



BioLineRx Reports Year End 2018 Financial Results and Provides Corporate Update

March 28, 2019

BL-8040 and AGI-134 oncology programs progressing, with multiple data read-outs expected in the next 12 months Management to hold conference call today, March 28, at 10:00 am EDT

TEL AVIV, Israel, March 28, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the year ended December 31, 2018 and provided a corporate update.

Highlights and achievements during the fourth quarter 2018 and subsequent period:

- Presented data from Phase 2a COMBAT/KEYNOTE-202 pancreatic cancer study in collaboration with Merck at the ESMO 2018 Congress demonstrating that BL-8040 in combination with KEYTRUDA® (pembrolizumab) showed encouraging disease control and overall survival in patients with metastatic pancreatic cancer; compelling pharmacodynamic data also demonstrated T-cell infiltration into tumors and a reduction of the tumor immuno-suppressive microenvironment;
- Initiated a triple combination arm of COMBAT/KEYNOTE-202 evaluating the safety, tolerability and efficacy of BL-8040 in combination with KEYTRUDA and chemotherapy;
- Entered into agreement with Biokine Therapeutics to increase the Company's economic stake in BL-8040 to 80% from the previous level of 60%;
- Initiated Phase 1/2a multicenter, open-label clinical study in the UK and Israel for AGI-134, a novel immunotherapy evoking a direct anti-tumor response and vaccine effect for the treatment of solid tumors;
- Announced FDA Orphan Drug Designation for BL-8040, for the treatment of pancreatic cancer. This is in addition to prior orphan drug designations received for BL-8040 in AML and stem cell mobilization;
- Announced FDA Biological Product Designation for AGI-134, providing the Company with eligibility to obtain 12 years of market exclusivity upon approval of the product for commercial use by the FDA; and
- Completed an underwritten public offering for gross proceeds of \$15.4 million.

"During the fourth quarter, we continued to advance our novel pipeline of promising anti-cancer therapies toward significant and potentially value-creating milestones, and this progress was a key driver in our previously announced decision to acquire an additional 20% economic stake in BL-8040 from Biokine Therapeutics," said Philip Serlin, Chief Executive Officer of BioLineRx. "In cancer immunotherapy, following the encouraging results we announced from the dual combination arm, we initiated the triple combination arm of the COMBAT/KEYNOTE-202 study evaluating our lead therapeutic candidate, BL-8040, in combination with Merck's KEYTRUDA and chemotherapy for the treatment of metastatic pancreatic cancer, an indication for which we also recently received FDA Orphan Drug Designation."

"In stem-cell mobilization, our most advanced indication, we continue to move forward with the Phase 3 GENESIS study in the randomized placebo-controlled phase of the trial, and we hope that we will be able to replicate the compelling results observed in the lead-in portion of the trial. Concurrently, in relapsed/refractory AML, we are evaluating our future development plan, and anticipate meeting with the regulatory authorities to discuss the plan during the second half of this year. In consolidation AML, we hope to announce interim data from the large, randomized placebo-controlled Phase 2b BLAST study by the end of this year as well."

"Finally, our second oncology program, the cancer immunotherapy vaccine AGI-134, is also progressing as planned, with initial safety data from the ongoing Phase 1/2a study expected later this year. As we progress through 2019, we are rapidly approaching important data readouts that we believe can create significant shareholder value and additional partnering interest, and we look forward to providing future updates throughout the year."

Expected significant milestones through end of 2019 and early 2020:

- Top-line results from the Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under collaboration with Merck toward the end of 2019;
- Potential interim results from Phase 2 AML consolidation study in the second half of 2019;
- Initial safety results from part 1 of Phase 1/2a trial for AGI-134 in second half of 2019;
- Top-line results from one or more of the solid tumor trials under collaboration with Genentech, potentially by end of 2019 or early 2020.

Financial Results for the Year Ended December 31, 2018

Research and development expenses for the year ended December 31, 2018 were \$19.8 million, an increase of \$0.3 million, or 1.5%, compared to \$19.5 million for the year ended December 31, 2017. The small increase resulted primarily from an increase in share-based compensation.

Sales and marketing expenses for the year ended December 31, 2018 were \$1.4 million, a decrease of \$0.3 million, or 19.6%, compared to \$1.7 million for the year ended December 31, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134, as well as market research for BL-8040 and AGI-134, incurred in the 2017 period.

General and administrative expenses for the year ended December 31, 2018 were \$4.4 million, an increase of \$0.4 million, or 9.9% compared to \$4.0 million for the year ended December 31, 2017. The increase resulted primarily from an increase in share-based compensation.

The Company's operating loss for the year ended December 31, 2018 amounted to \$25.6 million, compared with an operating loss of \$25.2 million for the year ended December 31, 2017.

Non-operating income amounted to \$2.4 million for the year ended December 31, 2018, compared with non-operating expenses of \$0.3 million for the year ended December 31, 2017. Non-operating income for the year ended December 31, 2018 primarily relates to fair-value adjustments of warrant liabilities and a capital gain from realization of the investment in iPharma. Non-operating expenses for the year ended December 31, 2017 primarily relate to fair-value adjustments of warrant liabilities.

Net financial income amounted to \$0.2 million for the year ended December 31, 2018 compared to net financial income of \$1.1 million for the year ended December 31, 2017. 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. Net financial income for the year ended December 31, 2017 relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits.

The Company's net loss for the year ended December 31, 2018 amounted to \$23.0 million, compared with a net loss of \$24.4 million for the year ended December 31, 2017.

The Company held \$30.2 million in cash, cash equivalents and short-term bank deposits as of December 31, 2018. Subsequent to year end, the Company raised \$15.4 million of gross proceeds from an underwritten public offering.

Net cash used in operating activities for the year ended December 31, 2018 was \$24.2 million, compared to \$20.5 million for the year ended December 31, 2017. The \$3.7 million increase in 2018 was the result of a decrease in accounts payable and an increase in prepaid expenses and other receivables.

Net cash provided by investing activities for the year ended December 31, 2018 was \$9.6 million, compared to net cash used in investing activities of \$15.9 million for the year ended December 31, 2017. 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 Agalimmune in 2017, and the acquisition of an additional 20% of BL-8040 sublicense receipts, as well as realization of the investment in iPharma, during 2018.

Net cash provided by financing activities for the year ended December 31, 2018 was \$13.1 million, compared to \$38.7 million for the year ended December 31, 2017. The cash flows in 2018 primarily reflect the net proceeds of the loan from Kreos Capital, as well as net proceeds from the ATM program. The cash flows in 2017 primarily reflect the underwritten public offering of our ADSs in March 2017 and the direct placement of ADSs and warrants to BVF Partners in July 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, March 28, 2019 at 10:00 a.m. EDT. To access the conference call, please dial +1-866-229-7198 from the U.S. or +972-3-918-0664 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 30, 2019; please dial +1-888-295-2634 from the U.S. or +972-3-925-5938 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA[®] (pembrolizumab), and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

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 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

December 31,

2017 2018

in USD thousands

Assets

CURRENT ASSETS

Cash and cash equivalents	5,110	3,404
Short-term bank deposits	44,373	26,747
Prepaid expenses	307	488
Other receivables	586	1,339
Total current assets	50,376	31,978

NON-CURRENT ASSETS

Long-term prepaid expenses	61	56
Long-term investment	1,000	-
Property and equipment, net	2,505	2,227
Intangible assets, net	7,023	21,972
Total non-current assets	10,589	24,255
Total assets	60,965	56,233

Liabilities and equity

CURRENT LIABILITIES

Current maturities of long-term loans	93	895
Accounts payable and accruals:		
Trade	5,516	4,493
Other	1,113	1,363
Total current liabilities	6,722	6,751

NON-CURRENT LIABILITIES

Long-term loans, net of current maturities	157	7,838
Warrants	1,205	323
Total non-current liabilities	1,362	8,161

COMMITMENTS AND CONTINGENT LIABILITIES

Total liabilities	8,084	14,912
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EQUITY

Ordinary shares	2,836	3,110
Share premium	240,682	250,192
Capital reserve	10,337	11,955
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(199,558)	(222,520)
Total equity	52,881	41,321
Total liabilities and equity	60,965	56,233

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2016	2017	2018
	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(11,177)	(19,510)	(19,808)
SALES AND MARKETING EXPENSES	(1,352)	(1,693)	(1,362)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,984)	(4,037)	(4,435)
OPERATING LOSS	(16,513)	(25,240)	(25,605)
NON-OPERATING INCOME (EXPENSES), NET	214	(260)	2,397
FINANCIAL INCOME	480	1,169	719
FINANCIAL EXPENSES	(22)	(21)	(473)

NET LOSS AND COMPREHENSIVE LOSS	(15,841)	(24,352)	(22,962)
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in USD

LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.28)	(0.27)	(0.21)
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WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	56,144,727	89,970,713	108,595,702
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STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Share premium	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
in USD thousands						
BALANCE AT JANUARY 1, 2016	1,455	196,201	10,735	(1,416)	(159,365)	47,610
CHANGES IN 2016:						
Issuance of share capital, net	57	2,126	-	-	-	2,183
Employee stock options exercised	1	171	(172)	-	-	-
Employee stock options expired	-	1,069	(1,069)	-	-	-
Share-based compensation	-	-	1,075	-	-	1,075
Comprehensive loss for the year	-	-	-	-	(15,841)	(15,841)
BALANCE AT DECEMBER 31, 2016	1,513	199,567	10,569	(1,416)	(175,206)	35,027
CHANGES IN 2017:						
Issuance of share capital, net	1,322	39,376	-	-	-	40,698
Employee stock options exercised	1	328	(329)	-	-	-
Employee stock options expired	-	1,411	(1,411)	-	-	-
Share-based compensation	-	-	1,508	-	-	1,508
Comprehensive loss for the year	-	-	-	-	(24,352)	(24,352)
BALANCE AT DECEMBER 31, 2017	2,836	240,682	10,337	(1,416)	(199,558)	52,881

CHANGES IN 2018:

Issuance of share capital, net	263	8,567	-	-	-	8,830
Employee stock options exercised	11	415	(380)	-	-	46
Employee stock options expired	-	528	(528)	-	-	-
Share-based compensation	-	-	2,526	-	-	2,526
Comprehensive loss for the year	-	-	-	-	(22,962)	(22,962)
BALANCE AT DECEMBER 31, 2018	3,110	250,192	11,955	(1,416)	(222,520)	41,321

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CONSOLIDATED CASH FLOW STATEMENTS

Year ended December 31,**2016 2017 2018****in USD thousands****CASH FLOWS - OPERATING ACTIVITIES**

Net loss	(15,841)	(24,352)	(22,962)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,328	3,805	(1,230)
Net cash used in operating activities	(14,513)	(20,547)	(24,192)

CASH FLOWS - INVESTING ACTIVITIES

Increase in long-term investment	-	(1,000)	-
Realization of long-term investment			1,500
Investments in short-term deposits	(32,982)	(44,016)	(26,500)
Maturities of short-term deposits	42,334	33,327	44,771
Purchase of property and equipment	(52)	(338)	(173)
Purchase of intangible assets	(3)	(3,900)	(10,043)
Net cash provided by (used in) investing activities	9,297	(15,927)	9,555

CASH FLOWS - FINANCING ACTIVITIES

Issuance of share capital and warrants, net of issuance costs	2,183	38,773	3,830
Employee stock options exercised	-	-	46
Proceeds of long-term loan and warrants, net of issuance costs	-	-	9,632
Repayment of long-term loan	-	-	(318)
Repayments of bank loan	(93)	(93)	(93)
Net cash provided by financing activities	2,090	38,680	13,097
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(3,126)	2,206	(1,540)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	5,544	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	51	435	(166)
CASH AND CASH EQUIVALENTS - END OF YEAR	2,469	5,110	3,404

BioLineRx Ltd.**CONSOLIDATED CASH FLOW STATEMENTS****Year ended December 31,****2016 2017 2018****in USD thousands****APPENDIX****Adjustments required to reflect net cash used in operating activities:****Income and expenses not involving cash flows:**

Depreciation and amortization	482	481	545
Long-term prepaid expenses	6	(9)	5
Exchange differences on cash and cash equivalents	(51)	(435)	166

Loss (gain) on adjustment of warrants to fair value	(207)	127	(1,743)
Share-based compensation	1,075	1,508	2,526
Interest and exchange differences on short-term deposits	(387)	(530)	(645)
Interest and linkage differences on loans	(1)	-	123
Gain on realization of long-term investment	-	-	(500)
Warrant issuance costs	-	17	-
	917	1,159	477

Changes in operating asset and liability items:

Decrease (increase) in prepaid expenses and other receivables	42	(415)	(934)
Increase (decrease) in accounts payable and accruals	369	3,061	(773)
	411	2,646	(1,707)
	1,328	3,805	(1,230)

Supplemental information on interest received in cash 453 494 834

Supplemental information on non-cash transactions - 2,985 5,000

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