BioLineRx Reports Third Quarter 2014 Financial Results

November 10, 2014

JERUSALEM--(BUSINESS WIRE)--Nov. 10, 2014-- BioLineRx (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reported its financial results for the third quarter ended September 30, 2014.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "Our focus during the third quarter of 2014 was on continued clinical execution, focusing primarily on BL-8040, our lead oncology platform for the treatment of acute myeloid leukemia (AML), stem cell mobilization and other hematological indications, and on BL-7010, our lead immunology program for the treatment of celiac disease. This quarter we announced significant clinical and preclinical advancements for each of our lead programs and we continue to progress toward meaningful value inflection points for these and other pipeline candidates over the next 12 months."

"BL-8040 is currently advancing towards completing the dose escalation stage of the ongoing Phase 2 trial for the treatment of AML. We recently announced the addition of higher dosing cohorts due to encouraging efficacy and excellent safety results from all doses tested to date. Under the amended trial protocol, we expect to complete the dose escalation early next year and anticipate reporting final Phase 2 data in the second half of 2015. Additionally, we initiated patient dosing in a second indication for our BL-8040 platform - a Phase 1 trial for stem cell mobilization for which we expect final results in late 2014 or early 2015. Finally, we announced compelling preclinical results from a combination study of BL-8040 and the investigational FLT3 inhibitor AC220, in which BL-8040 demonstrated profound synergy in minimizing residual disease in this particularly difficult-to-treat form of AML, potentially opening a future avenue of BL-8040 development. We look forward to updating the market on our continued progress, including new clinical studies that we plan to start in 2015."

"We also announced final results from our Phase 1/2 safety study of BL-7010, our novel, non-absorbable, orally available, co-polymer intended for the treatment of celiac disease. Consistent with the interim results announced in July 2014, BL-7010 showed no serious or dose-limiting adverse events after the 14-day repeated administration stage of the study, and the gastrointestinal-related adverse events observed at higher doses were substantially reduced in lower dose cohorts. Similar side effects were also observed in the placebo group. We have selected an optimal dose to carry forward into a randomized, placebo-controlled efficacy study, and following additional non-clinical studies and formulation development, we expect to initiate our first efficacy study for BL-7010 in the second half of 2015. Importantly, pharmacokinetic analyses confirmed that there was no systemic exposure to BL-7010 after single and repeated doses. This is significant, as the lack of systemic absorption may allow BL-7010 to be regulated as a medical device in Europe, accelerating its pathway to commercialization."

"For our lead partnered asset, BL-1040, a novel resorbable polymer solution for the prevention of ventricular remodeling following an acute myocardial infarction (AMI), we announced an update from the ongoing pivotal CE Mark registration PRESERVATION I trial. Our out-licensing partner Bellerophon has enrolled over 280 patients into the study, out of a total of approximately 300 patients. Based on this enrollment update, we continue to expect Bellerophon to complete enrollment by the end of the year, and complete the study in mid-2015."

Financial Results for Quarter and Nine Months Ended September 30, 2014

Research and development expenses for the three months ended September 30, 2014 were NIS 10.4 million ($2.8 million), an increase of NIS 2.2 million ($0.6 million), or 27%, compared to NIS 8.2 million ($2.2 million) for the three months ended September 30, 2013. The increase resulted primarily from an increase in spending on BL-8040 in the 2014 period, as well as the reversal of an accrual for project termination costs related to BL-1020 that was recorded in the 2013 period. Research and development expenses for the nine months ended September 30, 2014 were NIS 29.6 million ($8.0 million), a decrease of NIS 16.1 million ($4.4 million), or 35%, compared to NIS 45.7 million ($12.4 million) for the nine months ended September 30, 2013. The decrease resulted primarily from termination of the BL-1020 CLARITY clinical trial in March 2013 and certain one-time costs associated with several clinical-stage projects in 2013, partially offset by increased spending on BL-7010 in the 2014 period.

Sales and marketing expenses for the three months ended September 30, 2014 were NIS 1.1 million ($0.3 million), an increase of NIS 0.4 million ($0.1 million), or 46%, compared to NIS 0.7 million ($0.2 million) for the three months ended September 30, 2013. The increase resulted primarily from professional fees related to increased business development activities. Sales and marketing expenses for the nine months ended September 30, 2014 were NIS 3.3 million ($0.9 million), an increase of NIS 0.7 million ($0.2 million), or 30%, compared to NIS 2.6 million ($0.7 million) for the nine months ended September 30, 2013. 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, 2014 were NIS 2.8 million ($0.8 million), substantially similar to the comparable period in 2013. General and administrative expenses for the nine months ended September 30, 2014 were NIS 9.1 million ($2.5 million), a decrease of NIS 0.7 million ($0.2 million), or 7%, compared to NIS 9.8 million ($2.7 million) for the nine months ended September 30, 2013. The decrease resulted primarily from a one-time expense for professional services incurred in the 2013 period.

The Company's operating loss for the three months ended September 30, 2014 amounted to NIS 14.3 million ($3.9 million), compared with an operating loss of NIS 11.6 million ($3.1 million) for the comparable period in 2013. The Company's operating loss for the nine months ended September 30, 2014 amounted to NIS 42.1 million ($11.4 million), compared with an operating loss of NIS 52.1 million ($14.1 million) for the comparable period in 2013.

The Company's net non-operating income amounted to NIS 4.8 million ($1.3 million) for the three months ended September 30, 2014, a change of NIS 9.4 million ($2.6 million), compared to net non-operating expenses of NIS 4.6 million ($1.3 million) for the three months ended September 30, 2013. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by the Company's share price at each period end (revaluation date). The Company's net non-operating income amounted to NIS 11.7 million ($3.2 million) for the nine months ended September 30, 2014, an increase of NIS 2.5 million ($0.7 million), compared to net non-operating income of NIS 9.2 million ($2.5 million) for the nine months ended September 30, 2013. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company's net financial income amounted to NIS 7.0 million ($1.9 million) for the three months ended September 30, 2014, a change of NIS 8.4 million ($2.3 million), compared to net financial expenses of NIS 1.4 million ($0.4 million) for the three months ended September 30, 2013. Net financial income and expenses result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on our net assets denominated in dollars. The Company's net financial income amounted to NIS 6.4 million ($1.7 million) for the nine months ended September 30, 2014, a change of NIS 9.6 million ($2.6 million), compared to net financial expenses of NIS 3.2 million ($0.9 million) for the nine months ended September 30, 2013. The reason for the change is similar to the one discussed above in the three-month comparison.

The Company's net loss for the three months ended September 30, 2014 amounted to NIS 2.5 million ($0.7 million), compared with a net loss of NIS 17.7 million ($4.8 million) for the comparable period in 2013. The Company's net loss for the nine months ended September 30, 2014 amounted to NIS 24.0 million ($6.5 million), compared with a net loss of NIS 46.1 million ($12.5 million) for the comparable period in 2013.

The Company held NIS 109.3 million ($29.6 million) in cash, cash equivalents and short-term bank deposits as of September 30, 2014.

Net cash used in operating activities was NIS 38.3 million ($10.4 million) for the nine months ended September 30, 2014, compared with net cash used in operating activities of NIS 55.9 million ($15.1 million) for the nine months ended September 30, 2013. The NIS 17.6 million ($4.8 million) decrease in net cash used in operating activities during the nine-month period in 2014, compared to the nine-month period in 2013, was primarily the result of decreased research and development spending.

Net cash used in investing activities for the nine months ended September 30, 2014 was NIS 54.5 million ($14.8 million), compared to net cash used in investing activities of NIS 17.5 million ($4.7 million) for the nine months ended September 30, 2013. 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, 2014 was NIS 78.6 million ($21.3 million), compared to net cash provided by financing activities of NIS 50.0 million ($13.5 million) for the nine months ended September 30, 2013. The cash flows from financing activities in 2014 primarily reflect the underwritten public offering of our ADSs in March 2014. The cash flows from financing activities in 2013 primarily reflect the direct placement to OrbiMed completed in February 2013, as well as funding under a previous share purchase agreement with LPC.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its third quarter 2014 results today, November 10, 2014, at 10:00 a.m. ET. A presentation will be available on BioLineRx's website to accompany management's remarks on the call. To access the conference call, please dial 1-866-229-7198 from the U.S. or +972-3-918-0685 internationally. The call will also be available via live webcast through BioLineRx's website. 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 1-888-295-2634 from the U.S. or +972-3-925-5937 internationally. The replay will be available through November 13, 2014.

(Tables download)

About BioLineRx

BioLineRx is a publicly-traded, 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 current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-1040 for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Bellerophon BCM (f/k/a Ikaria) and is in the midst of a pivotal CE-Mark registration trial scheduled for completion in mid-2015; BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for acute myeloid leukemia (AML) as well as a Phase 1 study for stem cell mobilization; and BL-7010 for celiac disease, which has completed a Phase 1/2 study.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

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 17, 2014. 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.

Source: BioLineRx

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