



BioLineRx Reports Year End 2013 Financial Results

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JERUSALEM--(BUSINESS WIRE)--Mar. 17, 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 year ended December 31, 2013.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "2013 was a significant year for BioLineRx, with increased efforts in the specific therapeutic areas of oncology and immunology, as well as an emphasis on clinical-stage programs. This objective was achieved primarily by establishing collaboration agreements in the last year for three of our assets, which has enabled us to focus our resources on our lead development programs, while still maintaining substantial upside potential from the partnered programs. As a result of our concentrated efforts, we succeeded in rapidly advancing our two lead clinical programs - BL-8040 for the treatment of both acute myeloid leukemia (AML) and stem cell mobilization, and BL-7010 for the treatment of celiac disease. We have a strong balance sheet with enough cash to support our activities over the next three years – thus giving us the runway necessary to reach significant clinical milestones for our lead programs."

Recent Highlights and Achievements

Lead In-House Clinical Development Programs:

BL-8040: Best-in-class CxCR4 antagonist for treating AML and other hematological indications, including stem cell mobilization:

- Promising initial Phase 2 results in AML
- Regulatory submission for stem cell mobilization
- Orphan disease designation for both AML and stem cell mobilization
- U.S. patent issued for method of obtaining stem cells
- U.S. patent granted covering use in immunotherapy

"Over the last year, we made significant progress with BL-8040, our lead oncology asset. Early results from our Phase 2 study for AML indicate that BL-8040 is safe at all doses tested to date, and triggers substantial mobilization of cancer cells from the bone marrow into the blood stream, thereby increasing their vulnerability to chemotherapy treatment. In addition, there are initial signs of robust apoptosis of the cancer cells. We look forward to providing additional information on the study at the end of the ongoing dose escalation phase, expected during the second quarter of 2014, with final study results expected toward the end of 2014/beginning of 2015. Future development plans for BL-8040 involve additional hematological indications, including commencement of a clinical study in stem cell mobilization during the first half of 2014, with final results expected in the second half of the year," added Dr. Savitsky.

BL-7010: Novel gliadin binding polymer for celiac disease

- Initiated blinded Phase 1/2 study in celiac patients
- Successfully completed dose escalation stage

"Last week, we reported results from the single administration, dose-escalation stage of our ongoing Phase 1/2 clinical study for our novel celiac treatment, BL-7010. The escalation stage reached the highest planned dose without any dose-limiting adverse events, and all planned doses were found to be safe and well-tolerated. Based on these positive safety and tolerability results, we plan to proceed with the repeated administration stage of the study. We expect to report top-line results and pharmacokinetic (PK) data in mid-2014, and assuming they are successful, we expect to commence a pivotal efficacy study in celiac patients by the end of the year. Celiac disease is clearly attracting increased interest by the pharmaceutical industry over the last year. In addition, despite the significant need for new treatments, there are only a handful of clinical-stage projects under development worldwide for this disease, and we view this as a significant opportunity for our product."

Partnered Development Programs:

BL-1040: First-in-class myocardial implant for prevention of ventricular remodeling following AMI

"BL-1040, being developed by Bellerophon (*f/k/a* Ikaria) as a Bioabsorbable Cardiac Matrix (BCM), is in the midst of a pivotal CE Mark Registration trial. The trial continues to progress at full steam with more than 75 sites currently active, including approximately 15 in the U.S., and we are looking forward to the results, which are expected toward the end of the year."

Other collaborations

- Regional collaboration with JHL Biotech for BL-9020, a novel monoclonal antibody for the treatment of Type 1 diabetes, covering China and additional Southeast Asia countries

- Regional co-development deal with CTTQ for BL-8030, for the treatment of HCV, covering China and Hong Kong
- Global collaboration agreement for BL-8020, for the treatment of HCV and other viral indications, covering the transfer of development rights to Genoscience and Panmed in return for BioLineRx receiving a percentage of future revenues from the product.

"We successfully entered into three collaboration agreements over the last year, enabling us to focus our resources on our lead development programs, while still maintaining substantial upside potential on the partnered programs. Our collaboration with JHL Biotech also provides us with a platform for the development and manufacturing of biologics, which is a capability that we were previously lacking. JHL is a rising star in the biologics space, backed by a consortium of top-tier venture capital firms, with an existing world-class facility in Taiwan and the largest single-use cell culture plant in the world under construction in China, and we are very excited about this partnership."

Termination of BL-1020:

"In March 2013, we discontinued the Phase 2/3 CLARITY study of BL-1020, for the treatment of schizophrenia, following an interim analysis that indicated the trial would not meet the pre-specified primary efficacy endpoint. We subsequently performed a complete analysis of the un-blinded study data on all enrolled patients in order to ascertain whether there could be potential for the product. No such potential was determined, and we terminated the program in March 2014."

Corporate:

- Appointment of BJ Bormann, Ph.D., to Board of Directors in August 2013
- Appointment of Sandra Panem, Ph.D., to Board of Directors in February 2014
- Successful \$24.1 million underwritten public offering in March 2014

"We are very excited to welcome Drs. Bormann and Panem to our Board of Directors. Their combined decades of experience in the healthcare space will help guide the strategy and development of our pipeline from a business, scientific and financial perspective. Together with our recent fundraising, we view both these accomplishments as important steps in the development and growth of our company, as we continue to strengthen our presence in the U.S. financial markets and in the global biopharmaceutical industry. We also look forward with great anticipation to the several significant catalysts coming up over the next 12 months," concluded Dr. Savitsky.

Financial Results for Year Ended December 31, 2013

Research and development expenses for the year ended December 31, 2013 were NIS 44.1 million (\$12.7 million), a decrease of NIS 20.2 million (\$5.8 million), or 31%, compared to NIS 64.3 million (\$18.5 million) for the year ended December 31, 2012. Without regard to a NIS 6.0 million one-time reversal of amounts previously accrued to the OCS in respect of BL-1020, research and development expenses decreased by NIS 14.2 million (\$4.1 million). The decrease resulted primarily from lower expenses in 2013 associated with BL-1020, due to termination of the CLARITY clinical trial in March 2013, which was partially offset by a ramp-up in spending on other clinical-stage projects introduced during 2011 and 2012.

Sales and marketing expenses for the year ended December 31, 2013 were NIS 4.1 million (\$1.2 million), an increase of NIS 0.9 million (\$0.3 million), or 28%, compared to NIS 3.2 million (\$0.9 million) for the year ended December 31, 2012. The increase resulted primarily from increased business development activities, as well as professional services incurred in connection with the collaboration agreement signed with JHL Biotech.

General and administrative expenses for the year ended December 31, 2013 were NIS 13.2 million (\$3.8 million), a decrease of NIS 0.8 million (\$0.2 million) or 6%, compared to NIS 14.0 million (\$4.0 million) for the year ended December 31, 2012. The small decrease resulted primarily from one-time expenses for professional services incurred in 2012.

The Company's operating loss for the year ended December 31, 2013 amounted to NIS 61.4 million (\$17.7 million), compared with an operating loss of NIS 81.6 million (\$23.5 million) for the year ended December 31, 2012.

The Company recognized net non-operating income of NIS 4.2 million (\$1.2 million) for the year ended December 31, 2013, an increase of NIS 0.2 million (\$0.1 million), compared to net non-operating income of NIS 4.0 million (\$1.1 million) for the year ended December 31, 2012. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of warrants. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

Net financial expenses amounted to NIS 4.2 million (\$1.2 million) for the year ended December 31, 2013, a change of NIS 5.5 million (\$1.6 million), compared to net financial income of NIS 1.3 million (\$0.4 million) for the year ended December 31, 2012. 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 loss for the year ended December 31, 2013 amounted to NIS 61.4 million (\$17.7 million), compared with a net loss of NIS 76.3 million (\$22.0 million) for the year ended December 31, 2012.

The Company held NIS 63.2 million (\$18.2 million) in cash, cash equivalents and short-term bank deposits as of December 31, 2013. In March 2014, the Company completed an underwritten public offering of its American Depositary Shares for gross proceeds of \$24.1 million.

Net cash used in operating activities was NIS 70.5 million for the year ended December 31, 2013, compared with NIS 75.1 million for the year ended December 31, 2012. The NIS 4.6 million (\$1.3 million) decrease in net cash used in operating activities during 2013 resulted primarily from the decrease in research and development spending.

Net cash used in investing activities for the year ended December 31, 2013 was NIS 19.8 million, compared to net cash provided by investing activities of NIS 51.3 million for the year ended December 31, 2012. 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 year ended December 31, 2013 was NIS 55.2 million, compared to net cash provided by financing activities of NIS 58.9 million for the year ended December 31, 2012. The cash flows from financing activities in 2013 reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the share purchase agreement with Lincoln Park Capital. The cash flows from financing activities in 2012 reflect the private placement completed in February 2012.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its year-end 2013 results today, March 17, 2014, at 10:00 a.m. EDT. A presentation will be available on BioLineRx's website to accompany management's remarks on the call. To access the conference call, please dial 1-888-668-9141 from the U.S., or +972-3-918-0609 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 1-888-269-0005 from the U.S. or +972-3-925-5938 internationally. The replay will be available through March 20, 2014.

(Tables follow)

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; BL-8040 for treating acute myeloid leukemia (AML) and other hematological indications, which is in the midst of a Phase 2 study; BL-7010 for celiac disease, which is in the midst of a Phase 1/2 study; and BL-5010 for non-surgical removal of skin lesions, which is expected to commence a pivotal CE-mark registration trial in the first half of 2014.

For more information on BioLineRx, please visit www.bioglinerx.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.

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,		Convenience translation into USD
	2012	2013	December 31, 2013
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	68,339	30,888	8,899
Short-term bank deposits	11,459	32,345	9,319
Prepaid expenses	804	896	258
Other receivables	2,254	1,249	360
Total current assets	<u>82,856</u>	<u>65,378</u>	<u>18,836</u>
NON-CURRENT ASSETS			
Restricted deposits	3,513	573	165
Long-term prepaid expenses	204	169	49
Property and equipment, net	3,172	2,471	712
Intangible assets, net	1,063	878	253
Total non-current assets	<u>7,952</u>	<u>4,091</u>	<u>1,179</u>
Total assets	<u>90,808</u>	<u>69,469</u>	<u>20,015</u>
Liabilities and equity			
CURRENT LIABILITIES			
Current maturities of long-term bank loan	137	-	-
Accounts payable and accruals:			
Trade	12,283	7,945	2,289
OCS	6,148	-	-
Other	5,443	2,499	720

Total current liabilities	<u>24,011</u>	<u>10,444</u>	<u>3,009</u>
NON-CURRENT LIABILITIES			
Retirement benefit obligations	143	152	44
Warrants	<u>10,725</u>	<u>18,187</u>	<u>5,240</u>
Total non-current liabilities	<u>10,868</u>	<u>18,339</u>	<u>5,284</u>
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	<u>34,879</u>	<u>28,783</u>	<u>8,293</u>
EQUITY			
Ordinary shares	1,837	2,414	696
Share premium	464,629	509,857	146,890
Capital reserve	33,802	34,192	9,851
Accumulated deficit	<u>(444,339)</u>	<u>(505,777)</u>	<u>(145,715)</u>
Total equity	<u>55,929</u>	<u>40,686</u>	<u>11,722</u>
Total liabilities and equity	<u>90,808</u>	<u>69,469</u>	<u>20,015</u>

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	<u>Year ended December 31,</u>			<u>Convenience translation into USD</u>
	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2013</u>
	<u>NIS in thousands</u>			<u>In thousands</u>
RESEARCH AND DEVELOPMENT EXPENSES, NET	(42,623)	(64,304)	(44,057)	(12,692)
SALES AND MARKETING EXPENSES	(3,308)	(3,227)	(4,101)	(1,182)
GENERAL AND ADMINISTRATIVE EXPENSES	<u>(12,722)</u>	<u>(14,026)</u>	<u>(13,225)</u>	<u>(3,810)</u>
OPERATING LOSS	(58,653)	(81,557)	(61,383)	(17,684)
NON-OPERATING INCOME, NET	-	3,958	4,191	1,207
FINANCIAL INCOME	12,730	8,819	2,600	749
FINANCIAL EXPENSES	<u>(4,263)</u>	<u>(7,490)</u>	<u>(6,846)</u>	<u>(1,972)</u>
NET LOSS AND COMPREHENSIVE LOSS	<u>(50,186)</u>	<u>(76,270)</u>	<u>(61,438)</u>	<u>(17,700)</u>
	<u>NIS</u>			<u>USD</u>
LOSS PER ORDINARY SHARE - BASIC	<u>(0.41)</u>	<u>(0.45)</u>	<u>(0.27)</u>	<u>(0.08)</u>
LOSS PER ORDINARY SHARE - DILUTED	<u>(0.41)</u>	<u>(0.45)</u>	<u>(0.27)</u>	<u>(0.08)</u>

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	<u>Year ended December 31,</u>			<u>Convenience translation into USD</u>
	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2013</u>
	<u>NIS in thousands</u>			<u>In thousands</u>
CASH FLOWS - OPERATING ACTIVITIES				
Net loss	(50,186)	(76,270)	(61,438)	(17,700)
Adjustments required to reflect net cash used in operating activities (see appendix below)	7,445	1,125	(9,026)	(2,600)
Net cash used in operating activities	<u>(42,711)</u>	<u>(75,145)</u>	<u>(70,464)</u>	<u>(20,300)</u>
CASH FLOWS - INVESTING ACTIVITIES				
Investments in short-term deposits	(63,456)	(12,025)	(129,359)	(37,268)
Maturities of short-term deposits	27,308	64,801	107,049	30,841
Investments in restricted deposits	(1,000)	(775)	-	-
Maturities of restricted deposits	675	-	2,900	835
Purchase of property and equipment	(951)	(598)	(309)	(89)
Purchase of intangible assets	<u>(133)</u>	<u>(61)</u>	<u>(99)</u>	<u>(29)</u>
Net cash provided by (used in) investing activities	<u>(37,557)</u>	<u>51,342</u>	<u>(19,818)</u>	<u>(5,710)</u>

CASH FLOWS - FINANCING ACTIVITIES

Issuance of share capital and warrants, net of issuance expenses	-	59,207	55,306	15,934
Repayments of bank loan	(308)	(300)	(127)	(37)
Proceeds from exercise of employee stock options	1	2	10	3
Net cash provided by (used in) financing activities	<u>(307)</u>	<u>58,909</u>	<u>55,189</u>	<u>15,900</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(80,605)	35,106	(35,093)	(10,110)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	111,746	33,061	68,339	19,689
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	1,920	172	(2,358)	(680)
CASH AND CASH EQUIVALENTS - END OF YEAR	<u>33,061</u>	<u>68,339</u>	<u>30,888</u>	<u>8,899</u>

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS (cont.)

	Year ended December 31,			Convenience
	2011	2012	2013	translation
	NIS in thousands			into USD
				2013
				In thousands
APPENDIX				
Adjustments required to reflect net cash provided by (used in) operating activities:				
Income and expenses not involving cash flows:				
Depreciation and amortization	1,563	1,524	1,147	330
Impairment of intangible assets	88	-	137	40
Retirement benefit obligations	53	60	9	3
Long-term prepaid expenses	(8)	-	35	10
Exchange differences on cash and cash equivalents	(1,920)	(172)	2,358	679
Warrant issuance costs	-	1,204	470	135
Gain on adjustment of warrants to fair value	-	(7,265)	(5,169)	(1,489)
Commitment fee paid by issuance of share capital	-	880	-	-
Share-based compensation	3,983	3,138	3,040	876
Interest and exchange differences on short-term deposits	(1,597)	1,547	1,424	410
Interest and linkage differences on bank loan	(14)	20	(10)	(3)
Interest and exchange differences on restricted deposits	(7)	8	40	12
	<u>2,141</u>	<u>944</u>	<u>3,481</u>	<u>1,003</u>
Changes in operating asset and liability items:				
Decrease in trade accounts receivable and other receivables	1,847	1,454	913	263
Decrease in accounts payable and accruals	<u>3,457</u>	<u>(1,273)</u>	<u>(13,420)</u>	<u>(3,866)</u>
	<u>5,304</u>	<u>181</u>	<u>(12,507)</u>	<u>(3,603)</u>
	<u>7,445</u>	<u>1,125</u>	<u>(9,026)</u>	<u>(2,600)</u>
Supplementary information on investing and financing activities not involving cash flows:				
Credit received in connection with purchase of property and equipment	<u>265</u>	<u>10</u>	<u>-</u>	<u>-</u>
Supplementary information on interest received in cash	<u>1,825</u>	<u>1,720</u>	<u>503</u>	<u>145</u>



Source: BioLineRx

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