



BioLineRx Reports Second Quarter 2019 Financial Results and Provides Corporate Update

August 6, 2019 11:00 AM IDT

On track for Phase 2 data read-out in pancreatic cancer by year-end 2019

Management to hold conference call today, August 6, at 10:00 am EDT

TEL AVIV, Israel, Aug. 6, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended June 30, 2019 and provides a corporate update.

Highlights and achievements during the second quarter 2019 and subsequent period:

- Continued to advance multiple clinical trials of its lead therapeutic candidates, BL-8040 and AGI-134, and anticipates top-line data from the triple combination arm of the COMBAT/KEYNOTE-202 pancreatic cancer trial by year-end.
- Received approval from the FDA for an Investigational New Drug (IND) application for AGI-134, which will enable expansion of the ongoing Phase 1/2a study, currently being carried out in the UK and Israel, to the US by the first half of 2020.

"BL-8040, our lead drug candidate, is rapidly advancing in multiple promising programs. The triple combination arm of our ongoing COMBAT/KEYNOTE-202 Phase 2 study of BL-8040, KEYTRUDA® and chemotherapy in metastatic pancreatic cancer is progressing as planned, and top-line results are expected by year end. AML consolidation also remains an important indication in our BL-8040 development plan, and we, with our partners, continue to progress our BLAST Phase 2b study towards a robust interim analysis. In addition, the GENESIS Phase 3 study in stem cell mobilization, our most advanced indication and most direct path to registration, is progressing as planned with top-line results expected in the second half of next year," stated Philip Serlin, Chief Executive Officer of BioLineRx.

"Regarding our second clinical candidate, the universal anti-cancer vaccine AGI-134, we continue to advance our phase 1/2a clinical trial toward initial safety data later this year, and with the acceptance of our IND, we look forward to the next part of the study, which will assess potential efficacy. Taken together, we believe our broad development pipeline provides multiple opportunities for long-term value creation and we are diligently working toward that goal," Mr. Serlin concluded.

Upcoming Milestones

Second half of 2019

- Top-line results from COMBAT/KEYNOTE-202 Phase 2 pancreatic cancer trial
- Initial safety results from part 1 of Phase 1/2a trial of AGI-134
- Potential interim results from Phase 2b AML consolidation study
- Initiation of monotherapy basket arm of Part 2 of Phase 1/2a trial of AGI-134

2020

- Progression-free survival (PFS) and overall survival (OS) data from COMBAT/KEYNOTE-202 trial in mid-2020
- Top-line results from Phase 3 GENESIS registration trial in stem-cell mobilization in second half of 2020

Financial Results for the Second Quarter Ended June 30, 2019

Research and development expenses for the three months ended June 30, 2019 were \$5.3 million, an increase of \$0.8 million, or 18%, compared to \$4.5 million for the three months ended June 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT clinical trials. Research and development expenses for the six months ended June 30, 2019 were \$9.7 million, an increase of \$0.1 million, or 2%, compared to \$9.6 million for the six months ended June 30, 2018. The small increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT clinical trials, offset by a decrease in expenses related to BL-1230, a project which was terminated, as well as a decrease in payroll and related expenses.

Sales and marketing expenses for the three months ended June 30, 2019 were \$0.2 million, a decrease of \$0.1 million, or 37%, compared to \$0.3 million for the three months ended June 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses. Sales and marketing expenses for the six months ended June 30, 2019 were \$0.5 million, a decrease of \$0.4 million, or 43%, compared to \$0.9 million for the six months ended June 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses, including a one-time compensation payment in the 2018 period.

General and administrative expenses for the three months ended June 30, 2019 were \$0.9 million, similar to the comparable period in 2018. General and administrative expenses for the six months ended June 30, 2019 were \$1.9 million, similar to the comparable period in 2018.

The Company's operating loss for the three months ended June 30, 2019 was \$6.5 million, compared to \$5.7 million for the three months ended June 30, 2018. The Company's operating loss for the six months ended June 30, 2019 was \$12.1 million, compared to \$12.4 million for the comparable period in 2018.

Non-operating income for the three and six months ended June 30, 2019 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses. Non-operating income for the six months ended June 30, 2018 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet, as well as a capital gain from realization of the investment in iPharma.

Net financial expenses amounted to \$0.3 million for the three months ended June 30, 2019 compared to net financial income of \$0.3 million for the three months ended June 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on bank deposits. 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 expenses amounted to \$0.5 million for the six months ended June 30, 2019 compared to net financial income of \$0.3 million for the six months ended June 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on bank deposits. 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.

The Company's net loss for the three months ended June 30, 2019 amounted to \$5.5 million, compared with a net loss of \$4.8 million for the comparable period in 2018. The Company's net loss for the six months ended June 30, 2019 amounted to \$11.6 million, compared with a net loss of \$11.0 million for the comparable period in 2018.

The Company held \$35.2 million in cash, cash equivalents and short-term bank deposits as of June 30, 2019.

Net cash used in operating activities was \$11.1 million for the six months ended June 30, 2019, compared with net cash used in operating activities of \$13.0 million for the six months ended June 30, 2018. The \$1.9 million decrease in net cash used in operating activities during the six-month period in 2019, compared to the six-month period in 2018, was primarily the result of changes in operating asset and liability items in the two periods, i.e., a decrease in prepaid expenses and other receivables in 2019 versus an increase in 2018, as well as a higher decrease in accounts payable and accruals in 2018.

Net cash used in investing activities was \$3.1 million for the six months ended June 30, 2019, compared to net cash provided by investing activities of \$10.8 million for the six months ended June 30, 2018. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and the realization of the investment in iPharma in 2018.

Net cash provided by financing activities was \$15.7 million for the six months ended June 30, 2019, compared to net cash provided by financing activities of \$2.8 million for the six months ended June 30, 2018. The increase in cash flows from financing activities reflects the underwritten public offering completed in February 2019.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, August 6, 2019 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0644 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 8, 2019; please dial +1-888-295-2634 from the U.S. or +972-3-925-5904 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 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 being investigated in 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 two Phase 1b/2 studies for solid tumor indications.

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.

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

December 31, June 30,

	2018	2019
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	3,404	4,972
Short-term bank deposits	26,747	30,256
Prepaid expenses	488	451
Other receivables	1,339	528
Total current assets	31,978	36,207
NON-CURRENT ASSETS		
Long-term prepaid expenses	56	60
Property and equipment, net	2,227	2,047
Right-of-use assets	-	1,716
Intangible assets, net	21,972	21,928
Total non-current assets	24,255	25,751
Total assets	56,233	61,958
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	895	2,395
Accounts payable and accruals:		
Trade	4,493	4,565
Other	1,363	927
Lease liabilities	-	672
Total current liabilities	6,751	8,559
NON-CURRENT LIABILITIES		
Warrants	323	3,938
Long-term loans, net of current maturities	7,838	6,583
Lease liabilities	-	1,096
Total non-current liabilities	8,161	11,617
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	14,912	20,176
EQUITY		
Ordinary shares	3,110	4,001
Share premium	250,192	261,522
Capital reserve	11,955	11,835
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(222,520)	(234,160)
Total equity	41,321	41,782
Total liabilities and equity	56,233	61,958

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

	Three months ended June 30,		Six months ended June 30,	
	2018	2019	2018	2019
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,484)	(5,302)	(9,554)	(9,694)
SALES AND MARKETING EXPENSES	(360)	(226)	(844)	(482)
GENERAL AND ADMINISTRATIVE EXPENSES	(883)	(949)	(1,958)	(1,879)
OPERATING LOSS	(5,727)	(6,477)	(12,356)	(12,055)
NON-OPERATING INCOME, NET	663	1,261	1,125	921
FINANCIAL INCOME	287	171	462	381
FINANCIAL EXPENSES	(11)	(440)	(217)	(887)
NET LOSS AND COMPREHENSIVE LOSS	(4,788)	(5,485)	(10,986)	(11,640)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.05)	(0.04)	(0.10)	(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	106,630,704	145,461,598	106,524,332	139,270,178

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

	OrdinaryShare	Capital	Other	Accumulated	Total	
	shares	premium	reserveloss	deficit		
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(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	1	38	(39)	-	-	-

Employee stock options forfeited and expired	-	399	(399)	-	-	-
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	11,343	(1,416)	(210,544)	46,186

	OrdinaryShare shares in USD thousands	premium reserves	Other Capital loss	Accumulated deficit	Total	
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2019:						
Issuance of share capital, net	890	10,437	-	-	-	11,327
Employee stock options exercised	1	27	(27)	-	-	1
Employee stock options forfeited and expired	-	866	(866)	-	-	-
Share-based compensation	-	-	773	-	-	773
Comprehensive loss for the period	-	-	-	-	(11,640)	(11,640)
BALANCE AT JUNE 30, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782

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

Six months ended June 30,
2018 **2019**
in USD thousands

CASH FLOWS - OPERATING ACTIVITIES

Comprehensive loss for the period	(10,986)	(11,640)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(2,054)	573
Net cash used in operating activities	(13,040)	(11,067)

CASH FLOWS - INVESTING ACTIVITIES

Investments in short-term deposits	(15,000)	(27,510)
Maturities of short-term deposits	24,385	24,441
Proceeds from realization of long-term investment	1,500	-
Purchase of property and equipment	(76)	(53)
Purchase of intangible assets	(37)	-
Net cash provided by (used in) investing activities	10,772	(3,122)

CASH FLOWS - FINANCING ACTIVITIES

Issuances of share capital and warrants, net of issuance cost	2,847	15,879
Employee stock options exercised	-	1
Repayments of loans	(47)	(47)
Repayments of lease liabilities	-	(110)
Net cash provided by financing activities	2,800	15,723

INCREASE IN CASH AND CASH EQUIVALENTS	532	1,534
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,110	3,404
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	147	34
CASH AND CASH EQUIVALENTS - END OF PERIOD	5,789	4,972

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

Six months ended June 30,
2018 2019
in USD thousands

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:

Depreciation and amortization	288	439
Long-term prepaid expenses	(2)	(4)
Exchange differences on cash and cash equivalents	(147)	(34)
Gain on adjustment of warrants to fair value	(625)	(1,354)
Gain on realization of long-term investment	(500)	-
Share-based compensation	1,444	773
Warrant issuance costs	-	417
Interest and exchange rate differences on short-term deposits	(351)	(440)
Interest on loans	(1)	292
	106	89

Changes in operating asset and liability items:

Decrease (increase) in prepaid expenses and other receivables	(776)	848
Decrease in accounts payable and accruals	(1,384)	(364)
	(2,160)	484
	(2,054)	573

Supplemental information on interest received in cash 377 442

Supplemental information on interest paid in cash 167 477

Supplemental information on non-cash transaction -
Initial establishment of right-of-use assets against lease liabilities - 1,878

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