



BioLineRx Reports Second Quarter 2020 Financial Results and Provides Corporate Update

August 6, 2020

- On track to report three significant data readouts in next few months -

- Completes successful financings, raising gross proceeds of \$13.4 million; sufficient to reach multiple important milestones -

- Management to hold conference call today, August 6, at 10:00 am EDT -

TEL AVIV, Israel, Aug. 6, 2020 /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, 2020 and provides a corporate update.

Highlights and achievements during the second quarter 2020 and subsequent period:

- Continued to advance clinical programs, with three key data readouts in pancreatic cancer, stem cell mobilization and AML expected between now and year-end;
- Announced publication in the peer-reviewed journal *Nature Medicine* of previously disclosed biomarker and clinical data from the COMBAT/KEYNOTE-202 trial in pancreatic cancer, showing encouraging clinical activity, as well as proof-of-mechanism;
- Strengthened balance sheet with \$13.4 million in gross proceeds from two registered direct offerings.

"We continue to eagerly await important survival data from the triple combination arm of our COMBAT/KEYNOTE-202 clinical trial of motixafortide in combination with KEYTRUDA and chemotherapy in metastatic pancreatic cancer," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The compelling data on 22 patients that we reported in December give us conviction that this combination has the potential to be a real breakthrough in one of the most difficult to treat cancers. As this is an event-driven trial, we are obviously very pleased that there are still patients on study, although we now anticipate a modest delay of a few months in announcing the data from our original expectation."

"Turning to stem cell mobilization, this continues to be our most efficient path to registration. Given a significantly lower patient dropout rate than we had anticipated in our Phase 3 GENESIS trial, we now plan to conduct an interim analysis in the second half of this year. If the primary endpoint is met, we plan to immediately announce cessation of recruitment, without the need to enroll the full planned sample size. In order to maintain study blinding for all study endpoints, including those related to engraftment for a period of 100 days subsequent to transplantation, we expect to announce top-line results in the first half of 2021. At the same time, our Phase 2b BLAST consolidation study in AML is progressing, and we anticipate results from a planned interim analysis in the second half of this year."

"As we indicated last quarter, development of our second clinical candidate, AGI-134, has been impacted by COVID-19, as enrollment in the Phase 1/2a trial has been temporarily suspended. We have, however, recently begun activities to restart study recruitment and we expect data from that study in the second half of next year."

"The COVID-19 pandemic has caused significant disruptions in drug development timelines across the industry. We are pleased that we expect to report on three important and potentially value-creating data readouts by the end of the year, and with the additional \$13.4 million that we raised during the second quarter, we have the resources to reach these important milestones. We believe the broad clinical utility of motixafortide across a wide range of cancer indications that we have observed in data generated to date highlight its potential as a promising new treatment option, and we look forward to reporting these data as they become available," concluded Mr. Serlin.

Upcoming Expected 2020 and 2021 Milestones

- Overall results, including progression free survival (PFS) and overall survival (OS) data, from the COMBAT/KEYNOTE-202 Phase 2a triple combination study in the second half of this year;
- Newly planned interim analysis of the Phase 3 GENESIS registrational study in stem cell mobilization in the second half of this year. If the primary endpoint is reached, recruitment would be stopped immediately (and announced); topline data are expected in the first half of 2021;
- Interim analysis from the BLAST Phase 2b AML consolidation study during the second half of 2020, unchanged from prior guidance;
- Initial results from Part 2 of Phase 1/2a trial of AGI-134 in the second half of 2021.

Financial Results for the Second Quarter Ended June 30, 2020

Research and development expenses for the three months ended June 30, 2020 were \$4.6 million, a decrease of \$0.7 million, or 12.5%, compared to \$5.3 million for the three months ended June 30, 2019. The decrease resulted primarily from lower expenses associated with the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second quarter of 2020. Research and development expenses for the six months ended June 30, 2020 were \$10.1 million, an increase of \$0.4 million, or 3.8%, compared to \$9.7 million for the six months ended June 30, 2019. The increase resulted primarily from higher expenses associated with the motixafortide COMBAT and GENESIS clinical trials, offset by a decrease in expenses associated with the AGI-134 study.

Sales and marketing expenses for the three months ended June 30, 2020 were \$0.2 million, similar to the comparable period in 2019. Sales and marketing expenses for the six months ended June 30, 2020 were \$0.4 million, a decrease of \$0.1 million, or 25.9%, compared to \$0.5 million for the six months ended June 30, 2019. The decrease resulted primarily from a decrease in payroll and related expenses related to a decrease in share-based compensation from the 2019 period.

General and administrative expenses for the three months ended June 30, 2020 were \$0.7 million, a decrease of \$0.2 million, or 21.6% compared to \$0.9 million for the three months ended June 30, 2019. The decrease resulted primarily from a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second quarter of 2020, as well as a decrease in professional fees. General and administrative expenses for the six months ended June 30, 2020 were \$2.0 million, an increase of \$0.1 million, or 5.7%, compared to \$1.9 million for the six months ended June 30, 2019. The increase resulted primarily from an increase in share-based compensation.

The Company's operating loss for the three months ended June 30, 2020 amounted to \$5.6 million, compared to an operating loss of \$6.5 million for the three months ended June 30, 2019. The Company's operating loss for the six months ended June 30, 2020 was \$12.4 million, compared to \$12.1 million for the comparable period in 2019.

Non-operating income (expenses) for the three and six months ended June 30, 2020 and for the three and six months ended June 30, 2019 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, 2020 amounted to \$0.4 million compared to net financial expenses of \$0.3 million for the three months ended June 30, 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial expenses for the six months ended June 30, 2020 amounted to \$0.6 million compared to net financial expenses of \$0.5 million for the six months ended June 30, 2019. Net financial expenses for both 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, 2020 amounted to \$6.8 million, compared with a net loss of \$5.5 million for the comparable period in 2019. The Company's net loss for the six months ended June 30, 2020 amounted to \$13.4 million, compared with a net loss of \$11.6 million for the comparable period in 2019.

The Company held \$27.3 million in cash, cash equivalents and short-term bank deposits as of June 30, 2020.

Net cash used in operating activities was \$12.3 million for the six months ended June 30, 2020, compared with net cash used in operating activities of \$11.1 million for the six months ended June 30, 2019. The \$1.2 million increase in net cash used in operating activities during the six-month period in 2020 was primarily the result of changes in operating asset and liability items in two periods, i.e., an increase in prepaid expenses and other receivables in 2020 versus a decrease in 2019, as well as a larger decrease in accounts payable and accruals in 2020 versus 2019.

Net cash provided by investing activities was \$0.6 million for the six months ended June 30, 2020, compared to net cash used in investing activities of \$3.1 for the six months ended June 30, 2019. 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 \$12.0 for the six months ended June 30, 2020, compared to net cash provided by financing activities of \$15.7 million for the six months ended June 30, 2019. The cash flows in 2020 primarily reflect the May and June financings, and the net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering completed in February 2019, as well as net proceeds from the ATM facility.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, August 6, 2020 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-668-9141 from the US or +972-3-918-0610 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 8, 2020; please dial +1-888-782-4291 from the US or +972-3-925-5921 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 currently being evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA[®] and chemotherapy under a collaboration agreement with MSD. Motixafortide is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation.

BioLineRx is 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. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).

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. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. 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 12, 2020. 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,	June 30,
	2019	2020
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	5,523
Short-term bank deposits	22,192	21,779
Prepaid expenses	108	426
Other receivables	613	441
Total current assets	<u>28,210</u>	<u>28,169</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,580
Right-of-use assets, net	1,650	1,490
Intangible assets, net	21,891	21,750
Total non-current assets	<u>25,357</u>	<u>24,820</u>
Total assets	<u>53,567</u>	<u>52,989</u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	2,867
Accounts payable and accruals:		
Trade	7,794	7,396
Other	1,280	1,260
Lease liabilities	202	200
Total current liabilities	<u>11,968</u>	<u>11,723</u>
NON-CURRENT LIABILITIES		
Warrants	658	6,077
Long-term loans, net of current maturities	5,799	4,329
Lease liabilities	1,762	1,630
Total non-current liabilities	<u>8,219</u>	<u>12,036</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>20,187</u>	<u>23,759</u>
EQUITY		
Ordinary shares	4,692	8,281
Share premium	265,938	271,107
Capital reserve	12,132	12,639
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(261,381)
Total equity	<u>33,380</u>	<u>29,230</u>
Total liabilities and equity	<u>53,567</u>	<u>52,989</u>

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2019	2020	2019	2020
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,302)	(4,640)	(9,694)	(10,062)
SALES AND MARKETING EXPENSES	(226)	(182)	(482)	(357)
GENERAL AND ADMINISTRATIVE EXPENSES	(949)	(744)	(1,879)	(1,987)
OPERATING LOSS	(6,477)	(5,566)	(12,055)	(12,406)
NON-OPERATING INCOME (EXPENSES), NET	1,261	(843)	921	(374)
FINANCIAL INCOME	171	35	381	175
FINANCIAL EXPENSES	(440)	(396)	(887)	(810)
NET LOSS AND COMPREHENSIVE LOSS	(5,485)	(6,770)	(11,640)	(13,415)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.04)	(0.03)	(0.08)	(0.07)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	145,461,598	220,317,889	139,270,178	198,277,447

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CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

	Ordinary shares	Share premium	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2019:						
Issuance of share capital, net	890	10,437	-	-	-	11,327
Employee stock options exercised	1	27	(27)	-	-	1
Employee stock options forfeited and expired	-	866	(866)	-	-	-
Share-based compensation	-	-	773	-	-	773
Comprehensive loss for the period	-	-	-	-	(11,640)	(11,640)
BALANCE AT JUNE 30, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782
	Ordinary shares	Share premium	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	8,281	271,107	12,639	(1,416)	(261,381)	29,230

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

Ordinary shares	Share premium	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
in USD thousands					

BALANCE AT APRIL 1, 2019	3,928	259,860	12,191	(1,416)	(228,675)	45,888
CHANGES FOR THREE MONTHS ENDED JUNE 30, 2019:						
Issuance of share capital, net	73	817	-	-	-	890
Employee stock options exercised	-	9	(9)	-	-	-
Employee stock options forfeited and expired	-	836	(836)	-	-	-
Share-based compensation	-	-	489	-	-	489
Comprehensive loss for the period	-	-	-	-	(5,485)	(5,485)
BALANCE AT JUNE 30, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782

	Ordinary shares	Share premium	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	8,281	271,107	12,639	(1,416)	(261,381)	29,230

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

	Six months ended June 30,	
	2019	2020
in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(11,640)	(13,415)
Adjustments required to reflect net cash used in operating activities (see appendix below)	573	1,112
Net cash used in operating activities	(11,067)	(12,303)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(27,510)	(23,751)
Maturities of short-term deposits	24,441	24,335
Purchase of property and equipment	(53)	(1)
Net cash provided by (used in) investing activities	(3,122)	583
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	15,879	13,411
Employee stock options exercised	1	8
Repayments of loans	(47)	(1,331)
Repayments of lease liabilities	(110)	(121)
Net cash provided by financing activities	15,723	11,967
INCREASE IN CASH AND CASH EQUIVALENTS	1,534	247
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	34	(21)
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,972	5,523

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

	Six months ended June 30,	
	2019	2020
in USD thousands		

Adjustments required to reflect net cash used in operating activities:**Income and expenses not involving cash flows:**

Depreciation and amortization	439	533
Long-term prepaid expenses	(4)	-
Exchange differences on cash and cash equivalents	(34)	21
Fair value adjustments of warrants	(1,354)	(250)
Share-based compensation	773	922
Warrant issuance costs	417	593
Interest and exchange differences on short-term deposits	(440)	(171)
Interest on loans	292	36
Exchange differences on lease liability	-	(8)
	<u>89</u>	<u>1,676</u>

Changes in operating asset and liability items:

Decrease (increase) in prepaid expenses and other receivables	848	(146)
Decrease in accounts payable and accruals	(364)	(418)
	<u>484</u>	<u>(564)</u>
	<u>573</u>	<u>1,112</u>

Supplemental information on interest received in cash

<u>442</u>	<u>300</u>
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Supplemental information on interest paid in cash

<u>477</u>	<u>534</u>
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