BioLineRx Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 16, 2022

- Submission of New Drug Application to FDA for Motixafortide in stem cell mobilization (SCM) for autologous stem cell transplantation expected within next 4-6 weeks -

- Announced appointment of commercial strategy and operations veteran Holly May as U.S.-based Chief Commercial Officer -

- Entered into collaboration agreement with GenFleet Therapeutics to advance Motixafortide in pancreatic cancer (PDAC) -

- Management to hold conference call today, August 16, at 10:00 am EDT -

TEL AVIV, Israel, Aug. 16, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today reports its financial results for the second quarter ended June 30, 2022 and provides a corporate update.

Significant events and achievements during the second quarter 2022 and subsequent period:

- Progressed the New Drug Application (NDA) for Motixafortide in stem cell mobilization (SCM), with submission to the FDA expected within the next 4-6 weeks;
- Appointed commercial strategy and operations veteran Holly May as Chief Commercial Officer, based in the U.S.;
- Continued to advance critical pre-launch activities with respect to Motixafortide commercialization in the U.S., if approved;
- Entered into a development collaboration agreement with GenFleet Therapeutics to execute a randomized Phase 2b clinical trial of Motixafortide, in combination with anti-PD1 and chemotherapy, for first-line treatment in approximately 200 pancreatic cancer (PDAC) patients in China;
- Ended the second quarter on solid financial footing, with cash and cash equivalents of $43.2 million, sufficient to fund operations, as currently planned, into the first half of 2024.

"Since our last quarterly update, we achieved significant progress across both our Motixafortide stem cell mobilization and pancreatic cancer (PDAC) programs," stated Philip Serlin, Chief Executive Officer of BioLineRx. "With respect to stem cell mobilization, we are in the final stages of preparing for submission of our NDA to the FDA. With Holly May on board as our new Chief Commercial Officer, we are rapidly advancing critical pre-launch activities while we continue to assess all of our options with respect to commercialization of Motixafortide in the U.S., if approved."

"The totality of data that we have compiled in stem cell mobilization, both clinical and pharmacoeconomic, make an extremely strong case for Motixafortide as the standard of care in this indication for all multiple myeloma patients undergoing autologous stem-cell transplantation, which is a highly concentrated end market estimated to be $360 million in the U.S. alone and growing consistently."

"In PDAC, the development collaboration agreement that we announced with GenFleet builds upon the positive results from our COMBAT/KEYNOTE-202 study, and we look forward to the initiation of a randomized Phase 2b PDAC trial next year. Importantly, this collaboration allows us to advance the development of Motixafortide in PDAC while retaining rights to the molecule across all indications and geographies."

"Finally, we are nearing a significant milestone for our second program, the anti-cancer vaccine AGI-134, with the upcoming release of proof-of-mechanism data from part 2 of a Phase 1/2a trial in solid tumors. If positive, we plan to initiate a randomized Phase 2 study next year."

"In summary, we believe we are well-positioned to deliver several meaningful potential regulatory, commercial and clinical catalysts over the next 12-18 months," concluded Mr. Serlin.

Upcoming Expected Milestones:

- Submission of NDA to FDA for Motixafortide as novel mobilization agent for multiple myeloma patients undergoing autologous stem cell transplantation in next 4-6 weeks;
- Initial results from Part 2 of Phase 1/2a trial of AGI-134 in solid tumors in H2 2022;
- Potential FDA approval of Motixafortide in 2023;
- Potential US launch of Motixafortide in SCM in 2023;
- Initiation of randomized Phase 2b study in PDAC under collaboration with GenFleet in 2023;
- Potential initiation of randomized Phase 2 study of AGI-134 in 2023.

Financial Results for the Quarter Ended June 30, 2022:

Research and development expenses for the three months ended June 30, 2022 were $5.4 million, an increase of $0.3 million, or 5.0%, compared to $5.1 million for the three months ended June 30, 2021. The increase resulted primarily from an increase in expenses associated with the AGI-134 study, offset by lower expenses associated with the completed Motixafortide GENESIS trial, as well as lower expenses related to NDA supporting activities related to Motixafortide. Research and development expenses for the six months ended June 30, 2022 were $9.8 million, an increase of $0.4 million, or 4.4%, compared to $9.4 million for the six months ended June 30, 2021. The reason for the increase is similar to the aforementioned increase in the three-month period.

Sales and marketing expenses for the three months ended June 30, 2022 were $1.2 million, an increase of $0.8 million, or 250.9% compared to $0.3 million for the three months ended June 30, 2021. The increase resulted primarily from initiation of pre-commercialization activities related to

Motixafortide, as well as an increase in market research. Sales and marketing expenses for the six months ended June 30, 2022 were $1.8 million, an increase of $1.3 million, or 270.9% compared to $0.5 million for the six months ended June 30, 2021. 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, 2022 were $1.0 million, similar to the comparable period in 2021. General and administrative expenses for the six months ended June 30, 2022 were $2.1 million, similar to the comparable period in 2021.

The Company's operating loss for the three months ended June 30, 2022 amounted to $7.6 million, compared to an operating loss of $6.5 million for the comparable period in 2021. The Company's operating loss for the six months ended June 30, 2022 was $13.7 million, compared to $12.0 million for the comparable period in 2021.

Non-operating income (expenses) for the three and six months ended June 30, 2022 and for the three and six months ended June 30, 2021 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses.

Net financial expenses for the three months ended June 30, 2022 amounted to $0.3 million, compared to net financial expenses of $0.1 million for the three months ended June 30, 2021. Net financial expenses for the 2022 period primarily relate to loan interest paid and losses recorded on foreign currency (primarily NIS) cash balances due to the strengthening of the US dollar during the period, offset by investment income earned on bank deposits. Net financial expenses for the 2021 period primarily relate to loan interest paid, offset by investment income earned on bank deposits. Net financial expenses for the six months ended June 30, 2022 amounted to $0.4 million, compared to net financial expenses of $0.3 million for the six months ended June 30, 2021. The composition of the expenses is similar to the aforementioned composition detailed in the three-month periods.

The Company's net loss for the three months ended June 30, 2022 amounted to $7.4 million, compared with a net loss of $6.8 million for the comparable period in 2021. The Company's net loss for the six months ended June 30, 2022 amounted to $12.4 million, compared with a net loss of $17.0 million for the comparable period in 2021.

The Company held $43.2 million in cash, cash equivalents and short-term bank deposits as of June 30, 2022.

Net cash used in operating activities was $11.9 million for the six months ended June 30, 2022, compared with net cash used in operating activities of $13.1 million for the six months ended June 30, 2021. The $1.2 million decrease 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 smaller increase in prepaid expenses and other receivables in 2022 versus 2021, as well as an increase in accounts payable and accruals in 2022 versus decrease in the 2021 period.

Net cash provided by investing activities was $15.1 million for the six months ended June 30, 2022, compared to net cash used in investing activities of $42.3 million for the six months ended June 30, 2021. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash used in financing activities was $1.6 million for the six months ended June 30, 2022, compared to net cash provided by financing activities of $56.0 million for the six months ended June 30, 2021. The cash flows in 2022 primarily reflect the repayments of the loan from Kreos Capital. The cash flows in 2021 primarily reflect the underwritten public offering of the Company's ADSs in January 2021, warrant exercises and 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, Tuesday, August 16 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the US or +972-3-918-0685 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 18, 2022; 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 pre-commercial-stage biopharmaceutical company focused on oncology. 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, has reported positive results from a pre-planned pharmacoeconomic study, has successfully completed a pre-NDA meeting with the FDA, 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, 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.biolinerx.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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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 and ability to access sufficient 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; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above. 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 March 16, 2022. 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.

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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2021	June 30, 2022
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	12,990	14,000
Short-term bank deposits	44,145	29,146
Prepaid expenses	127	717
Other receivables	142	240
Total current assets	57,404	44,103
NON-CURRENT ASSETS		
Property and equipment, net	952	810
Right-of-use assets, net	1,331	1,221
Intangible assets, net	21,704	21,704
Total non-current assets	23,987	23,735
Total assets	81,391	67,838
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	2,757	1,013
Accounts payable and accruals:		
Trade	5,567	7,338
Other	1,227	1,132
Current maturities of lease liabilities	168	149
Total current liabilities	9,719	9,632
NON-CURRENT LIABILITIES		
Warrants	1,859	186
Lease liabilities	1,726	1,452
Total non-current liabilities	3,585	1,638
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	13,304	11,270
EQUITY		
Ordinary shares	21,066	21,157
Share premium	339,346	339,670
Warrants	975	975
Capital reserve	13,157	13,596
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(305,041)	(317,414)
Total equity	68,087	56,568

Total liabilities and equity	81,391	67,838

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2021	2022	2021	2022
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,139)	(5,395)	(9,417)	(9,830)
SALES AND MARKETING EXPENSES	(330)	(1,158)	(484)	(1,795)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,044)	(1,049)	(2,061)	(2,056)
OPERATING LOSS	(6,513)	(7,602)	(11,962)	(13,681)
NON-OPERATING INCOME (EXPENSES), NET	(217)	458	(4,778)	1,726
FINANCIAL INCOME	130	80	247	147
FINANCIAL EXPENSES	(242)	(379)	(541)	(565)
NET LOSS AND COMPREHENSIVE LOSS	(6,842)	(7,443)	(17,034)	(12,373)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.01)	(0.03)	(0.02)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	669,138,994	715,365,554	614,780,845	715,260,781

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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, 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, 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	20,496	335,887	975	12,972	(1,416)	(295,021)	73,893

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2022	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2022:							
Issuance of share capital, net	89	177	-	-	-	-	266
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options forfeited and expired	-	135	-	(135)	-	-	-
Share-based compensation	-	-	-	586	-	-	586
Comprehensive loss for the period	-	-	-	-	-	(12,373)	(12,373)
BALANCE AT JUNE 30, 2022	21,157	339,670	975	13,596	(1,416)	(317,414)	56,568

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, 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	20,496	335,887	975	12,972	(1,416)	(295,021)	73,893

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT APRIL 1, 2022	21,066	339,444	975	13,315	(1,416)	(309,971)	63,413
CHANGES FOR THREE MONTHS ENDED JUNE 30, 2022:							
Issuance of share capital, net	89	177	-	-	-	-	266
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options forfeited and expired	-	37	-	(37)	-	-	-
Share-based compensation	-	-	-	330	-	-	330
Comprehensive loss for the period	-	-	-	-	-	(7,443)	(7,443)
BALANCE AT JUNE 30, 2022	21,157	339,670	975	13,596	(1,416)	(317,414)	56,568

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2021	2022
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(17,034)	(12,373)
Adjustments required to reflect net cash used in operating activities (see appendix below)	3,977	498
Net cash used in operating activities	(13,057)	(11,875)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(58,000)	(9,000)
Maturities of short-term deposits	15,776	24,141
Purchase of property and equipment	(38)	(62)
Net cash provided by (used in) investing activities	(42,262)	15,079
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	46,856	266
Exercise of warrants	10,907	-
Employee stock options exercised	7	2
Repayments of loan	(1,648)	(1,812)
Repayments of lease liabilities	(122)	(88)
Net cash provided by (used in) financing activities	56,000	(1,632)
INCREASE IN CASH AND CASH EQUIVALENTS	681	1,572
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	16,831	12,990
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(28)	(562)
CASH AND CASH EQUIVALENTS - END OF PERIOD	17,484	14,000

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2021	2022
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	362	314
Exchange differences on cash and cash equivalents	28	562
Fair value adjustments of warrants	4,889	(1,673)
Share-based compensation	832	586
Interest and exchange differences on short-term deposits	(103)	(142)
Interest on loan	176	68
Exchange differences on lease liability	(26)	(205)
	6,158	(490)
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(1,212)	(688)
Increase (decrease) in accounts payable and accruals	(969)	1,676
	(2,181)	988
	3,977	498
Supplemental information on interest received in cash	39	146
Supplemental information on interest paid in cash	350	217
Supplemental information on non-cash transactions:		
Acquisition of right-of-use asset	171	-
Exercise of warrants (portion related to accumulated fair value adjustments)	10,295	-

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