BioLineRx Reports Second Quarter 2018 Financial Results

August 13, 2018

TEL AVIV, Israel, Aug. 13, 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 second quarter ended June 30, 2018.

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

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

- Positive data from successful completion of first lead-in patient cohort of the GENESIS trial, a double-blind, placebo-controlled, Phase 3 trial comparing BL-8040 in combination with granulocyte colony-stimulating factor (G-CSF), to G-CSF alone, for the mobilization of hematopoietic stem cells (HSCs) used for autologous transplantation in multiple myeloma patients. Results from first 11 patients prompted Data Monitoring Committee (DMC) to recommend early continuation to randomized placebo-controlled part 2 of trial; data show that 9/11 patients (82%) reached primary endpoint threshold of ≥ $6x10^6$ CD34 cells/kg with only one dose of BL-8040 and in up to 2 apheresis sessions;
- Expansion of immuno-oncology collaboration with Merck & Co., Inc., Kenilworth, N.J. (Merck), supporting a Phase 2a program investigating BL-8040 in combination with KEYTRUDA in pancreatic cancer patients. Under the expansion, a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy will be added to the ongoing COMBAT/KEYNOTE-202 study, with a specific focus on second line patients;
- Presentation at the 2018 European Hematology Association (EHA) Conference of very encouraging long-term overall survival results in Phase 2a trial in relapsed/refractory AML, demonstrating that the combination of BL-8040 with high-dose Cytarabine (HiDAC) significantly improved overall survival, compared with historical data for HiDAC monotherapy;
- 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.

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

- Initiation of multicenter, open-label Phase 1/2a study in the UK and Israel, with possible expansion to the US and additional countries in Europe in 2019; study will evaluate the safety and tolerability of AGI-134, as a monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors.

Expected significant milestones in next 18 months:

- Top-line results in immuno-oncology Phase 2a COMBAT study in pancreatic cancer for BL-8040 in combination with KEYTRUDA, under collaboration with Merck, to be presented at the European Society for Medical Oncology (ESMO) Congress in October 2018;
- Partial results in Phase 1b/2 study in pancreatic cancer under Genentech immuno-oncology collaboration, investigating BL-8040 in combination with Genentech's atezolizumab, expected in H2 2018;
- Potential interim analysis of Phase 2b BLAST study in AML consolidation in mid-2019:
- Results from additional cohort in Phase 2a COMBAT study under expansion of Merck collaboration, investigating triple combination of BL-8040, KEYTRUDA and chemotherapy in pancreatic cancer, by end of 2019;

"We are very encouraged by the clinical results achieved to-date in the major indications being developed under our BL-8040 platform, as we continue to advance the asset towards registration," stated Philip A. Serlin, Chief Executive Officer of BioLineRx. "Specifically, positive results from the initial lead-in cohort in the Phase 3 GENESIS trial, and the resulting DMC recommendation for an early continuation to the randomized, double-blind, placebo-controlled part of the trial, is an important clinical achievement for BL-8040. The data continue to demonstrate BL-8040's robust efficacy in stem-cell mobilization for autologous transplantation, including the potential to reduce the number of required apheresis sessions to one session in the majority of patients, versus multiple sessions under current practice. Building on this success, data from our ongoing COMBAT Phase 2a immuno-oncology trial support continued development in pancreatic cancer, as we expand our collaboration with Merck, with the addition to the existing study of a new cohort with 30-50 patients investigating the triple combination of BL-8040, KEYTRUDA and chemotherapy. The new cohort will focus on second-line pancreatic cancer patients and we are hopeful for significant synergies from the triple drug combination in this very difficult-to-treat population."

Mr. Serlin added, "In addition, we are excited about the data we continue to accumulate from our Phase 2a study in relapsed/refractory AML, with further significant improvement in overall survival data recently presented at EHA. We are focused on determining the appropriate next clinical development steps for this indication, in light of this very encouraging data. With regarding to our second main asset, AGI-134, we were pleased to initiate a Phase 1/2a study in multiple solid tumors. AGI-134 represents a new mechanistic class of cancer immunotherapies with a unique and highly differentiated mode of action, and we are pleased to begin our clinical evaluation of its potential."

"Over the next few quarters, we look forward to reporting on key milestones. These include top line results in our Phase 2a COMBAT study, partial results in the Phase 1b/2 pancreatic cancer trial under our collaboration with Genentech, and a potential interim analysis on the Phase 2b BLAST study in AML consolidation therapy," concluded Mr. Serlin.

Financial Results for the Second Quarter Ended June 30, 2018

Research and development expenses for the three months ended June 30, 2018 were $4.5 million, an increase of $0.4 million, or 10.4%, compared to $4.1 million for the three months ended June 30, 2017. The increase resulted primarily from higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230. Research and development expenses for the six months ended June 30, 2018 were $9.6 million, an increase of $1.9 million, or 24.9%, compared to $7.7 million for the six months ended June 30, 2017. The increase resulted primarily from higher expenses associated with new BL-8040 clinical studies commenced during 2017, as well as higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230.

Sales and marketing expenses for the three months ended June 30, 2018 were $0.4 million, an increase of $0.1 million, or 25%, compared to $0.3 million for the three months ended June 30, 2017. The increase resulted primarily from one-time consulting fees related to market research in the 2018 period. Sales and marketing expenses for the six months ended June 30, 2018 were $0.9 million, a decrease of $0.1 million, or 12.9%, compared to $1.0 million for the six months ended June 30, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 paid in the 2017 period.

General and administrative expenses for the three months ended June 30, 2018 were $0.9 million, similar to the comparable period in 2017. General and administrative

expenses for the six months ended June 30, 2018 were $1.9 million, similar to the comparable period in 2017.

The Company's operating loss for the three months ended June 30, 2018 amounted to $5.7 million, compared with an operating loss of $5.2 million for the corresponding 2017 period. The Company's operating loss for the six months ended June 30, 2018 amounted to $12.4 million, compared with an operating loss of $10.5 million for the corresponding 2017 period.

Non-operating income (expenses) for the three and six months ended June 30, 2018 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet and the capital gain from realization of the investment in iPharma. Non-operating income (expenses) for the three and six months ended June 30, 2017 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial income amounted to $0.3 million for the three months ended June 30, 2018, similar to the comparable period in 2017. Net financial income for both periods relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits. Net financial income amounted to $0.3 million for the six months ended June 30, 2018, compared to net financial income of $0.8 million for the six months ended June 30, 2017. Net financial income for the 2018 period primarily relates 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 June 30, 2018 amounted to $4.8 million, compared with a net loss of $4.9 million for the corresponding period. The Company's net loss for the six months ended June 30, 2018 amounted to $11.0 million, compared with a net loss of $9.8 million for the corresponding 2017 period.

The Company held $41.1 million in cash, cash equivalents and short-term bank deposits as of June 30, 2018.

Net cash used in operating activities was $13.0 million for the six months ended June 30, 2018, compared with net cash used in operating activities of $8.0 million for the six months ended June 30, 2017. The $5.0 million increase in net cash used in operating activities during the six-month period in 2018, compared to the six-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 and accruals.

Net cash provided by investing activities was $10.8 million for the six months ended June 30, 2018, compared to net cash used in investing activities of $16.0 million for the six months ended June 30, 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 and realization of the investment in iPharma in 2018.

Net cash provided by financing activities was $2.8 million for the six months ended June 30, 2018, compared to net cash provided by financing activities of $28.3 million for the six months ended June 30, 2017. The decrease in cash flows from financing activities reflects the public offering completed in April 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, August 13, 2018 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0664 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 August 16, 2018; please dial +1-877-456-0009 from the U.S. or +972-3-925-5937 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 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 (known as Merck in the US and Canada), on the basis of which the Company is conducting 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	June 30, 2018
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,110	5,789
Short-term bank deposits	44,373	35,339
Prepaid expenses	307	1,231
Other receivables	586	438
Total current assets	50,376	42,797

NON-CURRENT ASSETS		
Long-term prepaid expenses	61	63
Long-term investment	1,000	-
Property and equipment, net	2,505	2,318
Intangible assets, net	7,023	7,035
Total non-current assets	10,589	9,416
Total assets	60,965	52,213
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	4,128
Other	1,113	1,117
Total current liabilities	6,722	5,338
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	109
Warrants	1,205	580
Total non-current liabilities	1,362	689
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	6,027
EQUITY		
Ordinary shares	2,836	2,920
Share premium	240,682	243,883
Capital reserve	10,337	11,343
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(199,558)	(210,544)
Total equity	52,881	46,186
Total liabilities and equity	60,965	52,213

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2018	2017	2018
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,062)	(4,484)	(7,652)	(9,554)
SALES AND MARKETING EXPENSES	(288)	(360)	(969)	(844)
GENERAL AND ADMINISTRATIVE EXPENSES	(844)	(883)	(1,874)	(1,958)
OPERATING LOSS	(5,194)	(5,727)	(10,495)	(12,356)
NON-OPERATING INCOME (EXPENSES), NET	(4)	663	(9)	1,125
FINANCIAL INCOME	304	287	761	462
FINANCIAL EXPENSES	(3)	(11)	(9)	(217)
NET LOSS AND COMPREHENSIVE LOSS	(4,897)	(4,788)	(9,752)	(10,986)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.05)	(0.05)	(0.13)	(0.10)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	94,487,470	106,630,704	76,571,351	106,524,332

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

	Ordinary shares	Share premium	Other Comprehensive loss	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

	Ordinary shares	Share premium	Other Comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	(1,416)	10,337	(199,558)	52,881
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2018:						
Issuance of share capital, net	83	2,764	-	-	-	2,847
Employee stock options exercised	-	399	-	(399)	-	-
Employee stock options forfeited and expired	1	38	-	(39)	-	-
Share-based compensation	-	-	-	1,444	-	1,444
Comprehensive loss for the period	-	-	-	-	(10,986)	(10,986)
BALANCE AT JUNE 30, 2018	2,920	243,883	(1,416)	11,343	(210,544)	46,186

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

	Six months ended June 30,	
	2017	2018
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(9,752)	(10,986)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,746	(2,054)
Net cash used in operating activities	(8,006)	(13,040)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(36,422)	(15,000)
Maturities of short-term deposits	24,233	24,385
Proceeds from realization of long-term investment	-	1,500
Purchase of property and equipment	(90)	(76)
Purchase of intangible assets	(3,721)	(37)
Net cash provided by (used in) investing activities	(16,000)	10,772
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	28,312	2,847
Repayments of bank loan	(47)	(47)
Net cash provided by financing activities	28,265	2,800
INCREASE IN CASH AND CASH EQUIVALENTS	4,259	532
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	218	147
CASH AND CASH EQUIVALENTS - END OF PERIOD	6,946	5,789

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

	Six months ended June 30,	
	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	250	288
Long-term prepaid expenses	(1)	(2)
Exchange differences on cash and cash equivalents	(218)	(147)
Gain on adjustment of warrants to fair value	-	(625)
Gain on realization of long-term investment	-	(500)
Share-based compensation	858	1,444
Interest and exchange rate differences on short-term deposits	(273)	(351)
Interest and linkage differences on bank loan	-	(1)
	616	106
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(623)	(776)
Increase (decrease) in accounts payable and accruals	1,753	(1,384)
	1,130	(2,160)
	1,746	(2,054)
Supplementary information on interest received in cash	258	377
Supplementary non-cash investment	2,985	-

Contact:

PCG Advisory
Vivian Cervantes
Investor Relations
+1-646-863-6274
vivian@pcgadvisory.com

or

Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsipihai5@gmail.com

View original content:http://www.prnewswire.com/news-releases/biolinerx-reports-second-quarter-2018-financial-results-300695895.html

SOURCE BioLineRx Ltd.