BioLineRx Reports Second Quarter 2017 Financial Results

August 8, 2017

TEL AVIV, Israel, Aug. 8, 2017 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the second quarter ended June 30, 2017.

Highlights and achievements during the second quarter 2017 and to date:

Continued execution on multiple clinical development programs for the Company's lead project, BL-8040:

- Announced plans to initiate Phase 3 pivotal study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation in H2 2017, following successful meeting with the FDA;
- Reported regulatory submissions of three Phase 1b/2 trials for BL-8040 in combination with atezolizumab, Genentech's anti-PDL1 cancer immunotherapy agent, in pancreatic, gastric and non-small cell lung cancers, under immunotherapy collaboration with Genentech, a member of the Roche Group. All three studies will be conducted as part of MORPHEUS, Roche's Novel Cancer Immunotherapy Development Platform, and are expected to commence in H2 2017;
- Reported filing of regulatory submissions to commence Phase 1b/2 trial for BL-8040 in combination with Genentech's atezolizumab in acute myeloid leukemia (AML), to be led by BioLineRx. This study is expected to commence in H2 2017;
- Announced initiation of first Phase 1b/2 trial under immunotherapy collaboration with Genentech - in pancreatic cancer;

The Company also announced an additional, direct investment by BVF Partners, L.P., its largest shareholder, increasing its economic interest in the Company to 24.9%. The $9.6 million investment was priced at $1.13 per unit, each unit consisting of 1 ordinary share, 0.35 of Series A warrant with an exercise price of $2.00 per share, and 0.35 of Series B warrant with an exercise price of $4.00 per share. The warrants are exercisable for a period of 4 years.

Expected significant upcoming milestones for 2017 and 2018:

- Partial results from immuno-oncology Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA® expected in H2 2017; top line results expected in H2 2018;
- Initiation of Phase 3 pivotal study for BL-8040 in stem-cell mobilization for autologous transplantation planned for H2 2017;
- Initiation of Phase 1b/2 immuno-oncology studies for BL-8040 in combination with Genentech's atezolizumab in gastric cancer and non-small cell lung cancer, as well as AML, all expected in H2 2017; partial results expected in H2 2018;
- Initiation of Phase 1 immuno-oncology study for AGI-134 in several solid tumor indications expected in H1 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, remarked, "We are pleased to report second quarter-to-date activities that reinforce our focus to deliver on our objectives. This included timely initiation of our cancer immunotherapy collaboration with Genentech for pancreatic cancer, as well as regulatory advancements for additional indications in other solid tumors, AML, and stem cell mobilization. Thus, by the end of the year, we remain poised to have one Phase 3 and seven Phase 2 or 1b/2 clinical trials up and running, in addition to announcing partial results in our Phase 2 study in pancreatic cancer under our immunotherapy collaboration with Merck."

"We are also pleased to have received a strong vote of confidence from BVF Partners last month. The $9.6 million direct investment we received will allow us to accelerate the development of our clinical programs. With over $60 million in cash on a pro forma basis, including BVF's investment, as of June 30th, we have a strong balance sheet which will enable us to fully execute on our current operating plans," Mr. Serlin concluded.

Financial Results for the Second Quarter Ended June 30, 2017

Research and development expenses for the three months ended June 30, 2017 were $4.0 million, an increase of $1.3 million, or 48.2%, compared to $2.7 million for the three months ended June 30, 2016. The increase resulted primarily from spending on AGI-134 and BL-8040 in the 2017 period. Research and development expenses for the six months ended June 30, 2017 were $7.7 million, an increase of $2.4 million, or 45.0%, compared to $5.3 million for the six months ended June 30, 2016. The reason for the increase is the same as that presented in the three-month comparison above.

Sales and marketing expenses for the three months ended June 30, 2017 were $0.3 million, similar to the comparable period in 2016. Sales and marketing expenses for the six months ended June 30, 2017 were $1.0 million, an increase of $0.5 million, or 86.3%, compared to $0.5 million for the six months ended June 30, 2016. The increase resulted primarily from market research activities and one-time professional fees related to business development activities.

General and administrative expenses for the three months ended June 30, 2017 were $0.8 million, similar to the comparable period in 2016. General and administrative expenses for the six months ended June 30, 2017 were $1.8 million, similar to the comparable period in 2016.

The Company's operating loss for the three months ended June 30, 2017 amounted to $5.2 million, compared with an operating loss of $3.9 million for the corresponding 2016 period. The Company's operating loss for the six months ended June 30, 2017 amounted to $10.5 million, compared with an operating loss of $7.6 million for the corresponding 2016 period.

Non-operating income (expenses) for the three and six months ended June 30, 2017 and 2016 were not material, and primarily relate to fair-value adjustments of warrant liabilities on the balance sheet.

Net financial income amounted to $0.3 million for the three months ended June 30, 2017 compared to net financial income of $0.1 million for the three months ended June 30, 2016. Net financial income amounted to $0.8 million for the six months ended June 30, 2017 compared to net financial income of $0.2 million for the six months ended June 30, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on our bank deposits.

The Company's net loss for the three months ended June 30, 2017 amounted to $4.9 million, compared with a net loss of $3.7 million for the corresponding 2016 period. The Company's net loss for the six months ended June 30, 2017 amounted to $9.8 million, compared with a net loss of $7.2 million for the corresponding 2016 period.

The Company held $52.6 million in cash, cash equivalents and short-term bank deposits as of June 30, 2017. In July 2017, the Company completed a direct placement of its securities for net proceeds of $9.5 million.

Net cash used in operating activities was $8.0 million for the six months ended June 30, 2017, compared with net cash used in operating activities of $7.5 million for the six months ended June 30, 2016. The $0.5 million increase in net cash used in operating activities during the six-month period in 2017, compared to the six-month period in 2016, was primarily the result of an increase in the Company's operating loss in the 2017 period.

Net cash used in investing activities for the six months ended June 30, 2017 was $16.0 million, compared to net cash provided by investing activities of $4.2 million for the six months ended June 30, 2016. 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.

Net cash provided by financing activities for the six months ended June 30, 2017 was $28.3 million, compared to net cash provided by financing activities of $1.6 million for the six months ended June 30, 2016. The increase in cash flows from financing activities primarily reflects the public offering completed in April 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, August 8, 2017, at 10:00 a.m. EDT. 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 at the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until August 11, 2017; please dial 1-877-456-0009 from the U.S. or +972-3-925-5946 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 acute myeloid leukemia (AML), is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 1b/2 study in pancreatic cancer, and is expected to initiate 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 the first half of 2018. In addition, BioLineRx has a strategic collaboration with Novartis Pharma AG 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 Inc., 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 23, 2017. 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, 2016	June 30, 2017

	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	6,946
Short-term bank deposits	33,154	45,616
Prepaid expenses	255	560
Other receivables	223	541
Total current assets	36,101	53,663
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	53
Property and equipment, net	2,605	2,463
Intangible assets, net	181	6,869
Total non-current assets	2,838	9,385
Total assets	38,939	63,048
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	4,262
Other	978	1,059
Total current liabilities	3,661	5,414
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	203
Warrants	1	1
Total non-current liabilities	251	204
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,912	5,618
EQUITY		
	1,513	
Ordinary shares		2,570
Share premium	199,567	231,368
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,569	9,866
Accumulated deficit	(175,206)	(184,958)
Total equity	35,027	57,430
Total liabilities and equity	38,939	63,048

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2016	2017	2016	2017
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(2,740)	(4,062)	(5,279)	(7,652)
SALES AND MARKETING EXPENSES	(272)	(288)	(520)	(969)
GENERAL AND ADMINISTRATIVE EXPENSES	(854)	(844)	(1,843)	(1,874)
OPERATING LOSS	(3,866)	(5,194)	(7,642)	(10,495)
NON-OPERATING INCOME (EXPENSES)	48	(4)	196	(9)
FINANCIAL INCOME	88	304	232	761
FINANCIAL EXPENSES	(5)	(3)	(9)	(9)
NET LOSS AND COMPREHENSIVE LOSS	(3,735)	(4,897)	(7,223)	(9,752)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.07)	(0.05)	(0.13)	(0.13)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	56,423,601	94,487,470	55,651,371	76,571,351

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

	Ordinary shares	Share premium	Other reserves	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options forfeited and expired	-	66	-	(66)	-	-
Share-based compensation	-	-	-	582	-	582
Comprehensive loss for the period	-	-	-	-	(7,223)	(7,223)
BALANCE AT JUNE 30, 2016	1,459	197,858	(1,416)	11,251	(166,588)	42,564

	Ordinary shares	Share premium	Other reserves	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2017	1,513	199,567	(1,416)	10,569	(175,206)	35,027
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2017:						
Issuance of share capital, net	1,056	30,241	-	-	-	31,297
Employee stock options exercised	1	320	-	(321)	-	-
Employee stock options forfeited and expired	-	1,240	-	(1,240)	-	-
Share-based compensation	-	-	-	858	-	858
Comprehensive loss for the period	-	-	-	-	(9,752)	(9,752)
BALANCE AT JUNE 30, 2017	2,570	231,368	(1,416)	9,866	(184,958)	57,430

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Six months ended June 30,	
	2016	2017
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(7,223)	(9,752)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(223)	1,746
Net cash used in operating activities	(7,446)	(8,006)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(19,804)	(36,422)
Maturities of short-term deposits	24,182	24,233
Purchase of property and equipment	(164)	(90)
Purchase of intangible assets	(24)	(3,721)
Net cash provided by (used in) investing activities	4,190	(16,000)
CASH FLOWS - FINANCING ACTIVITIES		

Issuances of share capital, net	1,595	28,312
Repayments of bank loan	(48)	(47)
Net cash provided by financing activities	1,547	28,265
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,709)	4,259
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,544	2,469
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	42	218
CASH AND CASH EQUIVALENTS - END OF PERIOD	3,877	6,946

BioLineRx Ltd.
APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Six months ended June 30,	
	2016	2017
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	245	250
Long-term prepaid expenses	4	(1)
Interest and exchange rate differences on short-term deposits	(204)	(273)
Share-based compensation	582	858
Exchange differences on cash and cash equivalents	(42)	(218)
Gain on adjustment of warrants to fair value	(193)	-
	392	616
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(352)	(623)
Increase (decrease) in accounts payable and accruals	(263)	1,753
	(615)	1,130
	(223)	1,746
Supplementary information on interest received in cash	192	258
Supplementary non-cash investment (see Note 4b)		2,985

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