



BioLineRx Reports Third Quarter 2017 Financial Results

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TEL AVIV, Israel, Nov. 21, 2017 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the third quarter ended September 30, 2017.

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

Continued execution on multiple clinical development studies for BL-8040, the Company's lead oncology program:

- Initiation of two additional Phase 1b/2 studies under collaboration with Genentech, following the first study which was initiated in July 2017. All studies are exploring the combination of BL-8040 with Tecentriq (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy agent.
 - Phase 1b/2 trial for the maintenance treatment of patients with intermediate- and high-risk acute myeloid leukemia (AML) who have achieved complete response (CR) following induction and consolidation therapy.
 - Phase 1b/2 trial for the treatment of gastric cancer. This study is conducted as part of MORPHEUS, Roche's Novel Cancer Immunotherapy Development Platform.
- Completion of enrollment to the COMBAT study, which is investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda, in the treatment of pancreatic cancer patients.
- Regulatory submission to initiate Phase 3 pivotal study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation, expected to commence by the end of 2017, following receipt of regulatory approvals; and
- Several abstracts accepted to key scientific conferences:
 - Oral presentation at the American Society of Hematology (ASH) in December 2017 of pre-clinical data supporting BL-8040 as a robust mobilizer of hematopoietic stem cells associated with long-term engraftment.
 - Poster presentation at the ASCO GI conference of partial results from the monotherapy portion of the Phase 2a COMBAT study in pancreatic cancer. The abstract for this presentation will be published prior to the conference in January 2018.

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 to be announced at ASCO GI conference in January 2018; top line results expected in H2 2018;
- Initiation of Phase 3 pivotal study for BL-8040 in stem-cell mobilization for autologous transplantation, expected by the end of 2017;
- Initiation of Phase 1b/2 immuno-oncology study for BL-8040 in combination with Genentech's atezolizumab for non-small cell lung cancer, expected by early 2018. Partial results in Phase 1b/2 solid tumors and AML trials in collaboration with Genentech are 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 third quarter-to-date activities that continue to demonstrate clinical and regulatory execution on our multiple programs. This included timely initiation of the studies under our cancer immunotherapy collaboration with Genentech for gastric cancer and AML, as well as finalization of all preparations for initiation of our Phase 3 GENESIS study in stem cell mobilization. We are also very excited about the completion of enrollment to the COMBAT study, which will allow us to report topline results as planned in H2 2018. By year-end 2017, we remain on track to have one Phase 3 and seven Phase 2 or 1b/2 clinical trials up and running, and in January 2018 we plan to announce partial results from our Phase 2 study in pancreatic cancer under our immunotherapy collaboration with Merck."

Financial Results for the Third Quarter Ended September 30, 2017

Research and development expenses for the three months ended September 30, 2017 were \$5.7 million, an increase of \$2.7 million, or 91.4%, compared to \$3.0 million for the three months ended September 30, 2016. The increase resulted primarily from spending on the recently acquired AGI-134 near-clinical project and from higher expenses in 2017 associated with new BL-8040 studies commenced during the third quarter of 2016 and during 2017. Research and development expenses for the nine months ended September 30, 2017 were \$13.3 million, an increase of \$5.1 million, or 61.6%, compared to \$8.2 million for the nine months ended September 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 September 30, 2017 were \$0.2 million, a decrease of \$0.2 million, or 39.1%, compared to \$0.4 million for the three months ended September 30, 2016. The decrease resulted primarily from market research activities related to BL-8040, as well as legal expenses related to business development collaborations and in-licensing activities, in the 2016 period. Sales and marketing expenses for the nine months ended September 30, 2017 were \$1.2 million, an increase of \$0.3 million, or 31.2%, compared to \$0.9 million for the nine months ended September 30, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

General and administrative expenses for the three months ended September 30, 2017 were \$1.1 million, similar to the comparable period in 2016. General and administrative expenses for the nine months ended September 30, 2017 were \$3.0 million, similar to the comparable period in 2016.

The Company's operating loss for the three months ended September 30, 2017 amounted to \$7.1 million, compared with an operating loss of \$4.5 million for the corresponding 2016 period. The Company's operating loss for the nine months ended September 30, 2017 amounted to \$17.6 million, compared with an operating loss of \$12.1 million for the corresponding 2016 period. The increase in operating loss reflects a significant increase in research and development expenses for the respective periods.

Non-operating income (expenses) for the three and nine months ended September 30, 2017 and 2016 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. Non-operating expenses for the three-month and nine-month periods ended September 30, 2017 primarily result from a \$0.3 million fair-value adjustment of derivative liabilities on account of the warrants issued in the direct placement conducted in July 2017. These fair-value adjustments are highly influenced by the Company's share price at each period end (revaluation date).

Net financial income amounted to \$0.2 million for the three months ended September 30, 2017, similar to the comparable period in 2016. Net financial income amounted to \$0.9 million for the nine months ended September 30, 2017 compared to net financial income of \$0.4 million for the nine months ended September 30, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

The Company's net loss for the three months ended September 30, 2017 amounted to \$7.2 million, compared with a net loss of \$4.3 million for the corresponding 2016 period. The Company's net loss for the nine months ended September 30, 2017 amounted to \$17.0 million, compared with a net loss of \$11.6 million for the corresponding 2016 period.

The Company held \$55.0 million in cash, cash equivalents and short-term bank deposits as of September 30, 2017.

Net cash used in operating activities was \$14.2 million for the nine months ended September 30, 2017, compared with net cash used in operating activities of \$10.4 million for the nine months ended September 30, 2016. The \$3.8 million increase in net cash used in operating activities during the nine-month period in 2017, compared to the nine-month period in 2016, was primarily the result of increased research and development expenses in the 2017 period.

Net cash used in investing activities for the nine months ended September 30, 2017 was \$19.5 million, compared to net cash provided by investing activities of \$7.3 million for the nine months ended September 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 acquisition of Agalimmune and investment in iPharma.

Net cash provided by financing activities for the nine months ended September 30, 2017 was \$37.7 million, compared to net cash provided by financing activities of \$1.5 million for the nine months ended September 30, 2016. The increase in cash flows from financing activities primarily reflects our public offering completed in April 2017 and the registered direct placement completed in July 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 21, 2017, at 10:00 a.m. EST. To access the conference call, please dial 1-888-407-2553 from the U.S. or +972-3-918-0664 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 at the [Investor Relations](#) page of BioLineRx's website. A dial-in replay of the call will be available until November 24, 2017; please dial 1-866-500-4953 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 AML, is in the midst of a Phase 2b study as an AML consolidation treatment 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 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, 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.bioplinrx.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, September 30, | |
|--|-----------------------------------|----------------------|
| | 2016 | 2017 |
| | in USD thousands | |
| Assets | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | 2,469 | 6,712 |
| Short-term bank deposits | 33,154 | 48,295 |
| Prepaid expenses | 255 | 282 |
| Other receivables | 223 | 558 |
| Total current assets | <u>36,101</u> | <u>55,847</u> |
| NON-CURRENT ASSETS | | |
| Long-term prepaid expenses | 52 | 60 |
| Long-term investment | - | 1,000 |
| Property and equipment, net | 2,605 | 2,365 |
| Intangible assets, net | 181 | 6,855 |
| Total non-current assets | <u>2,838</u> | <u>10,280</u> |
| Total assets | <u><u>38,939</u></u> | <u><u>66,127</u></u> |
| Liabilities and equity | | |
| CURRENT LIABILITIES | | |
| Current maturities of long-term bank loan | 93 | 93 |
| Accounts payable and accruals: | | |
| Trade | 2,590 | 4,349 |
| Other | 978 | 1,084 |
| Total current liabilities | <u>3,661</u> | <u>5,526</u> |
| NON-CURRENT LIABILITIES | | |
| Long-term bank loan, net of current maturities | 250 | 180 |
| Warrants | 1 | 1,396 |
| Total non-current liabilities | <u>251</u> | <u>1,576</u> |
| COMMITMENTS AND CONTINGENT LIABILITIES | | |
| Total liabilities | <u>3,912</u> | <u>7,102</u> |
| EQUITY | | |
| Ordinary shares | 1,513 | 2,809 |
| Share premium | 199,567 | 239,606 |
| Other comprehensive loss | (1,416) | (1,416) |
| Capital reserve | 10,569 | 10,227 |
| Accumulated deficit | <u>(175,206)</u> | <u>(192,201)</u> |
| Total equity | <u>35,027</u> | <u>59,025</u> |
| Total liabilities and equity | <u><u>38,939</u></u> | <u><u>66,127</u></u> |

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

| | Three months ended | | Nine months ended | |
|---|--|----------------|-------------------|-----------------|
| | September 30, | | September 30, | |
| | 2016 | 2017 | 2016 | 2017 |
| | in USD thousands | | in USD thousands | |
| RESEARCH AND DEVELOPMENT EXPENSES, NET | (2,954) | (5,654) | (8,233) | (13,306) |
| SALES AND MARKETING EXPENSES | (409) | (249) | (928) | (1,218) |
| GENERAL AND ADMINISTRATIVE EXPENSES | (1,125) | (1,154) | (2,968) | (3,028) |
| OPERATING LOSS | (4,488) | (7,057) | (12,129) | (17,552) |
| NON-OPERATING INCOME (EXPENSES), NET | (14) | (333) | 182 | (342) |
| FINANCIAL INCOME | 172 | 153 | 403 | 914 |
| FINANCIAL EXPENSES | (4) | (6) | (12) | (15) |
| NET LOSS AND COMPREHENSIVE LOSS | (4,334) | (7,243) | (11,556) | (16,995) |
| | in USD | | in USD | |
| LOSS PER ORDINARY SHARE - BASIC AND DILUTED | (0.08) | (0.07) | (0.21) | (0.20) |
| WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE | <u>56,426,202</u><u>101,874,372</u><u>55,912,486</u><u>85,106,723</u> | | | |

BioLineRx Ltd.
CONDENSED CONSOLIDATED 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, 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 | 1,460 | 198,380 | (1,416) | 11,106 | (170,921) | 38,609 |

| | 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 NINE MONTHS ENDED SEPTEMBER 30, 2017: | | | | | | |
| Issuance of share capital, net | 1,295 | 38,388 | - | - | - | 39,683 |
| Employee stock options exercised | 1 | 326 | - | (326) | - | 1 |
| Employee stock options forfeited and expired | - | 1,325 | - | (1,325) | - | - |
| Share-based compensation | - | - | - | 1,309 | - | 1,309 |
| Comprehensive loss for the period | - | - | - | - | (16,995) | (16,995) |
| BALANCE AT SEPTEMBER 30, 2017 | 2,809 | 239,606 | (1,416) | 10,227 | (192,201) | 59,025 |

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

| | Nine months ended | |
|--|--------------------------------|---------------------|
| | September 30, | |
| | 2016 | 2017 |
| | <u>in USD thousands</u> | |
| CASH FLOWS - OPERATING ACTIVITIES | | |
| Comprehensive loss for the period | (11,556) | (16,995) |
| Adjustments required to reflect net cash used in operating activities (see appendix below) | <u>1,128</u> | <u>2,772</u> |
| Net cash used in operating activities | <u>(10,428)</u> | <u>(14,223)</u> |
| CASH FLOWS - INVESTING ACTIVITIES | | |
| Long-term investment | - | (1,000) |
| Investments in short-term deposits | (28,978) | (48,029) |
| Maturities of short-term deposits | 36,480 | 33,327 |
| Purchase of property and equipment | (164) | (109) |
| Purchase of intangible assets | <u>(24)</u> | <u>(3,721)</u> |
| Net cash provided by (used in) investing activities | <u>7,314</u> | <u>(19,532)</u> |
| CASH FLOWS - FINANCING ACTIVITIES | | |
| Issuance of share capital and warrants, net of issuance costs | 1,595 | 37,761 |
| Repayments of bank loan | (72) | (70) |
| Proceeds from exercise of employee stock options | <u>1</u> | <u>-</u> |
| Net cash provided by financing activities | <u>1,524</u> | <u>37,691</u> |
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (1,590) | 3,936 |
| CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD | 5,544 | 2,469 |
| EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS | 60 | 307 |
| CASH AND CASH EQUIVALENTS - END OF PERIOD | <u>4,014</u> | <u>6,712</u> |

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

Nine months ended
September 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 | 368 | 381 |
| Long-term prepaid expenses | 4 | (8) |
| Interest and exchange rate differences on short-term deposits | (277) | (439) |
| Share-based compensation | 959 | 1,309 |
| Warrant issuance costs | - | 17 |
| Exchange differences on cash and cash equivalents | (60) | (307) |
| Loss (gain) on adjustment of warrants to fair value | (179) | 316 |
| | <u>815</u> | <u>1,269</u> |

Changes in operating asset and liability items:

| | | |
|---|--------------|--------------|
| Decrease (Increase) in prepaid expenses and other receivables | 14 | (362) |
| Increase in accounts payable and accruals | 299 | 1,865 |
| | <u>313</u> | <u>1,503</u> |
| | <u>1,128</u> | <u>2,772</u> |

Supplementary information on interest received in cash 310 378**Supplementary non-cash investment (see Note 4b)** - 2,985**Contact:**

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