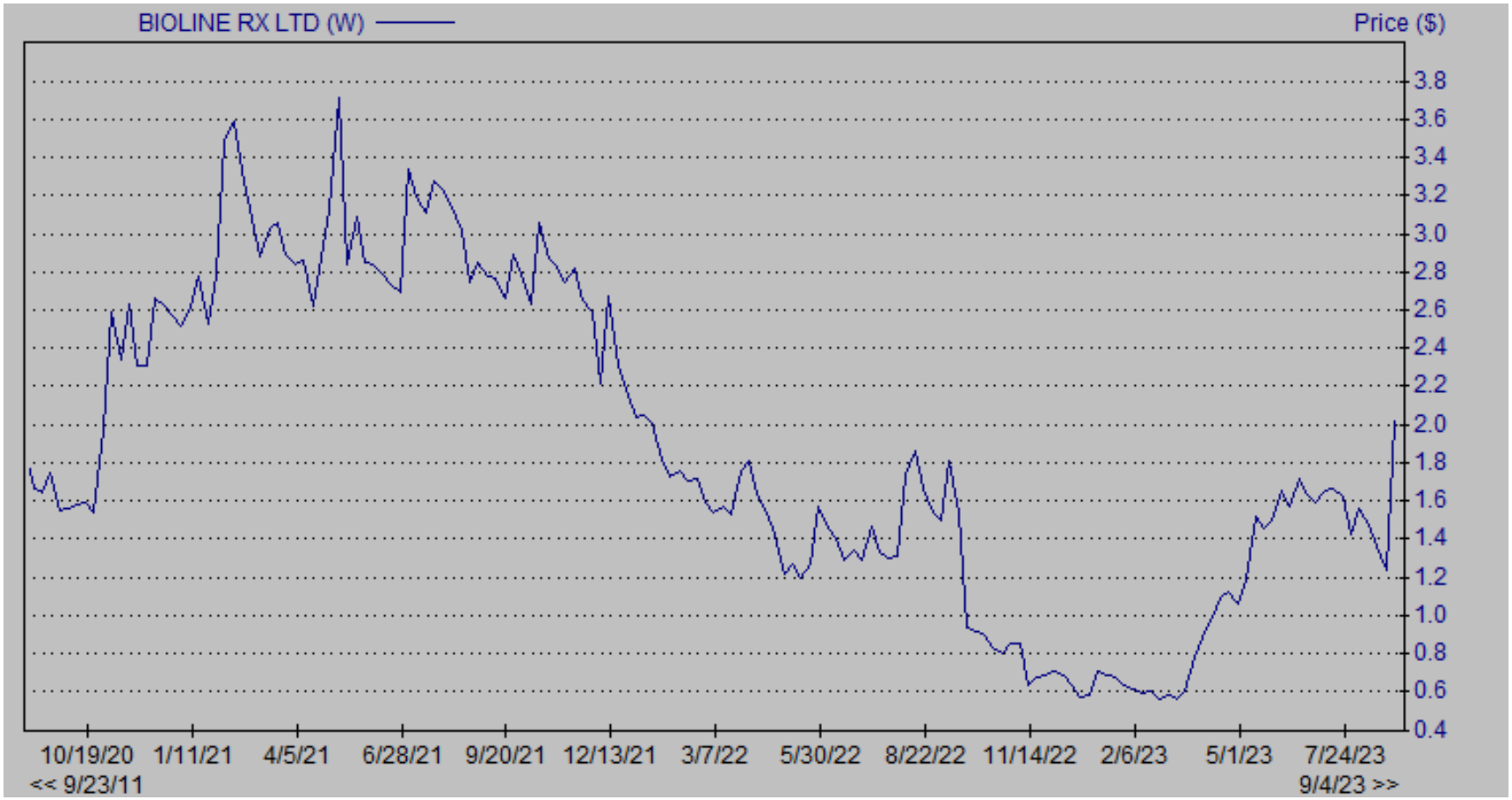
HISTORICAL STOCK PRICE

BioLineRx Ltd. – Share Price Chart[3]



[3] Source: Zacks Research System

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