



BioLineRx Reports Third Quarter 2019 Financial Results and Provides Corporate Update

November 11, 2019 12:00 PM IST

- On track for Phase 2 triple-combination data read-outs in pancreatic cancer by year-end 2019 -

- Management to hold conference call today, November 11, at 10:00am EST -

TEL AVIV, Israel, Nov. 11, 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 September 30, 2019 and provides a corporate update.

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

- Continued to advance its COMBAT/KEYNOTE-202 Phase 2a trial in collaboration with Merck, evaluating BL-8040 in combination with pembrolizumab and chemotherapy in metastatic pancreatic cancer;
- Obtained initial safety data from Part 1 of Phase 1/2a trial of AGI-134 and initiated patient dosing in Part 2, the monotherapy basket arm;
- Presented positive triple-combination preclinical data from the evaluation of BL-8040 in combination with an anti PD-1 and chemotherapy in pancreatic cancer, which support BL-8040's mechanism of action and provide a very strong rationale for the triple-combination clinical study, at the Society for Immunotherapy of Cancer Annual Meeting (SITC);
- Presented encouraging results from an MD Anderson investigator-sponsored, dual-combination study of BL-8040 in combination with KEYTRUDA in metastatic pancreatic cancer patients at SITC;
- Invited to deliver an oral presentation highlighting new clinical data from the triple-combination COMBAT/KEYNOTE-202 Phase 2a study at the European Society of Medical Oncology Immuno-Oncology Congress in December.

"We are quickly approaching a potentially transformational milestone for our Company with the anticipated release of results by the end of the year from the triple combination arm of our ongoing COMBAT/KEYNOTE-202 study of BL-8040, KEYTRUDA[®] and chemotherapy in metastatic pancreatic cancer," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Recent preclinical results from the triple combination of BL-8040, an anti PD-1 and chemotherapy, together with clinical results from two separate dual combination studies of BL-8040 and KEYTRUDA[®], give us a high degree of conviction in BL-8040's ability to modify the tumor microenvironment, thereby inducing infiltration of T-cells into the core and periphery of metastatic lesions. Based on our data to date, we believe we can potentially introduce a promising new treatment option not only for metastatic pancreatic cancer, but other difficult-to-treat solid tumor indications as well, where current standards of care are inadequate. At the same time, our trials of BL-8040 in AML and stem cell mobilization are progressing, with key data readouts expected next year."

"Regarding our second clinical candidate, the universal anti-cancer vaccine AGI-134, we successfully completed Part 1 of the ongoing Phase 1/2a clinical trial in a range of solid tumor types, and quickly initiated dosing in Part 2. We look forward to initial results by year-end 2020," Mr. Serlin concluded.

Upcoming Milestones

2019

- Response results from the Phase 2a triple combination COMBAT/KEYNOTE-202 pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under the collaboration with Merck;
- Oral presentation with additional data from the Phase 2a triple combination COMBAT/KEYNOTE-202 pancreatic cancer trial at the European Society of Medical Oncology Immuno-Oncology Congress in December

2020

- Progression-free survival and overall survival data from the COMBAT/KEYNOTE-202 Phase 2a triple combination study in mid-2020;

- Interim results from the Phase 2b AML consolidation study during the first half of 2020;
- Top-line results from Phase 3 GENESIS registrational study in stem cell mobilization in the second half of 2020;
- Initial results from Part 2 of Phase 1/2a trial of AGI-134 by year-end 2020.

Financial Results for the Third Quarter Ended September 30, 2019

Research and development expenses for the three months ended September 30, 2019 were \$5.6 million, an increase of \$0.6 million, or 11%, compared to \$5.0 million for the three months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT/KEYNOTE-202 clinical trials. Research and development expenses for the nine months ended September 30, 2019 were \$15.3 million, an increase of \$0.7 million, or 5%, compared to \$14.6 million for the nine months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT/KEYNOTE-202 clinical trials, offset by a decrease in expenses related to BL-1230, a project which was terminated.

Sales and marketing expenses for the three months ended September 30, 2019 were \$0.2 million, a decrease of \$0.1 million, or 31%, compared to \$0.3 million for the three months ended September 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses. Sales and marketing expenses for the nine months ended September 30, 2019 were \$0.7 million, a decrease of \$0.4 million, or 40%, compared to \$1.1 million for the nine months ended September 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 September 30, 2019 were \$0.9 million, similar to the comparable period in 2018. General and administrative expenses for the nine months ended September 30, 2019 were \$2.8 million, similar to the comparable period in 2018.

The Company's operating loss for the three months ended September 30, 2019 was \$6.6 million, compared to \$6.2 million for the three months ended September 30, 2018. The Company's operating loss for the nine months ended September 30, 2019 was \$18.7 million, compared to \$18.6 million for the comparable period in 2018.

Non-operating income for the three and nine months ended September 30, 2019 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses. Non-operating income (expense) for the three and nine months ended September 30, 2018 primarily relate 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 \$0.4 million for the three months ended September 30, 2019 compared to net financial income of \$0.1 million for the three months ended September 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. Net financial expenses amounted to \$0.9 million for the nine months ended September 30, 2019 compared to net financial income of \$0.4 million for the nine months ended September 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 September 30, 2019 amounted to \$3.9 million, compared with a net loss of \$6.3 million for the comparable period in 2018. The Company's net loss for the nine months ended September 30, 2019 amounted to \$15.6 million, compared with a net loss of \$17.3 million for the comparable period in 2018.

The Company held \$30.1 million in cash, cash equivalents and short-term bank deposits as of September 30, 2019.

Net cash used in operating activities was \$17.2 million for the nine months ended September 30, 2019, compared with net cash used in operating activities of \$19.0 million for the nine months ended September 30, 2018. The \$1.8 million decrease in net cash used in operating activities during the nine-month period in 2019, compared to the nine-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 an increase in accounts payable and accruals in 2019 versus a decrease in 2018.

Net cash provided by investing activities was \$2.1 million for the nine months ended September 30, 2019, compared to net cash provided by investing activities of \$16.0 million for the nine months ended September 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 \$16.6 million for the nine months ended September 30, 2019, compared to net cash provided by financing activities of \$2.8 million for the nine months ended September 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, November 11, 2019 at 10:00 a.m. EST. To access the conference call, please dial +1-888-407-2553 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 November 13, 2019; please dial +1-888-782-4291 from the U.S. or +972-3-925-5904 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on multiple oncology indications. The Company's lead program, BL-8040, is a cancer therapy platform currently being evaluated in a Phase 2a study in pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. BL-8040 is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation. In addition, the Company has an ongoing collaboration agreement with Genentech, a member of the Roche Group, evaluating BL-8040 in combination with Genentech's atezolizumab in two Phase 1b/2 solid tumor studies.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being evaluated in a Phase 1/2a study.

For additional information on BioLineRx, please visit the Company's website at www.bioginerx.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, September 30,	
	2018	2019
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	3,404	4,885
Short-term bank deposits	26,747	25,255
Prepaid expenses	488	277
Other receivables	1,339	1,285
Total current assets	31,978	31,702
NON-CURRENT ASSETS		
Long-term prepaid expenses	56	59
Property and equipment, net	2,227	1,923
Right-of-use assets	-	1,635
Intangible assets, net	21,972	21,906
Total non-current assets	24,255	25,523
Total assets	56,233	57,225

Liabilities and equity**CURRENT LIABILITIES**

Current maturities of long-term loans	895	3,164
Accounts payable and accruals:		
Trade	4,493	5,303
Other	1,363	973
Lease liabilities	-	651
Total current liabilities	6,751	10,091

NON-CURRENT LIABILITIES

Warrants	323	863
Long-term loans, net of current maturities	7,838	6,011
Lease liabilities	-	1,062
Total non-current liabilities	8,161	7,936

COMMITMENTS AND CONTINGENT LIABILITIES

Total liabilities	14,912	18,027
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EQUITY

Ordinary shares	3,110	4,129
Share premium	250,192	262,430
Capital reserve	11,955	12,153
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(222,520)	(238,098)
Total equity	41,321	39,198
Total liabilities and equity	56,233	57,225

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2019	2018	2019
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,027)	(5,558)	(14,581)	(15,252)
SALES AND MARKETING EXPENSES	(293)	(201)	(1,137)	(683)
GENERAL AND ADMINISTRATIVE EXPENSES	(892)	(884)	(2,850)	(2,763)
OPERATING LOSS	(6,212)	(6,643)	(18,568)	(18,698)
NON-OPERATING INCOME (EXPENSES), NET	(255)	3,055	870	3,976
FINANCIAL INCOME	154	247	534	628
FINANCIAL EXPENSES	(11)	(597)	(146)	(1,484)
NET LOSS AND COMPREHENSIVE LOSS	(6,324)	(3,938)	(17,310)	(15,578)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.06)	(0.03)	(0.16)	(0.11)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	107,110,585	148,920,707	107,040,191	142,527,942

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

	Other					
	OrdinaryShare	Capital	Comprehensive	Accumulated		
	shares	premium	reserves	loss	deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(199,558)	52,881
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	85	2,803	-	-	-	2,888

Employee stock options exercised	1	46	(47)	-	-	-
Employee stock options forfeited and expired	-	527	(527)	-	-	-
Share-based compensation	-	-	2,126	-	-	2,126
Comprehensive loss for the period	-	-	-	-	(17,310)	(17,310)
BALANCE AT SEPTEMBER 30, 2018	2,922	244,058	11,889	(1,416)	(216,868)	40,585

	Other					
	OrdinaryShare	Capital		ComprehensiveAccumulated		
	shares	premiumreserve	loss	deficit		Total
	in USD thousands					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	1,018	11,266	-	-	-	12,284
Employee stock options exercised	1	53	(53)	-	-	1
Employee stock options forfeited and expired	-	919	(919)	-	-	-
Share-based compensation	-	-	1,170	-	-	1,170
Comprehensive loss for the period	-	-	-	-	(15,578)	(15,578)
BALANCE AT SEPTEMBER 30, 2019	4,129	262,430	12,153	(1,416)	(238,098)	39,198

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

	Other					
	OrdinaryShare	Capital		ComprehensiveAccumulated		
	shares	premiumreserve	loss	deficit		Total
	in USD thousands					
BALANCE AT JULY 1, 2018	2,920	243,883	11,343	(1,416)	(210,544)	46,186
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	2	39	-	-	-	41

Employee stock options exercised	-	8	(8)	-	-	-
Employee stock options forfeited and expired	-	128	(128)	-	-	-
Share-based compensation	-	-	682	-	-	682
Comprehensive loss for the period	-	-	-	-	(6,324)	(6,324)
BALANCE AT SEPTEMBER 30, 2018	2,922	244,058	11,889	(1,416)	(216,868)	40,585

	Other					
	OrdinaryShare	Capital		ComprehensiveAccumulated		
	shares	premium	reserve	loss	deficit	Total
	in USD thousands					
BALANCE AT JULY 1, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	128	829	-	-	-	957
Employee stock options exercised	-	26	(26)	-	-	-
Employee stock options forfeited and expired	-	53	(53)	-	-	-
Share-based compensation	-	-	397	-	-	397
Comprehensive loss for the period	-	-	-	-	(3,938)	(3,938)
BALANCE AT SEPTEMBER 30, 2019	4,129	262,430	12,153	(1,416)	(238,098)	39,198

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

Nine months ended

September 30,

2018 2019

in USD thousands

CASH FLOWS - OPERATING ACTIVITIES

Comprehensive loss for the period	(17,310)	(15,578)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,741)	(1,658)
Net cash used in operating activities	(19,051)	(17,236)

CASH FLOWS - INVESTING ACTIVITIES

Investments in short-term deposits	(22,000)	(34,517)
Maturities of short-term deposits	36,613	36,637
Proceeds from realization of long-term investment	1,500	-
Purchase of property and equipment	(76)	(54)
Purchase of intangible assets	(40)	-
Net cash provided by investing activities	15,997	2,066

CASH FLOWS - FINANCING ACTIVITIES

Issuances of share capital and warrants, net of issuance cost	2,888	16,836
Employee stock options exercised	-	1
Repayments of loans	(70)	(70)
Repayments of lease liabilities	-	(165)
Net cash provided by financing activities	2,818	16,602

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS (236) 1,432

CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD 5,110 3,404

EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS (171) 49

CASH AND CASH EQUIVALENTS - END OF PERIOD 4,703 4,885

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

**Nine months ended
September 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	414	667
Long-term prepaid expenses	(5)	(3)
Exchange differences on cash and cash equivalents	171	(49)
Gain on adjustment of warrants to fair value	(401)	(4,429)
Gain on realization of long-term investment	(500)	-
Share-based compensation	2,126	1,170
Warrant issuance costs	-	417
Interest and exchange rate differences on short-term deposits	(540)	(628)
Interest on loans	(1)	512
	1,264	(2,343)

Changes in operating asset and liability items:

Decrease (increase) in prepaid expenses and other receivables	(1,208)	265
Increase (decrease) in accounts payable and accruals	(1,797)	420
	(3,005)	685
	(1,741)	(1,658)

Supplemental information on interest received in cash 598 628

Supplemental information on interest paid in cash - 782

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

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