



BioLineRx Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 18, 2021 11:00 AM IDT

- Company actively preparing for an NDA submission for Motixafortide in stem cell mobilization targeted for H1 2022 -

- Cash and cash equivalents of \$66 million at June 30, 2021 -

- Management to hold conference call today, August 18, at 10:00 am EDT -

TEL AVIV, Israel, Aug. 18, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended June 30, 2021 and provides a corporate update.

Significant events and achievements during the second quarter 2021 and subsequent period:

- Announced positive topline results from GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization (SCM). The data demonstrate that the study successfully met all primary and secondary endpoints with an exceptionally high level of statistical significance ($p < 0.0001$), including approximately 90% of patients who mobilized enough cells for transplantation with only one administration of Motixafortide and in only one apheresis session.
- Based on the positive results from the GENESIS study, the Company is aggressively proceeding with activities in support of an NDA submission in stem cell mobilization anticipated in the first half of 2022, including a pre-NDA meeting with the FDA planned for the second half of this year. This is consistent with prior guidance.
- Continued to advance a pharmacoeconomic cost effectiveness study of Motixafortide in SCM to establish Motixafortide as the new standard-of-care mobilization agent (in combination with G-CSF). The aim of the study is to demonstrate the cost benefits related to the use of Motixafortide, due to a reduction in the number of doses of G-CSF and apheresis sessions required, a reduction in the number of rescue therapies required, higher rates of transplantation, and quality-of-life benefits in Motixafortide-treated patients; initial data on track to be announced in the second half of this year.
- Ended the second quarter on a solid financial footing, with cash and cash equivalents of \$66 million.

"Following the overwhelmingly positive results from our Phase 3 GENESIS trial of Motixafortide in stem-cell mobilization that we announced in May, we are working vigorously to submit an NDA in the first half of next year," stated Philip Serlin, Chief Executive Officer of BioLineRx. "If approved, this would be transformative for BioLineRx as we would have a commercial-stage molecule in stem cell mobilization for transplantation in multiple myeloma, the standard of treatment for this disease, along with significant potential clinical utility in other cancer indications, most notably pancreatic cancer."

Mr. Serlin continued, "GENESIS has shown the ability of Motixafortide to mobilize substantially more than the target number of stem cells necessary for transplantation – in approximately 90% of cases with only one dose of Motixafortide and in one apheresis session – potentially resulting in significant clinical benefits for patients and cost savings for payers. We believe there is a compelling clinical and pharmacoeconomic case to be made for the use of Motixafortide as the new standard-of-care for all multiple myeloma patients. To that end, we are advancing a pharmacoeconomic cost effectiveness study that we believe will strongly support our case for the use of Motixafortide as the backbone of a new SCM treatment paradigm."

"In parallel with these activities, the versatility of Motixafortide demonstrated in studies to date has attracted interest from potential partners, and we continue to engage in productive discussions."

"We are very well financed with \$66 million of cash, sufficient to bring Motixafortide through potential FDA approval in stem-cell mobilization, while continuing to advance our other clinical programs, including our second asset, AGI-134, a novel agent in immunotherapy currently being investigated in a Phase 1/2a study, with initial results expected by the end of this year," concluded Mr. Serlin.

Upcoming Significant Expected Milestones:

- Results from pharmacoeconomic cost effectiveness study of Motixafortide in SCM in the

second half of 2021;

- Pre-NDA meeting with the FDA for SCM in the second half of 2021;
- Initial results from Part 2 of the Phase 1/2a trial of AGI-134 in solid tumors in the second half of 2021;
- NDA submission for SCM in the first half of 2022;
- Presentation of additional data and analyses from Phase 3 GENESIS study at future medical meetings to be determined.

Financial Results for the Quarter Ended June 30, 2021

Research and development expenses for the three months ended June 30, 2021 were \$5.1 million, an increase of \$0.5 million, or 10.8%, compared to \$4.6 million for the three months ended June 30, 2020. The increase resulted primarily from higher expenses related to NDA supporting activities for Motixafortide, an increase in payroll and related-expenses due to a company-wide salary reduction in connection with the COVID-19 pandemic in the 2020 comparable period, and an increase in expenses associated with the AGI-134 study; offset by a decrease in expenses related to the GENESIS and COMBAT clinical trials for Motixafortide, and a timing difference related to a tax credit received in respect of AGI-134. Research and development expenses for the six months ended June 30, 2021 were \$9.4 million, a decrease of \$0.6 million, or 6.4%, compared to \$10.1 million for the six months ended June 30, 2020. The decrease resulted primarily from lower expenses associated with the Motixafortide GENESIS and COMBAT clinical trials and a timing difference related to a tax credit received in respect of AGI-134; offset by higher expenses related to Motixafortide NDA supporting activities and by an increase in payroll and related-expenses due to a company-wide salary reduction in connection with the COVID-19 pandemic in the 2020 comparable period.

Sales and marketing expenses for the three months ended June 30, 2021 were \$0.3 million, an increase of \$0.1 million, or 81.3%, compared to \$0.2 million for the three months ended June 30, 2020. The increase resulted primarily from consultancy services related to Motixafortide. Sales and marketing expenses for the six months ended June 30, 2021 were \$0.5 million, an increase of \$0.1 million, or 35.6%, compared to \$0.4 million for the six months ended June 30, 2020. The reason for the increase is similar to the aforementioned increase in the three-month period.

General and administrative expenses for the three months ended June 30, 2021 were \$1.0 million, an increase of \$0.3 million, or 40.3%, compared to \$0.7 million for the three months ended June 30, 2020. The increase resulted primarily from an increase in directors' and officers' insurance. General and administrative expenses for the six months ended June 30, 2021 were \$2.1 million, an increase of \$0.1 million, or 3.7%, compared to \$2.0 million for the six months ended June 30, 2020. The reason for the increase is similar to the aforementioned increase in the three-month period.

The Company's operating loss for the three months ended June 30, 2021 amounted to \$6.5 million, compared to an operating loss of \$5.6 million for the comparable period in 2020. The Company's operating loss for the six months ended June 30, 2021 was \$12.0 million, compared to \$12.4 million for the comparable period in 2020.

Non-operating expenses for the three and six months ended June 30, 2021 and for the three and six months ended June 30, 2020 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial expenses for the three months ended June 30, 2021 amounted to \$0.1 million compared to net financial expenses of \$0.4 million for the three months ended June 30, 2020. Net financial expenses for the six months ended June 30, 2021 amounted to \$0.3 million compared to net financial expenses of \$0.6 million for the six months ended June 30, 2020. Net financial expenses for all periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits.

The Company's net loss for the three months ended June 30, 2021 amounted to \$6.8 million, similar to the comparable period in 2020. The Company's net loss for the six months ended June 30, 2021 amounted to \$17.0 million, compared with a net loss of \$13.4 million for the comparable period in 2020. The increase in net loss between the six-month periods results from an increase in 2021 non-operating expenses in connection with fair-value adjustments of warrant liabilities on the Company's balance sheet.

The Company held \$66 million in cash, cash equivalents and short-term bank deposits as of June 30, 2021.

Net cash used in operating activities was \$13.1 million for the six months ended June 30, 2021, compared with net cash used in operating activities of \$12.3 million for the six months ended June 30, 2020. The \$0.8 million increase in net cash used in operating activities between the two periods was primarily the result of changes in operating asset and liability items in the two periods, i.e., a larger increase in prepaid expenses and other receivables in 2021 versus 2020, as well as a larger decrease in accounts payable and accruals in 2021 versus 2020.

Net cash used in investing activities was \$42.3 million for the six months ended June 30, 2021, compared to net cash provided by investing activities of \$0.6 million for the six months ended June 30, 2020. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was \$56.0 million for the six months ended June 30, 2021, compared to net cash provided by financing activities of \$12.0 million for the six months ended June 30, 2020. The cash flows in 2021 primarily reflect an underwritten public offering of the Company's ADSs in January 2021, warrant exercises, and net proceeds from an ATM facility, offset by repayments of a loan from Kreos Capital. The cash flows in 2020 primarily reflect two registered direct offerings to institutional investors, net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Wednesday, August 18, 2021 at 10:00 a.m. EDT. To access the conference call, please dial +1-866-744-5399 from the US or +972-3-918-0644 internationally. The call will also be available via webcast and can be accessed through the [Investor Relations](#) page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call on the [Investor Relations](#) page of BioLineRx's website. A dial-in replay of the call will be available until August 20, 2021; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

(Tables follow)

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem-cell mobilization for autologous bone-marrow transplantation, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA[®] and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO[®] and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

For additional information on BioLineRx, please visit the Company's website at www.bioglinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on February 23, 2021. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

Contact:

Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

or

Moran Meir
LifeSci Advisors, LLC
+972-54-476-4945
moran@lifesciadvisors.com

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	<u>December 31,</u>	<u>June 30,</u>
	<u>2020</u>	<u>2021</u>
	<u>in USD thousands</u>	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	16,831	17,484
Short-term bank deposits	5,756	48,083
Prepaid expenses	152	837
Other receivables	141	668
Total current assets	<u>22,880</u>	<u>67,072</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,341	1,136
Right-of-use assets, net	1,355	1,415
Intangible assets, net	21,714	21,706
Total non-current assets	<u>24,410</u>	<u>24,257</u>
Total assets	<u>47,290</u>	<u>91,329</u>

Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,092	3,354
Accounts payable and accruals:		
Trade	5,918	5,318
Other	1,440	1,071
Lease liabilities	191	174
Total current liabilities	<u>10,641</u>	<u>9,917</u>
NON-CURRENT LIABILITIES		
Warrants	10,218	4,812
Long-term loan, net of current maturities	2,740	1,006
Lease liabilities	1,661	1,701
Total non-current liabilities	<u>14,619</u>	<u>7,519</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>25,260</u>	<u>17,436</u>
EQUITY		
Ordinary shares	9,870	20,496
Share premium	279,241	335,887
Warrants	-	975
Capital reserve	12,322	12,972
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	<u>(277,987)</u>	<u>(295,021)</u>
Total equity	<u>22,030</u>	<u>73,893</u>
Total liabilities and equity	<u><u>47,290</u></u>	<u><u>91,329</u></u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended June		Six months ended June	
	30,		30,	
	2020	2021	2020	2021
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,640)	(5,139)	(10,062)	(9,417)
SALES AND MARKETING EXPENSES	(182)	(330)	(357)	(484)
GENERAL AND ADMINISTRATIVE EXPENSES	(744)	(1,044)	(1,987)	(2,061)
OPERATING LOSS	(5,566)	(6,513)	(12,406)	(11,962)
NON-OPERATING EXPENSES, NET	(843)	(217)	(374)	(4,778)
FINANCIAL INCOME	35	130	175	247
FINANCIAL EXPENSES	(396)	(242)	(810)	(541)
NET LOSS AND COMPREHENSIVE LOSS	<u>(6,770)</u>	<u>(6,842)</u>	<u>(13,415)</u>	<u>(17,034)</u>
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.03)</u>	<u>(0.01)</u>	<u>(0.07)</u>	<u>(0.03)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>220,317,889</u>	<u>669,138,994</u>	<u>198,277,447</u>	<u>614,780,845</u>

BioLineRx Ltd.
CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	Ordinary shares	Share premium	Warrants	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total							
								in USD thousands						
BALANCE AT JANUARY 1, 2020	4,692	265,938	-	12,132	(1,416)	(247,966)	33,380							
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2020:														
Issuance of share capital, net	3,581	4,754	-	-	-	-	8,335							
Employee stock options exercised	8	224	-	(224)	-	-	8							
Employee stock options forfeited and expired	-	191	-	(191)	-	-	-							

Share-based compensation	-	-	-	922	-	-	922
Comprehensive loss for the period	-	-	-	-	-	(13,415)	(13,415)
BALANCE AT JUNE 30, 2020	<u>8,281</u>	<u>271,107</u>	<u>-</u>	<u>12,639</u>	<u>(1,416)</u>	<u>(261,381)</u>	<u>29,230</u>

	Ordinary shares	Share premium	Warrants	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2021	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2021:							
Issuance of share capital and warrants, net	8,386	37,495	975	-	-	-	46,856
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options forfeited and expired	-	143	-	(143)	-	-	-
Share-based compensation	-	-	-	832	-	-	832
Comprehensive loss for the period	-	-	-	-	-	(17,034)	(17,034)
BALANCE AT JUNE 30, 2021	<u>20,496</u>	<u>335,887</u>	<u>975</u>	<u>12,972</u>	<u>(1,416)</u>	<u>(295,021)</u>	<u>73,893</u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	Ordinary shares	Share premium	Warrants	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT APRIL 1, 2020	4,907	267,140	-	12,488	(1,416)	(254,611)	28,508
CHANGES FOR THREE MONTHS ENDED JUNE 30, 2020:							
Issuance of share capital, net	3,373	3,859	-	-	-	-	7,232
Employee stock options exercised	1	20	-	(20)	-	-	1
Employee stock options forfeited and expired	-	88	-	(88)	-	-	-
Share-based compensation	-	-	-	259	-	-	259
Comprehensive loss for the period	-	-	-	-	-	(6,770)	(6,770)
BALANCE AT JUNE 30, 2020	<u>8,281</u>	<u>271,107</u>	<u>-</u>	<u>12,639</u>	<u>(1,416)</u>	<u>(261,381)</u>	<u>29,230</u>

	Ordinary shares	Share premium	Warrants	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT APRIL 1, 2021	18,731	321,920	975	12,616	(1,416)	(288,179)	64,647
CHANGES FOR THREE MONTHS ENDED JUNE 30, 2021:							
Issuance of share capital, net	1,581	12,516	-	-	-	-	14,097
Warrants exercised	184	1,444	-	-	-	-	1,628
Employee stock options exercised	-	3	-	(1)	-	-	2
Employee stock options forfeited and expired	-	4	-	(4)	-	-	-
Share-based compensation	-	-	-	361	-	-	361
Comprehensive loss for the period	-	-	-	-	-	(6,842)	(6,842)
BALANCE AT JUNE 30, 2021	<u>20,496</u>	<u>335,887</u>	<u>975</u>	<u>12,972</u>	<u>(1,416)</u>	<u>(295,021)</u>	<u>73,893</u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	<u>Six months ended June 30,</u>	
	<u>2020</u>	<u>2021</u>
	<u>in USD thousands</u>	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(13,415)	(17,034)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,112	3,977
Net cash used in operating activities	<u>(12,303)</u>	<u>(13,057)</u>
CASH FLOWS – INVESTING ACTIVITIES		

Investments in short-term deposits	(23,751)	(58,000)
Maturities of short-term deposits	24,335	15,776
Purchase of property and equipment	(1)	(38)
Net cash provided by (used in) investing activities	<u>583</u>	<u>(42,262)</u>
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	13,411	46,856
Exercise of warrants	-	10,907
Employee stock options exercised	8	7
Repayments of loans	(1,331)	(1,648)
Repayments of lease liabilities	(121)	(122)
Net cash provided by financing activities	<u>11,967</u>	<u>56,000</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	247	681
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(21)	(28)
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u><u>5,523</u></u>	<u><u>17,484</u></u>

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

Six months ended June 30,
2020 **2021**
in USD thousands

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:

Depreciation and amortization	533	362
Exchange differences on cash and cash equivalents	21	28
Fair value adjustments of warrants	(250)	4,889
Share-based compensation	922	832
Warrant issuance costs	593	-
Interest and exchange differences on short-term deposits	(171)	(103)
Interest on loans	36	176
Exchange differences on lease liability	(8)	(26)
	<u>1,676</u>	<u>6,158</u>

Changes in operating asset and liability items:

Increase in prepaid expenses and other receivables	(146)	(1,212)
Decrease in accounts payable and accruals	(418)	(969)
	<u>(564)</u>	<u>(2,181)</u>
	<u>1,112</u>	<u>3,977</u>

Supplemental information on interest received in cash 300 39

Supplemental information on interest paid in cash 534 350

Supplemental information on non-cash transactions:

Acquisition of right-of-use asset	<u>-</u>	<u>171</u>
Exercise of warrants (portion related to accumulated fair value adjustments)	<u>-</u>	<u>10,295</u>

View original content: <https://www.prnewswire.com/news-releases/biolinerx-reports-second-quarter-2021-financial-results-and-provides-corporate-update-301357777.html>

SOURCE BioLineRx Ltd.