



## BioLineRx Reports Year-End 2019 Financial Results and Provides Corporate Update

March 12, 2020

- On track to report progression free survival and overall survival data from triple combination arm of ongoing COMBAT/KEYNOTE-202 Phase 2a trial in mid-2020 -
- Management to hold conference call today, March 12, at 10:00 am EDT -

TEL AVIV, Israel, March 12, 2020 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the year ended December 31, 2019 and provides a corporate update.

### Highlights and achievements during the fourth quarter 2019 and subsequent period:

- Presented updated preliminary Phase 2a data from the triple combination arm of the COMBAT/KEYNOTE-202 study, under collaboration with Merck, evaluating the safety, tolerability and efficacy of motixafortide ((BL-8040) in combination with KEYTRUDA® (pembrolizumab) and chemotherapy in patients with second-line metastatic pancreatic cancer, demonstrating a 32% overall response rate and a 77% disease control rate out of 22 evaluable patients at that time, with median duration of clinical benefit for all 17 patients with disease control (7 partial response and 10 stable disease patients) of 7.8 months; and reiterated expectation for progression free survival and overall survival data in mid-2020;
- Completed recruitment (N=43) of the triple combination arm of the COMBAT/KEYNOTE-202 study;
- Announced Notice of Allowance from USPTO for a broad patent covering motixafortide in combination with anti-PD-1 for the treatment of any and all types of cancer;
- Received Orphan Drug Designation for motixafortide for the treatment of pancreatic cancer in Europe;
- Presented positive triple-combination preclinical data from the evaluation of motixafortide in combination with an anti-PD-1 and chemotherapy in pancreatic cancer, supporting motixafortide's mechanism of action and providing additional strong rationale for the triple-combination clinical study, at the Society for Immunotherapy of Cancer Annual Meeting (SITC).

"We achieved a significant milestone during the fourth quarter of 2019 with the announcement of preliminary data from the ongoing triple combination arm of our COMBAT/KEYNOTE-202 study in second-line pancreatic cancer," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The promising initial results demonstrated robust and durable responses to the triple combination treatment, with an overall response rate almost double the current chemotherapy standard-of-care treatment in second-line patients, and a trend of patients receiving treatment for an extended period that move from stable disease to partial response. Looking ahead, we have now fully enrolled this study and remain on track to announce progression free and overall survival data in mid-year.

"In parallel, our late-stage trials of motixafortide in AML and stem cell mobilization are progressing, and we also look forward to these key data readouts later this year.

"Regarding our second clinical oncology candidate, the universal anti-cancer vaccine AGI-134, we successfully completed the dose-escalation Part 1 of the ongoing Phase 1/2a clinical trial in a range of solid tumor types, and are currently advancing Part 2 of the study as expeditiously as possible. We look forward to initial results of Part 2 by year-end 2020," Mr. Serlin concluded.

### Upcoming 2020 Milestones

- Progression-free survival and overall survival data from the triple combination arm of the COMBAT/KEYNOTE-202 Phase 2a study in mid-2020;
- Interim results from the Phase 2b AML consolidation study in the second half of 2020;
- Top-line results from Phase 3 GENESIS registrational study in stem cell mobilization in the second half of 2020;
- Initial results from Part 2 of Phase 1/2a trial of AGI-134 by year-end 2020.

### Financial Results for the Year Ended December 31, 2019

Research and development expenses for the year ended December 31, 2019 were \$23.4 million, an increase of \$3.6 million, or 18.3%, compared to \$19.8 million for the year ended December 31, 2018. The increase resulted primarily from higher expenses associated with the motixafortide GENESIS and COMBAT clinical trials, offset by a decrease in expenses related to BL-1230, a project that was terminated in 2018, as well as a decrease in payroll and share-based compensation.

Sales and marketing expenses for the year ended December 31, 2019 were \$0.9 million, a decrease of \$0.5 million, or 37.0%, compared to \$1.4 million for the year ended December 31, 2018. The decrease resulted primarily from a decrease in payroll and related expenses, including a one-time compensation payment in the 2018 period.

General and administrative expenses for the year ended December 31, 2019 were \$3.8 million, a decrease of \$0.6 million, or 14.0% compared to \$4.4 million for the year ended December 31, 2018. The decrease resulted primarily from a decrease in share-based compensation.

The Company's operating loss for the year ended December 31, 2019 amounted to \$28.1 million, compared to an operating loss of \$25.6 million for the year ended December 31, 2018.

Non-operating income amounted to \$4.2 million for the year ended December 31, 2019, compared to non-operating income of \$2.4 million for the year ended December 31, 2018. Non-operating income for the year ended December 31, 2019 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses. Non-operating income for the year ended December 31, 2018 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet, as well as a capital gain from realization of the investment in iPharma.

Net financial expenses amounted to \$1.5 million for the year ended December 31, 2019 compared to net financial income of \$0.2 million for the year ended December 31, 2018. Net financial expenses for the year ended December 31, 2019 primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial income for the year ended December 31, 2018 primarily relates to investment income earned on bank deposits, offset by interest paid on loans.

The Company's net loss for the year ended December 31, 2019 amounted to \$25.5 million, compared with a net loss of \$23.0 million for the year ended December 31, 2018.

The Company held \$27.5 million in cash, cash equivalents and short-term bank deposits as of December 31, 2019.

Net cash used in operating activities for the year ended December 31, 2019 was \$22.7 million, compared to \$24.2 million for the year ended December 31, 2018. The \$1.5 million decrease in net cash used in operating activities in 2019 was primarily the result of changes in operating asset and liability items in the two periods, i.e., a decrease in prepaid expenses and other receivables in 2019 versus an increase in 2018, as well as an increase in accounts payable and accruals in 2019 versus a decrease in 2018.

Net cash provided by investing activities for the year ended December 31, 2019 was \$5.3 million, compared to \$9.6 million for the year ended December 31, 2018. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during both periods, the acquisition of an additional 20% economic interest in Motixafortide in 2018, as well as a realization of the investment in iPharma during 2018.

Net cash provided by financing activities for the year ended December 31, 2019 was \$19.2 million, compared to \$13.1 million for the year ended December 31, 2018. The cash flows in 2019 primarily reflect the underwritten public offering of ADSs in February 2019, as well as net proceeds from the ATM program. The cash flows in 2018 reflect the net proceeds of the loan from Kreos Capital, as well as net proceeds from the ATM program.

#### **Conference Call and Webcast Information**

BioLineRx will hold a conference call today, March 12, 2020 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-668-9141 from the US or +972-3-918-0609 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 March 14, 2020; please dial +1-877-456-0009 from the US or +972-3-925-5927 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<sup>®</sup> 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](http://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 28, 2019. 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.*

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<b>December 31,</b>	
	<b>2018</b>	<b>2019</b>
	<b>in USD thousands</b>	
<b>Assets</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	3,404	5,297
Short-term bank deposits	26,747	22,192
Prepaid expenses	488	108
Other receivables	1,339	613
Total current assets	<u>31,978</u>	<u>28,210</u>
<b>NON-CURRENT ASSETS</b>		
Long-term prepaid expenses	56	-
Property and equipment, net	2,227	1,816
Right-of-use assets, net	-	1,650
Intangible assets, net	21,972	21,891
Total non-current assets	<u>24,255</u>	<u>25,357</u>
<b>Total assets</b>	<u><u>56,233</u></u>	<u><u>53,567</u></u>
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES</b>		
Current maturities of long-term loans	895	2,692
Accounts payable and accruals:		
Trade	4,493	7,794
Other	1,363	1,280
Lease liabilities	-	202
Total current liabilities	<u>6,751</u>	<u>11,968</u>
<b>NON-CURRENT LIABILITIES</b>		
Warrants	323	658
Long-term loans, net of current maturities	7,838	5,799
Lease liabilities	-	1,762
Total non-current liabilities	<u>8,161</u>	<u>8,219</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
Total liabilities	<u>14,912</u>	<u>20,187</u>
<b>EQUITY</b>		
Ordinary shares	3,110	4,692
Share premium	250,192	265,938
Capital reserve	11,955	12,132
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	<u>(222,520)</u>	<u>(247,966)</u>
Total equity	<u>41,321</u>	<u>33,380</u>
<b>Total liabilities and equity</b>	<u><u>56,233</u></u>	<u><u>53,567</u></u>

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	<b>Year ended December 31,</b>		
	<b>2017</b>	<b>2018</b>	<b>2019</b>
	<b>in USD thousands</b>		
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	(19,510)	(19,808)	(23,438)
<b>SALES AND MARKETING EXPENSES</b>	(1,693)	(1,362)	(857)
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	(4,037)	(4,435)	(3,816)
<b>OPERATING LOSS</b>	(25,240)	(25,605)	(28,111)
<b>NON-OPERATING INCOME (EXPENSES), NET</b>	(260)	2,397	4,165
<b>FINANCIAL INCOME</b>	1,169	719	777
<b>FINANCIAL EXPENSES</b>	(21)	(473)	(2,277)
<b>NET LOSS AND COMPREHENSIVE LOSS</b>	<u>(24,352)</u>	<u>(22,962)</u>	<u>(25,446)</u>

	in USD		
<b>LOSS PER ORDINARY SHARE – BASIC AND DILUTED</b>	(0.27)	(0.21)	(0.17)
<b>WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE</b>	89,970,713	108,595,702	146,407,055

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STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2017</b>	1,513	199,567	10,569	(1,416)	(175,206)	35,027
<b>CHANGES IN 2017:</b>						
Issuance of share capital, net	1,322	39,376	-	-	-	40,698
Employee stock options exercised	1	328	(329)	-	-	-
Employee stock options forfeited and expired	-	1,411	(1,411)	-	-	-
Share-based compensation	-	-	1,508	-	-	1,508
Comprehensive loss for the year	-	-	-	-	(24,352)	(24,352)
<b>BALANCE AT DECEMBER 31, 2017</b>	2,836	240,682	10,337	(1,416)	(199,558)	52,881
<b>CHANGES IN 2018:</b>						
Issuance of share capital, net	263	8,567	-	-	-	8,830
Employee stock options exercised	11	415	(380)	-	-	46
Employee stock options forfeited and expired	-	528	(528)	-	-	-
Share-based compensation	-	-	2,526	-	-	2,526
Comprehensive loss for the year	-	-	-	-	(22,962)	(22,962)
<b>BALANCE AT DECEMBER 31, 2018</b>	3,110	250,192	11,955	(1,416)	(222,520)	41,321
<b>CHANGES IN 2019:</b>						
Issuance of share capital, net	1,580	14,165	-	-	-	15,745
Employee stock options exercised	2	83	(84)	-	-	1
Employee stock options forfeited and expired	-	1,498	(1,498)	-	-	-
Share-based compensation	-	-	1,759	-	-	1,759
Comprehensive loss for the year	-	-	-	-	(25,446)	(25,446)
<b>BALANCE AT DECEMBER 31, 2019</b>	4,692	265,938	12,132	(1,416)	(247,966)	33,380

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CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2017	2018	2019
	in USD thousands		
<b>CASH FLOWS - OPERATING ACTIVITIES</b>			
Net loss	(24,352)	(22,962)	(25,446)
Adjustments required to reflect net cash used in operating activities (see appendix below)	3,805	(1,230)	2,780
Net cash used in operating activities	(20,547)	(24,192)	(22,666)
<b>CASH FLOWS - INVESTING ACTIVITIES</b>			
Increase in long-term investment	(1,000)	-	-
Realization of long-term investment	-	1,500	-
Investments in short-term deposits	(44,016)	(26,500)	(43,545)
Maturities of short-term deposits	33,327	44,771	48,875
Purchase of property and equipment	(338)	(173)	(67)
Purchase of intangible assets	(3,900)	(10,043)	(6)
Net cash provided by (used in) investing activities	(15,927)	9,555	5,257
<b>CASH FLOWS - FINANCING ACTIVITIES</b>			

Issuance of share capital and warrants, net of issuance cost	38,773	3,830	20,297
Employee stock options exercised	-	46	1
Proceeds of long-term loan and warrants, net of issuance costs	-	9,632	-
Repayment of loans	(93)	(411)	(889)
Repayments of lease liabilities	-	-	(215)
Net cash provided by financing activities	<u>38,680</u>	<u>13,097</u>	<u>19,194</u>
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	2,206	(1,540)	1,785
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR</b>	2,469	5,110	3,404
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	435	(166)	108
<b>CASH AND CASH EQUIVALENTS - END OF YEAR</b>	<u>5,110</u>	<u>3,404</u>	<u>5,297</u>

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CONSOLIDATED CASH FLOW STATEMENTS

Year ended December 31,  
2017 2018 2019  
in USD thousands

**APPENDIX**

**Adjustments required to reflect net cash used in operating activities:**

**Income and expenses not involving cash flows:**

Depreciation and amortization	481	545	940
Long-term prepaid expenses	(9)	5	56
Exchange differences on cash and cash equivalents	(435)	166	(108)
Fair value adjustments of warrants	127	(1,743)	(4,634)
Share-based compensation	1,508	2,526	1,759
Interest and exchange differences on short-term deposits	(530)	(645)	(775)
Interest on loans	-	123	647
Gain on realization of long-term investment	-	(500)	-
Warrant issuance costs	17	-	417
Exchange differences on lease liability	-	-	154
	<u>1,159</u>	<u>477</u>	<u>(1,544)</u>

**Changes in operating asset and liability items:**

Decrease (increase) in prepaid expenses and other receivables	(415)	(934)	1,106
Increase (decrease) in accounts payable and accruals	<u>3,061</u>	<u>(773)</u>	<u>3,218</u>
	<u>2,646</u>	<u>(1,707)</u>	<u>4,324</u>
	<u>3,805</u>	<u>(1,230)</u>	<u>2,780</u>

<b>Supplemental information on interest received in cash</b>	<u>494</u>	<u>834</u>	<u>868</u>
<b>Supplemental information on interest paid in cash</b>	<u>12</u>	<u>165</u>	<u>1,198</u>
<b>Supplemental information on non-cash transactions</b>	<u>2,985</u>	<u>5,000</u>	<u>147</u>

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