



BioLineRx Reports Year End 2017 Financial Results

March 6, 2018

TEL AVIV, Israel, March 6, 2018 /PRNewswire/ --

BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the year ended December 31, 2017.

Highlights and achievements in 2017 and to date:

Continued progress and execution according to plan on multiple clinical trials for the Company's lead oncology program, BL-8040:

- Initiation of pivotal Phase 3 GENESIS study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation, following successful meeting with the FDA earlier in the year;
- Partial monotherapy results from Phase 2a COMBAT study, investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda® (pembrolizumab), in pancreatic cancer, showed significantly increased infiltration of T cells into the tumor, as well as robust mobilization of immune cells;
- Initiation of three Phase 1b/2 studies under collaboration with Genentech, exploring the combination of BL-8040 with Tecentriq® (atezolizumab), Genentech's anti-PD-L1 cancer immunotherapy agent;
- Overall long-term survival results in Phase 2a trial in relapsed/refractory AML demonstrated that the combination of BL-8040 with high-dose Ara-C (HiDAC) significantly improved overall survival, compared with historical data of HiDAC monotherapy;
- Partial results of Phase 2 study for BL-8040 as novel stem cell mobilization treatment for allogeneic bone-marrow transplantation support BL-8040 as a one-day dosing regimen for rapid mobilization of stem cells.

The Company also announced progress in expanding and accelerating its growth potential and strengthening its balance sheet:

- Acquired Agalimmune Ltd., a UK-based biopharmaceutical company developing cancer immunotherapy treatments, thereby broadening BioLineRx's position in the immuno-oncology field with a second novel lead compound, AGI-134. Pre-clinical data presented at ASCO-SITC showed complete tumor regression in the majority of mice treated with AGI-134;
- Completed underwritten public offering of American Depository Shares for gross proceeds of \$28.9 million led by BVF Partners, L.P.; the Company also received an additional \$9.6 million direct investment from BVF Partners.

Expected significant upcoming milestones for 2018:

- Top-line results in immuno-oncology Phase 2a COMBAT study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA, expected in H2 2018;
- Results from the lead-in stage of the Phase 3 GENESIS study in stem-cell mobilization, expected in H2 2018;
- Initiation of Phase 1b/2 immuno-oncology study for BL-8040 in combination with Genentech's atezolizumab for non-small cell lung cancer. Partial results in Phase 1b/2 trials under collaboration with Genentech expected in H2 2018;
- Initiation of Phase 1/2a immuno-oncology study for AGI-134 in several solid tumor indications expected in mid-2018;
- Top-line results of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by mid-2018.

Philip A. Serlin, Chief Executive Officer of BioLineRx, stated, "We are very proud of the continued advancement and on-target execution of our oncology programs in 2017. During the year, we initiated several clinical studies for our lead asset, BL-8040, including our first pivotal Phase 3 study in autologous stem-cell mobilization, as well as a number of studies under our immunotherapy collaborations with Genentech and MD Anderson Cancer Center. Furthermore, we announced encouraging clinical results demonstrating the therapeutic potential of BL-8040 – the recently reported partial results from the monotherapy stage of our Phase 2a COMBAT study in pancreatic cancer showed robust mobilization and increased infiltration of anti-tumor-specific T cells into the tumor microenvironment, supporting previously reported BL-8040 data; and BL-8040 in combination with Ara-C demonstrated significant improvement in overall survival in our phase 2a study in relapsed/refractory AML."

"We are also excited by the potential of our second oncology asset, AGI-134, acquired in early 2017, with new pre-clinical data demonstrating induced regression of primary tumors following intratumoral injection. We expect to initiate a Phase 1/2a study for this product in multiple solid tumors by mid-2018. We will continue the steady execution on all our programs during 2018, and we look forward to reporting on key milestones over the next six to 12 months, including data read-outs from several Phase 2 studies and lead-in results from our Phase 3 trial in autologous stem cell mobilization," concluded Mr. Serlin.

Financial Results for the Year Ended December 31, 2017

Research and development expenses for the year ended December 31, 2017 were \$19.5 million, an increase of \$8.3 million, or 74.6%, compared to \$11.2 million for the year ended December 31, 2016. The increase resulted primarily from higher expenses in 2017 associated with new BL-8040 clinical studies commenced during the third quarter of 2016 and during 2017, as well as spending on the Company's recently acquired AGI-134 near-clinical project.

Sales and marketing expenses for the year ended December 31, 2017 were \$1.7 million, an increase of \$0.3 million, or 25.2%, compared to \$1.4

million for the year ended December 31, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

General and administrative expenses for the year ended December 31, 2017 were \$4.0 million, similar to those for the year ended December 31, 2016.

The Company's operating loss for the year ended December 31, 2017 amounted to \$25.2 million, compared with an operating loss of \$16.5 million for the year ended December 31, 2016. The increase in operating loss reflects the significant increase in research and development expenses during 2017.

Non-operating expenses amounted to \$0.3 million for the year ended December 31, 2017, compared with non-operating income of \$0.2 million for the year ended December 31, 2016. Non-operating expenses and income for both years primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial income amounted to \$1.1 million for the year ended December 31, 2017 compared to net financial income of \$0.5 million for the year ended December 31, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

The Company's net loss for the year ended December 31, 2017 amounted to \$24.4 million, compared with an operating loss of \$15.8 million for the year ended December 31, 2016.

The Company held \$49.5 million in cash, cash equivalents and short-term bank deposits as of December 31, 2017.

Net cash used in operating activities for the year ended December 31, 2017 was \$20.5 million, compared to \$14.5 million for the year ended December 31, 2016. The \$6.0 million increase in net cash used in operating activities in 2017 was primarily the result of increased research and development expenses.

Net cash used in investing activities for the year ended December 31, 2017 was \$15.9 million, compared to net cash provided by investing activities of \$9.3 million for the year ended December 31, 2016. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective periods, as well as the acquisition of Agalimmune and the investment in iPharma during 2017.

Net cash provided by financing activities for the year ended December 31, 2017 was \$38.7 million, compared to \$2.1 million for the year ended December 31, 2016. The cash flows in 2017 primarily reflect the underwritten public offering of 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 6, 2018 at 10:00 a.m. EST. To access the conference call, please dial +1-888-668-9141 from the U.S. 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 9, 2018; please dial +1-888-326-9310 from the U.S. or +972-3-925-5901 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. 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 is expected to initiate a first-in-man study in mid-2018. 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 (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA[®]; 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 <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 6, 2018. 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.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2016	2017
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	5,110
Short-term bank deposits	33,154	44,373
Prepaid expenses	255	307
Other receivables	223	586
Total current assets	<u>36,101</u>	<u>50,376</u>
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	61
Long-term investment	-	1,000
Property and equipment, net	2,605	2,505
Intangible assets, net	181	7,023
Total non-current assets	<u>2,838</u>	<u>10,589</u>
Total assets	<u><u>38,939</u></u>	<u><u>60,965</u></u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	5,516
Other	978	1,113
Total current liabilities	<u>3,661</u>	<u>6,722</u>
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	157
Warrants	1	1,205
Total non-current liabilities	<u>251</u>	<u>1,362</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>3,912</u>	<u>8,084</u>
EQUITY		
Ordinary shares	1,513	2,836
Share premium	199,567	240,682
Capital reserve	10,569	10,337
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	<u>(175,206)</u>	<u>(199,558)</u>
Total equity	<u>35,027</u>	<u>52,881</u>
Total liabilities and equity	<u><u>38,939</u></u>	<u><u>60,965</u></u>

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Year ended December 31,		
2015	2016	2017

	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(11,489)	(11,177)	(19,510)
SALES AND MARKETING EXPENSES	(1,003)	(1,352)	(1,693)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,704)	(3,984)	(4,037)
OPERATING LOSS	(16,196)	(16,513)	(25,240)
NON-OPERATING INCOME (EXPENSES), NET	1,445	214	(260)
FINANCIAL INCOME	457	480	1,169
FINANCIAL EXPENSES	(106)	(22)	(21)
NET LOSS AND COMPREHENSIVE LOSS	(14,400)	(15,841)	(24,352)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.28)	(0.28)	(0.27)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	51,406,434	56,144,727	89,970,713

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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, 2015	1,055	167,331	9,800	(1,416)	(144,965)	31,805
CHANGES IN 2015:						
Issuance of share capital, net	400	28,653	-	-	-	29,053
Employee stock options expired	-	217	(217)	-	-	-
Share-based compensation	-	-	1,152	-	-	1,152
Comprehensive loss for the year	-	-	-	-	(14,400)	(14,400)
BALANCE AT DECEMBER 31, 2015	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

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CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2015	2016	2017
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(14,400)	(15,841)	(24,352)
Adjustments required to reflect net cash used in operating activities (see appendix below)	232	1,328	3,805
Net cash used in operating activities	(14,168)	(14,513)	(20,547)
CASH FLOWS - INVESTING ACTIVITIES			
Long-term investment	-	-	(1,000)
Investments in short-term deposits	(63,130)	(32,982)	(44,016)
Maturities of short-term deposits	50,083	42,334	33,327
Maturities of restricted deposits	166	-	-

Purchase of property and equipment	(2,683)	(52)	(338)
Purchase of intangible assets	(36)	(3)	(3,900)
Net cash provided by (used in) investing activities	(15,600)	9,297	(15,927)
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	29,053	2,183	38,773
Proceeds of bank loan	467	-	-
Repayments of bank loan	(31)	(93)	(93)
Net cash provided by financing activities	29,489	2,090	38,680
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(279)	(3,126)	2,206
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	5,790	5,544	2,469
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	33	51	435
CASH AND CASH EQUIVALENTS - END OF YEAR	5,544	2,469	5,110

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CONSOLIDATED CASH FLOW STATEMENTS

Year ended December 31,		
2015	2016	2017
in USD thousands		

APPENDIX

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:

Depreciation and amortization	441	482	481
Long-term prepaid expenses	(9)	6	(9)
Exchange differences on cash and cash equivalents	(33)	(51)	(435)
Loss (gain) on adjustment of warrants to fair value	(1,292)	(207)	127
Share-based compensation	1,152	1,075	1,508
Interest and exchange differences on short-term deposits	(182)	(387)	(530)
Interest and linkage differences on bank loan	1	(1)	-
Warrant issuance costs	-	-	17
	78	917	1,159

Changes in operating asset and liability items:

Decrease (increase) in prepaid expenses and other receivables	(42)	42	(415)
Increase in accounts payable and accruals	196	369	3,061
	154	411	2,646
	232	1,328	3,805

Supplementary information on interest received in cash

	173	453	494
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Supplementary non-cash investment (see Note 19)

- - 2,985

Debt reconciliation for 2017:

	<u>Long-term bank loan</u>	<u>Warrants</u>	<u>Total</u>
Debt as of January 1, 2017	343	1	344
Cash flows	(93)	1,077	984
Other non-cash movements	-	127	127
Debt as of December 31, 2017	<u>250</u>	<u>1,205</u>	<u>1,455</u>

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