



BioLineRx Reports Year End 2014 Financial Results

March 23, 2015 11:00 AM IST

JERUSALEM--(BUSINESS WIRE)--Mar. 23, 2015-- BioLineRx Ltd. (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, 2014.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "2014 marks a year of significant progress for BioLineRx on multiple fronts, both from a product development perspective, as well as from a business perspective. We have continued our focus on the therapeutic areas of oncology and immunology, while increasing the emphasis on our clinical-stage programs."

"During the past year, we significantly enhanced and expanded the development strategy for our unique BL-8040 cancer therapy platform across a variety of hematological indications. Results to date from our ongoing Phase 2a clinical study of BL-8040 in relapsed and refractory AML patients continue to show substantial mobilization of leukemic cells from the bone marrow and robust induction of cancer cell apoptosis, as well as excellent safety and tolerability. Top-line results from this study are expected in the second half of 2015. BL-8040 is also in the midst of a Phase 1 safety and efficacy study in stem cell mobilization, with top-line results expected by the end of this month. We eagerly await the data from both of these important studies. In addition, we recently expanded our clinical strategy for BL-8040 to include new clinical trials in three additional hematological indications, all of which are expected to commence by the end of the second quarter of this year. We look forward to executing our comprehensive development plan for this promising treatment platform and to reaching several meaningful value inflection points during 2015."

"With regard to BL-7010, our product for the treatment of celiac disease, we are very pleased with the positive results we reported for the Phase 1/2 safety study completed in the fourth quarter of 2014, including the determination of the optimal safe dose for continued development. We are also very encouraged that the results further support previous preclinical data showing that BL-7010 is not absorbed systemically, which will likely support a medical-device classification and an expedited development pathway for the product in Europe. We are now conducting additional non-clinical studies and formulation development for BL-7010 in preparation for the upcoming efficacy study, which we plan to initiate in the second half of this year."

"In December 2014, our partner Bellerophon reached a significant milestone in the development of BL-1040 for the prevention of ventricular remodeling following AMI – the completion of enrollment in the large CE Mark registration trial that has been ongoing for the past three years. We look forward to the top-line results from this trial, expected in mid-2015."

"During the fourth quarter of 2014, we announced two significant business development achievements. First and foremost, we entered into a multi-year strategic collaboration with Novartis for the screening and co-development of therapeutic candidates through clinical proof-of-concept. As part of the collaboration, Novartis made an equity investment in BioLineRx of \$10 million. We are very excited about the future potential of this collaboration, and view it as a strong validation of our core competencies by a world leader in our industry. In addition, we also announced the out-licensing to Omega Pharma of BL-5010, our skin lesion product, which we hope will begin to provide a royalty stream to us beginning in 2016."

"Following the successful completion of our \$29 million follow-on public offering earlier this month, we have a strong balance sheet, with enough cash to carry out our operating plan for at least the next three years. We expect to reach multiple significant catalysts during this period of time, both in the short term during 2015, as well as in 2016 and 2017."

Financial Results for Year Ended December 31, 2014

Research and development expenses for the year ended December 31, 2014 were NIS 42.5 million (\$10.9 million), a decrease of NIS 1.6 million (\$0.4 million), or 3.7%, compared to NIS 44.1 million (\$11.3 million) for the year ended December 31, 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-8040, BL-7010 and BL-5010 in 2014.

Sales and marketing expenses for the year ended December 31, 2014 were NIS 5.7 million (\$1.5 million), an increase of NIS 1.6 million (\$0.4 million), or 38.6%, compared to NIS 4.1 million (\$1.1 million) for the year ended December 31, 2013. The increase resulted primarily from professional fees related to increased business development activities, including professional services related to the collaboration agreement with Novartis and the out-licensing agreement with Omega regarding BL-5010.

General and administrative expenses for the year ended December 31, 2014 were NIS 13.6 million (\$3.5 million), an increase of NIS 0.4 million (\$0.1 million) or 2.8%, compared to NIS 13.2 million (\$3.4 million) for the year ended December 31, 2013. The small increase resulted primarily from an increase in salary-related payments.

The Company's operating loss for the year ended December 31, 2014 amounted to NIS 61.7 million (\$15.9 million), compared with an operating loss of NIS 61.4 million (\$15.8 million) for the year ended December 31, 2013.

The Company recognized net non-operating income of NIS 11.0 million (\$2.8 million) for the year ended December 31, 2014, an increase of NIS 6.8 million (\$1.7 million), compared to net non-operating income of NIS 4.2 million (\$1.1 million) for the year ended December 31, 2013. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of 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).

Net financial income amounted to NIS 11.2 million (\$2.9 million) for the year ended December 31, 2014, a change of NIS 15.5 million (\$4.0 million), compared to net financial expenses of NIS 4.3 million (\$1.1 million) for the year ended December 31, 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 the Company's net assets denominated in dollars.

The Company's net loss for the year ended December 31, 2014 amounted to NIS 39.6 million (\$10.2 million), compared with a net loss of NIS 61.4 million (\$15.8 million) for the year ended December 31, 2013.

The Company held NIS 134.9 million (\$34.7 million) in cash, cash equivalents and short-term bank deposits as of December 31, 2014. In March 2015, the Company completed an underwritten public offering of its American Depositary Shares for gross proceeds of \$28.8 million.

Net cash used in operating activities was NIS 56.4 million for the year ended December 31, 2014, compared with NIS 70.5 million for the year ended December 31, 2013. The NIS 14.1 million decrease in net cash used in operating activities during 2014 resulted primarily from a large decrease in net trade payables and accruals during the 2013 period.

Net cash used in investing activities for the year ended December 31, 2014 was NIS 70.7 million, compared to net cash used for investing activities of NIS 19.8 million for the year ended December 31, 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 year ended December 31, 2014 was NIS 117.8 million, compared to net cash provided by financing activities of NIS 55.2 million for the year ended December 31, 2013. The cash flows from financing activities in 2014 primarily reflect the underwritten public offering in March 2014 and the investment by Novartis in December 2014. The cash flows from financing activities in 2013 reflect the direct placement to OrbiMed completed in February 2013, as well as funding under the previous share purchase agreement with LPC.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its year-end 2014 results today, March 23, 2015, at 10:00 a.m. EDT. To access the conference call, please dial 1-888-407-2553 from the US, or +972-3-918-0610 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 1-877-456-0009 from the US or +972-3-925-5944 internationally. The replay will be available through March 26, 2015.

(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 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 successfully completed a Phase 1/2 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

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 23, 2015. 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
	2013	2014	December 31, 2014
	NIS in thousands		In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	30,888	22,519	5,790
Short-term bank deposits	32,345	112,354	28,890
Prepaid expenses	896	859	221
Other receivables	1,249	1,000	257
Total current assets	65,378	136,732	35,158
NON-CURRENT ASSETS			
Restricted deposits	573	644	166
Long-term prepaid expenses	169	190	49

Property and equipment, net	2,471	2,804	721
Intangible assets, net	878	457	117
Total non-current assets	4,091	4,095	1,053
Total assets	69,469	140,827	36,211
Liabilities and equity			
CURRENT LIABILITIES			
Accounts payable and accruals:			
Trade	7,945	6,431	1,654
Other	2,499	4,869	1,252
Total current liabilities	10,444	11,300	2,906
NON-CURRENT LIABILITIES			
Retirement benefit obligations	152	-	-
Warrants	18,187	5,833	1,500
Total non-current liabilities	18,339	5,833	1,500
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	28,783	17,133	4,406
EQUITY			
Ordinary shares	2,414	3,911	1,006
Share premium	509,857	628,710	161,664
Capital reserve	34,192	36,470	9,378
Accumulated deficit	(505,777)	(545,397)	(140,242)
Total equity	40,686	123,694	31,806
Total liabilities and equity	69,469	140,827	36,211

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,			Convenience translation into USD
	2012	2013	2014	2014
	NIS in thousands			In thousands
RESEARCH AND DEVELOPMENT EXPENSES, NET	(64,304)	(44,057)	(42,443)	(10,914)
SALES AND MARKETING EXPENSES	(3,227)	(4,101)	(5,685)	(1,462)
GENERAL AND ADMINISTRATIVE EXPENSES	(14,026)	(13,225)	(13,591)	(3,495)
OPERATING LOSS	(81,557)	(61,383)	(61,719)	(15,871)
NON-OPERATING INCOME, NET	3,958	4,191	10,948	2,815
FINANCIAL INCOME	8,819	2,600	12,754	3,280
FINANCIAL EXPENSES	(7,490)	(6,846)	(1,603)	(412)
NET LOSS AND COMPREHENSIVE LOSS	(76,270)	(61,438)	(39,620)	(10,188)
	NIS			USD
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.45)	(0.27)	(0.12)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	169,404,730	224,885,157	324,338,834	324,338,834

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,			Convenience translation into USD
	2012	2013	2014	2014
	NIS in thousands			In thousands
CASH FLOWS - OPERATING ACTIVITIES				

Net loss	(76,270)	(61,438)	(39,620)	(10,188)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,125	(9,026)	(16,763)	(4,310)
Net cash used in operating activities	<u>(75,145)</u>	<u>(70,464)</u>	<u>(56,383)</u>	<u>(14,498)</u>
CASH FLOWS - INVESTING ACTIVITIES				
Investments in short-term deposits	(12,025)	(129,359)	(206,449)	(53,086)
Maturities of short-term deposits	64,801	107,049	136,408	35,075
Investments in restricted deposits	(775)	-	-	-
Maturities of restricted deposits	-	2,900	-	-
Purchase of property and equipment	(598)	(309)	(674)	(173)
Purchase of intangible assets	(61)	(99)	(21)	(5)
Net cash provided by (used in) investing activities	<u>51,342</u>	<u>(19,818)</u>	<u>(70,736)</u>	<u>(18,189)</u>
CASH FLOWS - FINANCING ACTIVITIES				
Issuance of share capital and warrants, net of issuance expenses	59,207	55,306	117,816	30,295
Repayments of bank loan	(300)	(127)	-	-
Proceeds from exercise of employee stock options	2	10	*	*
Net cash provided by financing activities	<u>58,909</u>	<u>55,189</u>	<u>117,816</u>	<u>30,295</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	35,106	(35,093)	(9,303)	(2,392)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	33,061	68,339	30,888	7,942
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	172	(2,358)	934	240
CASH AND CASH EQUIVALENTS - END OF YEAR	<u>68,339</u>	<u>30,888</u>	<u>22,519</u>	<u>5,790</u>

* Less than 1,000.

BioLineRx Ltd.
CONSOLIDATED CASH FLOW STATEMENTS

Year ended December 31,			Convenience translation into USD
2012	2013	2014	2014
NIS in thousands			In thousands

APPENDIX

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:

Depreciation and amortization	1,524	1,147	960	247
Write-off of intangible assets	-	137	377	97
Retirement benefit obligations	60	9	(152)	(39)
Long-term prepaid expenses	-	35	(21)	(6)
Exchange differences on cash and cash equivalents	(172)	2,358	(934)	(240)
Warrant issuance costs	1,204	470	-	-
Gain on adjustment of warrants to fair value	(7,265)	(5,169)	(12,354)	(3,177)
Commitment fee paid by issuance of share capital	880	-	1,040	267
Share-based compensation	3,138	3,040	3,772	970
Interest and exchange differences on short-term deposits	1,547	1,424	(9,968)	(2,563)
Interest and linkage differences on bank loan	20	(10)	-	-
Interest and exchange differences on restricted deposits	8	40	(71)	(18)
	<u>944</u>	<u>3,481</u>	<u>(17,351)</u>	<u>(4,462)</u>

Changes in operating asset and liability items:

Decrease in trade accounts receivable and other receivables	1,454	913	286	74
Increase (decrease) in accounts payable and accruals	(1,273)	(13,420)	302	78
	<u>181</u>	<u>(12,507)</u>	<u>588</u>	<u>152</u>
	<u>1,125</u>	<u>(9,026)</u>	<u>(16,763)</u>	<u>(4,310)</u>

Supplementary information on investing and financing activities not involving cash flows:

Credit received in connection with purchase of property and equipment	10	-	554	142
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Supplementary information on interest received in cash

	<u>1,720</u>	<u>503</u>	<u>348</u>	<u>90</u>
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Source: BioLineRx Ltd.

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