BioLineRx Reports First Quarter 2018 Financial Results

May 22, 2018

TEL AVIV, Israel, May 22, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the first quarter ended March 31, 2018.

Highlights and achievements during the first quarter 2018 and to date:

Steady progress made on multiple clinical trials for the Company's lead oncology program, BL-8040:

- 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 liver metastases in almost half of the pancreatic cancer patients who underwent a biopsy, as well as an increase in the number of total immune cells in the peripheral blood, alongside a decrease in the frequency of peripheral blood regulatory T cells (Tregs) – all of which support the mechanism of action proposed by pre-clinical studies. Study enrollment has been completed, with top-line results expected in H2 2018;
- Results from 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; primary endpoint of collection of ≥2 million CD34 cells/kg recipient weight after up to 2 leukapheresis (LP) sessions was reached in over 90% of patients (100% of patients at optimal BL-8040 dose of 1.25 mg/kg); all 19 transplanted recipients were successfully engrafted with BL-8040-mobilized grafts, and preliminary graft-versus-host disease (GVHD) data are in line with current standard-of-care incidence rates;
- 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. In the BL-8040 dose selected for expansion (1.5 mg/kg), the overall response rate was 39% (N=23) and median overall survival for this cohort was 9.2 months with 1-year and 2-year survival rates of 31.6% and 21.1%, respectively;
- Grant of European patent covering use of BL-8040 with Cytarabine for treating AML; valid through March 2034 with up to five years' patent term extension, thus providing significant additional patent protection in AML, one of BL-8040's key indications.

The Company also announced advancements made in its second immuno-oncology compound, AGI-134:

- Pre-clinical data presented at ASCO-SITC showed direct regression of established primary tumors after injection with AGI-134 in the majority of mice treated, and that this regression is associated with activation of the innate immune system;
- Notice of Allowance issued by the United States Patent and Trademark Office (USPTO) for a patent application claiming the use of AGI-134 for the treatment of solid cancer tumors; this patent, when issued, will be valid until May 2035 with a possibility of up to five years patent term extension. Additional corresponding patent applications for AGI-134 are pending in Europe, Japan, China, Canada, Australia and Israel.

Expected significant upcoming milestones for 2018:

- Results from the lead-in part of the Phase 3 GENESIS study in stem-cell mobilization for autologous transplantation are due mid-year 2018;
- Top-line results in immuno-oncology Phase 2a COMBAT study in pancreatic cancer for BL-8040 in combination with KEYTRUDA, under collaboration with Merck, expected in H2 2018;
- Initiation of Phase 1/2a immuno-oncology study for AGI-134 in several solid tumor indications expected in mid-2018;
- Additional overall long-term survival data from Phase 2a trial in relapsed/refractory AML to be presented at EHA in June 2018;
- Full top-line results of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation to be presented at the 23rd Congress of European Hematology Association (EHA) in June 2018.

Philip A. Serlin, Chief Executive Officer of BioLineRx, stated, "We continue to strongly focus on clinical execution of our oncology programs. Since the beginning of 2018, we have made significant progress with BL-8040, our lead clinical asset, with clinical results from our Phase 2a COMBAT study in pancreatic cancer showing robust mobilization and increased infiltration of anti-tumor-specific T cells into the tumor microenvironment; positive results from our Phase 2 study in allogeneic bone marrow transplantation; very encouraging overall survival data from our proof-of-concept Phase 2a study in relapsed/refractory AML; as well as significant strengthening of our patent protection for BL-8040 in the AML space. In addition, we also reported very encouraging pre-clinical data on our near-clinical second oncology asset, AGI-134, demonstrating induced regression of primary tumors following intra-tumoral injection.

"Over the next three to nine months, we look forward to reporting on key milestones. This includes the results from the lead-in part of our Phase 3

GENESIS trial in autologous stem cell mobilization, data read-outs from our Phase 2a COMBAT study in pancreatic cancer, and initiation of a Phase 1/2a study in multiple solid tumor indications for AGI-134," concluded Mr. Serlin.

Financial Results for the First Quarter Ended March 31, 2018

Research and development expenses for the three months ended March 31, 2018 were $5.1 million, an increase of $1.5 million, or 41.2%, compared to $3.6 million for the three months ended March 31, 2017. The increase resulted primarily from higher expenses associated with new BL-8040 clinical studies commenced during 2017, spending on our new AGI-134 near-clinical project, and higher expenses related to our BL-1230 project.

Sales and marketing expenses for the three months ended March 31, 2018 were $0.5 million, a decrease of $0.2 million, or 28.9%, compared to $0.7 million for the three months ended March 31, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 incurred in the 2017 period.

General and administrative expenses for the three months ended March 31, 2018 were $1.1 million, similar to the comparable period in 2017.

The Company's operating loss for the quarter ended March 31, 2018 amounted to $6.6 million, compared with an operating loss of $5.3 million for the quarter ended March 31, 2017.

Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of warrant liabilities. These fair-value adjustments were highly influenced by the Company's share price at each period end (revaluation date).

The Company recorded an immaterial amount of net financial expenses for the three months ended March 31, 2018 compared to net financial income of $0.5 million for the three months ended March 31, 2017. Net financial expenses for the 2018 period primarily relate to investment income earned on bank deposits, offset by losses recorded on foreign currency hedging transactions. Net financial income for the 2017 period relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits.

The Company's net loss for the three months ended March 31, 2018 amounted to $6.2 million, compared with a net loss of $4.9 million for the corresponding period.

The Company held $44.2 million in cash, cash equivalents and short-term bank deposits as of March 31, 2018.

Net cash used in operating activities was $6.8 million for the three months ended March 31, 2018, compared with net cash used in operating activities of $3.8 million for the three months ended March 31, 2017. The $3.0 million increase in net cash used in operating activities during the three-month period in 2018, compared to the three-month period in 2017, was the result of increased research and development expenses in the 2018 period, as well as a decrease in accounts payable.

Net cash provided by investing activities was $8.1 million for the three months ended March 31, 2018, compared to net cash provided by investing activities of $1.4 million for the three months ended March 31, 2017. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the investment in Agalimmune in 2017 period.

Net cash provided by financing activities was $1.4 million for the three months ended March 31, 2018, compared to net cash provided by financing activities of $2.1 million for the three months ended March 31, 2017. The cash flows from financing activities result primarily from funding under an ATM facility in the 2018 period and a share purchase agreement with Lincoln Park Capital in the 2017 period.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, May 22, 2018 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. 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 May 25, 2018; please dial +1-877-456-0009 from the U.S. or +972-3-925-5942 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 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.

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

	December 31, 2017	March 31, 2018
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,110	7,810
Short-term bank deposits	44,373	36,388
Prepaid expenses	307	564
Other receivables	586	782
Total current assets	50,376	45,544
NON-CURRENT ASSETS		
Long-term prepaid expenses	61	60
Long-term investment	1,000	1,000
Property and equipment, net	2,505	2,432
Intangible assets, net	7,023	7,039
Total non-current assets	10,589	10,531
Total assets	60,965	56,075
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	4,941
Other	1,113	1,146
Total current liabilities	6,722	6,180
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	133
Warrants	1,205	740
Total non-current liabilities	1,362	873
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	7,053
EQUITY		
Ordinary shares	2,836	2,874
Share premium	240,682	242,177
Capital reserve	10,337	11,143
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(199,558)	(205,756)
Total equity	52,881	49,022
Total liabilities and equity	60,965	56,075

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended March 31,	
	2017	2018

	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(3,590)	(5,070)
SALES AND MARKETING EXPENSES	(681)	(484)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,030)	(1,075)
OPERATING LOSS	(5,301)	(6,629)
NON-OPERATING INCOME (EXPENSES), NET	(5)	462
FINANCIAL INCOME	457	175
FINANCIAL EXPENSES	(6)	(206)
NET LOSS AND COMPREHENSIVE LOSS	(4,855)	(6,198)
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.08)	(0.06)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	58,620,094	106,169,273

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CONDENSED CONSOLIDATED 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, 2017	1,513	199,567	10,569	(1,416)	(175,206)	35,027
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2017:						
Issuance of share capital, net	128	4,944	-	-	-	5,072
Employee stock options exercised	1	296	(297)	-	-	-
Employee stock options forfeited and expired	-	1,085	(1,085)	-	-	-
Share-based compensation	-	-	472	-	-	472
Comprehensive loss for the period	-	-	-	-	(4,855)	(4,855)
BALANCE AT MARCH 31, 2017	1,642	205,892	9,659	(1,416)	(180,061)	35,716

	Ordinary shares	Share premium	Capital Reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(199,558)	52,881
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2018:						
Issuance of share capital, net	37	1,386	-	-	-	1,423
Employee stock options exercised	1	29	(30)	-	-	-
Employee stock options forfeited and expired	-	80	(80)	-	-	-
Share-based compensation	-	-	916	-	-	916
Comprehensive loss for the period	-	-	-	-	(6,198)	(6,198)
BALANCE AT MARCH 31, 2018	2,874	242,177	11,143	(1,416)	(205,756)	49,022

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2017	2018
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		

Comprehensive loss for the period	(4,855)	(6,198)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,062	(609)
Net cash used in operating activities	(3,793)	(6,807)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(7,013)	(4,000)
Maturities of short-term deposits	12,143	12,167
Purchase of property and equipment	(45)	(54)
Purchase of intangible assets	(3,718)	(29)
Net cash provided by investing activities	1,367	8,084
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital, net of issuance costs	2,087	1,423
Repayments of bank loan	(23)	(23)
Net cash provided by financing activities	2,064	1,400
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(362)	2,677
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	94	23
CASH AND CASH EQUIVALENTS - END OF PERIOD	2,201	7,810

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2017	**2018**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	119	140
Long-term prepaid expenses	(3)	1
Exchange differences on cash and cash equivalents	(94)	(23)
Gain on adjustment of warrants to fair value	-	(465)
Share-based compensation	472	916

Interest and exchange differences on short-term deposits	(143)	(182)
Interest and linkage differences on bank loan	-	(1)
	351	386
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(802)	(453)
Increase (decrease) in accounts payable and accruals	1,513	(542)
	711	(995)
	1,062	(609)
Supplementary information on interest received in cash	137	167

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