



BioLineRx Reports Third Quarter 2016 Financial Results

November 22, 2016 1:00 PM IST

TEL AVIV, Israel, Nov. 22, 2016 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reports its financial results for the third quarter ended September 30, 2016.

Highlights and achievements during third quarter of 2016 and to date:

- Signing of significant immuno-oncology collaboration with Genentech, a member of the Roche Group, for several Phase 1b studies for BL-8040 in combination with Genentech's Atezolizumab, in multiple solid tumor indications and AML
- Steady progress in existing immuno-oncology collaboration with MSD (known as Merck in the US and Canada), with initiation of a Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA®
- Signing of immuno-oncology collaboration with MD Anderson Cancer Center for additional Phase 2a combination study in pancreatic cancer, as part of strategic clinical research immunotherapy collaboration between MSD and MD Anderson Cancer Center
- In-licensing of three new projects under strategic collaboration with Novartis, including two novel liver fibrosis/failure projects, and a novel anti-inflammatory treatment for dry eye syndrome
- Presentation of growing body of clinical evidence surrounding BL-8040 at leading medical and scientific conferences, including an oral presentation at the upcoming ASH 2016
- Expanded geographic reach with new joint venture in China for development of novel drug candidates

Expected upcoming significant milestones for 2017:

- Partial results from Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by Q1 2017
- Partial results in immuno-oncology Phase 2a study for pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA® expected by H2 2017
- Phase 1b immuno-oncology studies for BL-8040 in combination with Genentech's Atezolizumab, in multiple solid tumor indications and AML, expected to commence during 2017

Philip A. Serlin, Chief Executive Officer of BioLineRx, remarked, "The third quarter of 2016 demonstrated our continued ability to leverage our leading BL-8040 oncology platform, as well as our access to cutting edge technologies. In particular, our immunotherapy collaboration efforts continued to bear fruit, with the signing of a significant agreement with Genentech to carry out multiple clinical trials in a variety of oncology indications, as well as a collaboration agreement with MD Anderson Cancer Center. Meanwhile, our immunotherapy collaboration with Merck, announced earlier in the year, steadily progressed, with our Phase 2a clinical trial in pancreatic cancer now in active enrollment. Further, following extensive due diligence, we are now pleased to roll out three programs under our Novartis collaboration, including two in the exciting field of liver fibrosis. We expect a number of additional novel assets to enter our pipeline in 2017, including several within the framework of the Novartis collaboration. Finally, we continue to highlight growing clinical evidence supporting our lead oncology program, BL-8040, which is regularly featured at leading medical and scientific conferences."

"We are excited about our prospects ahead and are focused on achieving our expected milestones for 2017 and beyond. With \$39 million of cash on hand, we remain well positioned to carry out our operational plans for the next few years," Mr. Serlin concluded.

Financial Results for the Third Quarter Ended September 30, 2016

Research and development expenses for the three months ended September 30, 2016 were \$3.0 million, an increase of \$0.4 million, or 14.7%, compared to \$2.6 million for the comparable period in 2015. The increase resulted primarily from spending on new projects and from increased spending on BL-8040 in the 2016 period. Research and development expenses for the nine months ended September 30, 2016 were \$8.2 million, a decrease of \$0.4 million, or 5.1%, compared to \$8.7 million for the comparable period in 2015. The decrease resulted primarily from lower expenditures for BL-7010 during the 2016 period and conclusion of one of the clinical trials for BL-8040 in 2015, partially offset by increased spending

on a new project.

Sales and marketing expenses for the three months ended September 30, 2016 were \$0.41 million, an increase of \$0.14 million, or 54.3%, compared to \$0.27 million for the comparable period in 2015. The increase resulted primarily from consultancy and legal expenses related to increased business development activity in the 2016 period. Sales and marketing expenses for the nine months ended September 30, 2016 were \$0.9 million, an increase of \$0.1 million, or 12.6%, compared to \$0.8 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

General and administrative expenses for the three months ended September 30, 2016 were \$1.1 million, an increase of \$0.4 million, or 47.6%, compared to \$0.8 million for the comparable period in 2015. The increase resulted primarily from an increase in non-cash share-based compensation. General and administrative expenses for the nine months ended September 30, 2016 were \$3.0 million, an increase of \$0.4 million, or 14.4%, compared to \$2.6 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company's operating loss for the three months ended September 30, 2016 amounted to \$4.5 million, compared with an operating loss of \$3.6 million for the corresponding 2015 period. The Company's operating loss for the nine months ended September 30, 2016 amounted to \$12.1 million, similar to the comparable period in 2015.

Non-operating income (expenses) for the three and nine months ended September 30, 2016 and 2015 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. These fair-value adjustments, which were material in the 2015 periods, but not material in the 2016 periods, are highly influenced by the Company's share price at each period end (revaluation date).

Net financial income (expenses) for the three and nine months ended September 30, 2016 and 2015 primarily relate to investment income earned on bank deposits, as well as banking fees.

The Company's net loss for the three months ended September 30, 2016 amounted to \$4.3 million, compared with a net loss of \$1.6 million for the corresponding 2015 period. The Company's net loss for the nine months ended September 30, 2016 amounted to \$11.6 million, compared with a net loss of \$10.7 million for the corresponding 2015 period.

The Company held \$38.9 million in cash, cash equivalents and short-term bank deposits as of September 30, 2016.

Net cash used in operating activities was \$10.4 million for the nine months ended September 30, 2016, compared with net cash used in operating activities of \$11.0 million for the comparable period in 2015. The \$0.6 million decrease in net cash used was primarily the result of an increase in other receivables.

Net cash provided by investing activities for the nine months ended September 30, 2016 was \$7.3 million, compared to net cash used in investing activities of \$18.7 million for the comparable period in 2015. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the nine months ended September 30, 2016 was \$1.5 million, compared to net cash provided by financing activities of \$29.3 million for the comparable period in 2015. The decrease in cash flows from financing activities reflects the underwritten public offering which was completed in March 2015.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its third quarter end September 30, 2016 results today, November 22, 2016, at 10:00 a.m. EST. To access the conference call, please dial 1-866-744-5399 from the US, or +972-3-918-0692 internationally. The call will also be available via live webcast through BioLineRx's website, www.biolineRx.com. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-866-276-1485 from the US or +972-3-925-5944 internationally. The replay will be available through November 25, 2016.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds, primarily from academic institutions and biotech companies based in Israel, 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 recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 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) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and has recently signed 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 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 10, 2016. 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,	
	2015	2016
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,544	4,014
Short-term bank deposits	42,119	34,894
Prepaid expenses	229	203
Other receivables	291	303
Total current assets	<u>48,183</u>	<u>39,414</u>
NON-CURRENT ASSETS		
Long-term prepaid expenses	58	54
Property and equipment, net	2,909	2,654
Intangible assets, net	152	155
Total non-current assets	<u>3,119</u>	<u>2,863</u>
Total assets	<u><u>51,302</u></u>	<u><u>42,277</u></u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	1,910	2,274
Other	1,137	1,000
Total current liabilities	<u>3,140</u>	<u>3,367</u>
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	344	272
Warrants	208	29
Total non-current liabilities	<u>552</u>	<u>301</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>3,692</u>	<u>3,668</u>
EQUITY		
Ordinary shares	1,455	1,460
Share premium	196,201	198,380
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,735	11,106
Accumulated deficit	<u>(159,365)</u>	<u>(170,921)</u>
Total equity	<u>47,610</u>	<u>38,609</u>
Total liabilities and equity	<u><u>51,302</u></u>	<u><u>42,277</u></u>

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2016	2015	2016
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,576)	(2,954)	(8,678)	(8,233)
SALES AND MARKETING EXPENSES	(265)	(409)	(824)	(928)
GENERAL AND ADMINISTRATIVE EXPENSES	(762)	(1,125)	(2,594)	(2,968)
OPERATING LOSS	(3,603)	(4,488)	(12,096)	(12,129)
NON-OPERATING INCOME (EXPENSES), NET	1,983	(14)	1,096	182
FINANCIAL INCOME	85	172	363	403
FINANCIAL EXPENSES	(91)	(4)	(111)	(12)
NET LOSS AND COMPREHENSIVE LOSS	<u>(1,626)</u>	<u>(4,334)</u>	<u>(10,748)</u>	<u>(11,556)</u>

	<u>in USD</u>	<u>in USD</u>	<u>in USD</u>	<u>in USD</u>
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.03)	(0.08)	(0.21)	(0.21)

WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>54,632,788</u>	<u>56,426,202</u>	<u>50,306,892</u>	<u>55,912,486</u>
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BioLineRx Ltd.
CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other comprehensive loss</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JANUARY 1, 2015	1,055	167,331	(1,416)	9,800	(144,965)	31,805
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2015:						
Issuance of share capital, net	395	28,449	-	-	-	28,844
Employee stock options forfeited and expired	-	170	-	(170)	-	-
Share-based compensation	-	-	-	770	-	770
Comprehensive loss for the period	-	-	-	-	(10,748)	(10,748)
BALANCE AT SEPTEMBER 30, 2015	<u>1,450</u>	<u>195,950</u>	<u>(1,416)</u>	<u>10,400</u>	<u>(155,713)</u>	<u>50,671</u>

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other comprehensive loss</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JANUARY 1, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options exercised	1	128	-	(128)	-	1
Employee stock options forfeited and expired	-	460	-	(460)	-	-
Share-based compensation	-	-	-	959	-	959
Comprehensive loss for the period	-	-	-	-	(11,556)	(11,556)
BALANCE AT SEPTEMBER 30, 2016	<u>1,460</u>	<u>198,380</u>	<u>(1,416)</u>	<u>11,106</u>	<u>(170,921)</u>	<u>38,609</u>

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

	<u>Nine months ended</u>	
	<u>September 30,</u>	
	<u>2015</u>	<u>2016</u>
	<u>in USD thousands</u>	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(10,748)	(11,556)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(232)	1,128
Net cash used in operating activities	<u>(10,980)</u>	<u>(10,428)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(51,262)	(28,978)
Maturities of short-term deposits	34,878	36,480

Maturities of restricted deposits	166	-
Purchase of property and equipment	(2,466)	(164)
Purchase of intangible assets	(22)	(24)
Net cash provided by (used in) investing activities	<u>(18,706)</u>	<u>7,314</u>
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	28,844	1,595
Proceeds of bank loan	467	-
Repayments of bank loan	(8)	(72)
Proceeds from exercise of employee stock options	-	1
Net cash provided by financing activities	<u>29,303</u>	<u>1,524</u>
DECREASE IN CASH AND CASH EQUIVALENTS	(383)	(1,590)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,790	5,544
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(87)	60
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>5,320</u>	<u>4,014</u>

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

Nine months ended
September 30,
2015 2016
in USD thousands

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:

Depreciation and amortization	322	368
Long-term prepaid expenses	(7)	4
Interest and exchange rate differences on short-term deposits	(113)	(277)
Share-based compensation	770	959
Exchange differences on cash and cash equivalents	87	(60)
Gain on adjustment of warrants to fair value	(1,096)	(179)
	<u>(37)</u>	<u>815</u>

Changes in operating asset and liability items:

Decrease (Increase) in prepaid expenses and other receivables	(700)	14
Increase in accounts payable and accruals	505	299
	<u>(195)</u>	<u>313</u>
	<u>(232)</u>	<u>1,128</u>

Supplementary information on investing activities not involving cash flows:

Property and equipment acquired on supplier trade credit	<u>228</u>	<u>-</u>
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Supplementary information on interest received in cash

	<u>105</u>	<u>310</u>
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