## SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

## FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2013

# **BioLineRx** Ltd.

(Translation of Registrant's name into English)

## P.O. Box 45158 19 Hartum Street Jerusalem 91450, Israel (Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

Yes o No 🗹

On May 7, 2013, the Registrant will issue a press release announcing its financial results for the three months ended March 31, 2013. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of March 31, 2013, and for the three months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated May 7, 2013;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of March 31, 2013, and for the three months then ended;

Exhibit 3 - Registrant's operating and financial review as of March 31, 2013, and for the three months then ended.

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## BioLineRx Ltd.

By: /s/ Philip Serlin

Philip Serlin Chief Financial and Operating Officer

Dated: May 7, 2013



## **BioLineRx Reports First Quarter 2013 Results**

JERUSALEM - May 7, 2013 - BioLineRx Ltd. (NASDAQ: BLRX; TASE: BLRX), a biopharmaceutical development company, today reported its results for the quarter ended March 31, 2013.

#### **Recent Highlights:**

- **BL-7040 (IBD)** Received positive results from a Phase 2 proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of inflammatory bowel disease (IBD)
  - Immediate next steps include evaluating the most advantageous ways to progress with this therapeutic candidate from a clinical and business perspective, including examining potential additional indications. Plans also include accelerating discussions with potential co-development and licensing partners.
- BL-8040 (AML) Received U.S. regulatory approvals to commence a Phase 2a trial for the treatment of relapsed/refractory acute myeloid leukemia (AML); trial to be conducted at three sites in the U.S. and five sites in Israel, with initial patient enrollment expected in Q2 2013; partial results expected in Q4 2013 and final results expected in the second half of 2014
- BL-1040 (ventricular remodeling) Recruitment commenced at U.S. sites for the PRESERVATION I clinical trial, a CE Mark registration trial for BL-1040 (BCM), a novel medical device for the prevention of ventricular remodeling following an acute myocardial infarction; there are currently multiple active sites recruiting in six countries
- BL-5010 (skin lesions) Reached final stages of development for proprietary pen-like applicator for BL-5010, a novel formulation of two acids being developed for the non-surgical removal of skin lesions; planning to commence pivotal CE-Mark registration trial for European approval in the second half of 2013
- BL-8020 (HCV) Commenced a Phase 1/2 clinical trial to evaluate the effectiveness of an orally-available, interferon-free treatment for Hepatitis C (HCV) at two sites in France, following approval from the French regulatory authorities; partial results expected in Q4 2013; final results expected in the first half of 2014
- **BL-1020 (schizophrenia)** Disappointing results of interim analysis for the Phase 2/3 CLARITY trial led to termination of the trial; full unblinded study data is expected during Q3 2013
- **BL-9010 (severe asthma)** Added a novel, bi-specific antibody for the treatment of severe and persistent asthma to the main therapeutic pipeline, following promising pre-clinical data
- Capital Raise \$8 million direct equity placement to the OrbiMed Group was completed in February 2013

"In the past few months, we have seen major progress on a number of clinical and pre-clinical programs in our pipeline, which offer exciting opportunities to address unmet medical needs in a wide range of therapeutic areas. We believe our active programs offer significant potential for patients around the world, as well as for the future success of our Company and its shareholders," stated Kinneret Savitsky, Ph.D, Chief Executive Officer of BioLineRx. "In the third quarter of this year, we expect to receive a full analysis of the unblinded study data for all participants in the CLARITY Phase 2/3 trial for BL-1020. While we discontinued this clinical trial in mid-March based on disappointing results of the interim analysis, we will not decide the future of the overall BL-1020 program until we have carried out a more thorough review of the full unblinded results."

"The PRESERVATION I study being conducted by our partner, Ikaria, for BL-1040, for the treatment of ventricular remodeling post-AMI, is moving forward at full steam, with multiple sites in six countries around the world actively recruiting, including a number of sites in the U.S. BL-1040 remains one of our leading compounds, with significant clinical data expected to be reported next year, and we hope that it will eventually offer a great benefit to heart attack patients," continued Dr. Savitsky.

"We continue to accelerate development of our clinical pipeline, with three of our compounds completing significant milestones since the beginning of the year. Our BL-7040 compound for IBD completed a Phase 2a open-label, proof-of-concept study with very encouraging and positive results. We are now evaluating next steps for BL-7040 in order to identify the best way to move forward from both a clinical and business perspective, including examining potential additional indications. In parallel, we are also planning to accelerate discussions with potential co-development and licensing partners for this asset."

"In addition, BL-8040, for hematological cancers, one of our most exciting programs, just received FDA approval to commence a Phase 2a trial for the treatment of relapsed/refractory AML. We are excited to initiate this multicenter, open-label study under an IND, which will be conducted in the U.S. and Israel, and will enroll up to 50 patients. MD Anderson Cancer Center in Houston will be the initial site for this trial, with two additional premier sites in the US and five other well-known sites in Israel expected to participate. We believe the excitement surrounding the trial, especially at these particular sites, is a testament to the need for an AML therapy, as well as the potential of BL-8040 shown in the previous pre-clinical and clinical data."

"Finally, we recently reported enrollment of the first patient in our Phase 1/2 trial for BL-8020, an oral treatment for HCV, at a leading hospital in Paris, France. We look forward to partial results from the trial in the fourth quarter of 2013, as well as final results in the first half of 2014. I would also like to point out that as our pipeline evolves, we continue to replenish our pre-clinical pipeline with the addition of promising assets, such as BL-9010 for the treatment of severe and persistent asthma, which recently graduated from our Early Development Program," concluded Dr. Savitsky

## Financial Results for Q1 2013:

During the three months ended March 31, 2013 and 2012, no revenues were recorded.

Research and development expenses for the three months ended March 31, 2013 were NIS 19.4 million (\$5.3 million), an increase of NIS 4.7 million (\$1.3 million) or 32% compared to NIS 14.7 million (\$4.0 million) for the three months ended March 31, 2012. In March 2013, due to the BL-1020 CLARITY study termination, the Company reversed the remaining liability to repay grants previously received from the OCS in respect of BL-1020, as it became more likely than not that such liability would not be repaid. As a result, a one-time credit to research and development expenses in the amount of NIS 6.0 million was recorded during the quarter. Without regard to this one-time credit, research and development expenses increased by NIS 10.8 million compared to the first quarter of 2012. The primary reason for this increase is significantly higher expenses in 2013 associated with the CLARITY clinical trial, as well as a ramp-up in spending on other clinical-stage projects introduced during 2012.

Sales and marketing expenses for the three months ended March 31, 2013 were NIS 0.8 million (\$0.2 million), similar to the three months ended March 31, 2012.

General and administrative expenses for the three months ended March 31, 2013 were NIS 3.5 million (\$1.0 million), similar to the three months ended March 31, 2012.

The Company's operating loss the three months ended March 31, 2013 amounted to NIS 23.7 million (\$6.5 million), compared with an operating loss of NIS 19.0 million (\$5.2 million) for the comparable period in 2012.

Non-operating income for the three months ended March 31, 2013 amounted to NIS million 12.3 (\$3.4 million), an increase of NIS 9.4 million (\$2.6 million), compared to net non-operating income of NIS 2.8 million (\$0.8 million) for the three months ended March 31, 2012. 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 which were completed 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 expenses for the three months ended March 31, 2013 amounted to NIS million 1.4 (\$0.4 million), a decrease of NIS 0.4 million (\$0.1 million), compared to net financial expenses of NIS 1.8 million (\$0.5 million) for the three months ended March 31, 2012. Net financial expenses for both periods result primarily from changes in the average exchange rate of the dollar in relation to the NIS, which had a negative effect on the Company's net assets denominated in dollars.

Net loss for the three months ended March 31, 2013 amounted to NIS 12.8 million (\$3.5 million), compared with a net loss of NIS 17.9 million (\$4.9 million) for the comparable period in 2012.

As of March 31, 2013, BioLineRx had NIS 102.4 million (\$28.1 million) in cash, cash equivalents and short-term bank deposits.

Net cash used in operating activities was NIS 19.2 million (\$5.3 million) for the three months ended March 31, 2013, compared with net cash used in operating activities of NIS 12.9 million (\$3.5 million) for the three months ended March 31, 2012. The NIS 6.3 million (\$1.8 million) increase in net cash used in operating activities during the three-month period in 2013, compared to the three-month period in 2012, was primarily the result of increased research and development spending.

Net cash used in investing activities for the three months ended March 31, 2013 was NIS 43.8 million (\$12.0 million), compared to net cash provided by investing activities of NIS 22.1 million (\$6.1 million) for the three months ended March 2012. The cash flows related to investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective quarters.

Net cash provided by financing activities for the three months ended March 31, 2013 was NIS 42.0 million (\$11.5 million), compared to net cash provided by financing activities of NIS 52.4 million (\$14.4 million) for the three months ended March 2012. The cash flows from financing activities primarily reflect the direct and private placements that were completed in February 2013 and 2012.

#### **Conference Call and Webcast Information**

BioLineRx will hold a conference call to discuss its first quarter 2013 results today, May 7, 2013, at 10:00 a.m. EDT. 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 1-888-295-2634 from the U.S. or +972-3-925-5921 internationally. The replay will be available through May 10, 2013.

#### (Tables follow)

#### About BioLineRx

BioLineRx is a publicly-traded biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of seven clinical stage candidates: BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions has completed a Phase 1/2 study; BL-7040 for treating inflammatory bowel disease (IBD) has completed a Phase 2a trial; BL-8040 for treating acute myeloid leukemia (AML) and other hematological cancers will shortly commence a Phase 2 study; BL-1021 for neuropathic pain is in Phase 1 development; BL-8020 for hepatitis C (HCV) has commenced a Phase 1/2 study; and BL-1020 for schizophrenia. In addition, BioLineRx has five products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase 3) and commercialization. For more information on BioLineRx, please visit www.biolinerx.com, the content of which does not form a part of this press release.

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 12, 2013. 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.

#### **Contact:**

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## **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

			Convenience translation into USD
	December 31,	March 31,	March 31,
	2012	2013	2013
	NIS in the	ousands	In thousands
Assets			
CURRENT ASSETS	60.000	46,620	10 505
Cash and cash equivalents	68,339	46,638	12,785
Short-term bank deposits	11,459	55,805	15,297
Prepaid expenses Other receivables	804 2,254	843 2,581	231 707
Total current assets	82,856	105,867	29,020
NON-CURRENT ASSETS			
Restricted deposits	3,513	1,950	535
Long-term prepaid expenses	204	192	53
Property and equipment, net	3,172	2,947	807
Intangible assets, net	1,063	1,056	290
Total non-current assets	7,952	6,145	1,685
Total assets	90,808	112,012	30,705
T 1 1 11/1			
Liabilities and equity CURRENT LIABILITIES			
Current maturities of long-term bank loan	137	54	15
Accounts payable and accruals:	137	54	15
Trade	12,283	21,873	5,996
OCS	6,148		-
Other	5,443	5,300	1,453
Total current liabilities	24,011	27,227	7,464
NON-CURRENT LIABILITIES			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Retirement benefit obligations	143	143	39
Warrants	10,725	10,625	2,913
Total non-current liabilities	10,868	10,768	2,952
COMMITMENTS AND CONTINGENT LIABILITIES			,
Total liabilities	34,879	37,995	10,416
EQUITY			
Ordinary shares	1,837	2,225	610
Share premium	464,629	494,749	135,622
Capital reserve	33,802	34,222	9,381
Accumulated deficit	(444,339)	(457,179)	(125,324)
Total equity	55,929	74,017	20,289
Total liabilities and equity	90,808	112,012	30,705



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

			Convenience translation into USD
			Three months ended
	Three months end	ed March 31,	March 31,
	2012	2013	2013
	NIS in thou	isands	In thousands
RESEARCH AND DEVELOPMENT EXPENSES, NET	(14,675)	(19,443)	(5,330)
SALES AND MARKETING EXPENSES	(766)	(771)	(211)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,525)	(3,522)	(965)
OPERATING LOSS	(18,966)	(23,736)	(6,506)
NON-OPERATING INCOME, NET	2,819	12,262	3,361
FINANCIAL INCOME	446	663	182
FINANCIAL EXPENSES	(2,231)	(2,029)	(556)
NET LOSS AND COMPREHENSIVE LOSS	(17,932)	(12,840)	(3,519)
	NIS		USD
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.12)	(0.06)	(0.02)

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

	Three months end	,	Convenience translation into USD Three months ended March 31,
	2012	2013	2013
	NIS in thou	isands	In thousands
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(17,932)	(12,840)	(3,519)
Adjustments required to reflect net cash used in operating activities (see appendix below)	5,012	(6,353)	(1,741)
Net cash used in operating activities	(12,920)	(19,193)	(5,260)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(22,872)	(56,695)	(15,542)
Maturities of short-term deposits	45,338	11,412	3,128
Maturities of restricted deposits	-	1,550	425
Purchase of property and equipment	(382)	(42)	(11)
Purchase of intangible assets	(16)	(30)	(8)
Net cash provided by (used in) investing activities	22,068	(43,805)	(12,008)
CASH FLOWS - FINANCING ACTIVITIES			
Repayments of bank loan	(77)	(76)	(21)
Issuance of share capital and warrants, net of issuance expenses	52,453	42,091	11,538
Proceeds from exercise of employee stock options	*	*	*
Net cash provided by financing activities	52,376	42,015	11,517
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	61,524	(20,983)	(5,751)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	33,061	68,339	18,733
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(836)	(718)	(197)
CASH AND CASH EQUIVALENTS - END OF PERIOD	93,749	46,638	12,785

\* Represents an amount less than 1,000.

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

	Three months end 2012 NIS in thou	2013	Convenience translation into USD Three months ended March 31, 2013 In thousands
ljustments required to reflect net cash used in operating activities:		.541105	in tiousalius
Income and expenses not involving cash flows:	10.5	20.4	
Depreciation and amortization	406	304	83
Long-term prepaid expenses	(1)	12	3
Exchange differences on cash and cash equivalents	836	718	197
Interest and exchange differences on short-term deposits	1,904	937	257
Interest and linkage on bank loan	(5)	(7)	(2)
Share-based compensation	965	999	273
Warrant issuance costs	1,204	470	130
Gain on adjustment of warrants to fair value	(4,023)	(12,732)	(3,490)
Interest and exchange differences on restricted deposits	4	13	4
	1,290	(9,286)	(2,545)
Changes in operating asset and liability items:			
Decrease (increase) in trade accounts receivable and other receivables	1,673	(366)	(100)
Increase in accounts payable and accruals	2,049	3,299	904
• •	3,722	2,933	804
	5,012	(6,353)	(1,741)

## BioLineRx Ltd. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED) AS OF MARCH 31, 2013

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## **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

	December 31, 2012	March 31, 2013	Convenience translation into USD (Note 1b) March 31, 2013
	NIS in the	ousands	In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	68,339	46,638	12,785
Short-term bank deposits	11,459	55,805	15,297
Prepaid expenses	804	843	231
Other receivables	2,254	2,581	707
Total current assets	82,856	105,867	29,020
NON-CURRENT ASSETS			
Restricted deposits	3,513	1,950	535
Long-term prepaid expenses	204	192	53
Property and equipment, net	3,172	2,947	807
Intangible assets, net	1,063	1,056	290
Total non-current assets	7,952	6,145	1,685
Total assets	90,808	112,012	30,705
Liabilities and equity CURRENT LIABILITIES			
Current maturities of long-term bank loan	137	54	15
Accounts payable and accruals:			
Trade	12,283	21,873	5,996
OCS	6,148	-	-
Other	5,443	5,300	1,453
Total current liabilities	24,011	27,227	7,464
NON-CURRENT LIABILITIES	,-		, -
Retirement benefit obligations	143	143	39
Warrants	10,725	10,625	2,913
Total non-current liabilities	10,868	10,768	2,952
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	34,879	37,995	10,416
EQUITY	4.005	0.007	010
Ordinary shares	1,837	2,225	610
Share premium	464,629	494,749	135,622
Capital reserve	33,802	34,222	9,381
Accumulated deficit	(444,339)	(457,179)	(125,324)
Total equity	55,929	74,017	20,289
Total liabilities and equity	90,808	112,012	30,705

The accompanying notes are an integral part of these condensed financial statements.

## **BioLineRx Ltd.** CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

	Three months en	ded March 31,	Convenience translation into USD (Note 1b) Three months ended March 31,
	2012	2013	2013
	NIS in tho	ousands	In thousands
RESEARCH AND DEVELOPMENT EXPENSES, NET	(14,675)	(19,443)	(5,330)
SALES AND MARKETING EXPENSES	(766)	(771)	(211)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,525)	(3,522)	(965)
OPERATING LOSS	(18,966)	(23,736)	(6,506)
NON-OPERATING INCOME, NET	2,819	12,262	3,361
FINANCIAL INCOME	446	663	182
FINANCIAL EXPENSES	(2,231)	(2,029)	(556)
NET LOSS AND COMPREHENSIVE LOSS	(17,932)	(12,840)	(3,519)
	NIS	5	USD
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.12)	(0.06)	(0.02)

The accompanying notes are an integral part of these condensed financial statements.

## BioLineRx Ltd. CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

	Ordinary shares	Share premium	Capital reserve	Accumulated deficit	Total
		N	NIS in thousands		
BALANCE AT JANUARY 1, 2012	1,236	421,274	31,317	(368,069)	85,758
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2012:					
Issuance of share capital , net	524	35,143	-	-	35,667
Share-based compensation	-	-	965	-	965
Employee stock options exercised	-	42	(42)	-	-
Comprehensive loss for the period				(17,932)	(17,932)
BALANCE AT MARCH 31, 2012	1,760	456,459	32,240	(386,001)	104,458
	Ordinary shares	Share 	Capital reserve NIS in thousands	Accumulated deficit	Total
BALANCE AT JANUARY 1, 2013	1,837	464,629	33,802	(444,339)	55,929
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2013:					
Issuance of share capital , net	386	29,283	-	-	29,669
Employee stock options exercised	*	224	(224)	-	-
Warrants exercised	2	258	-		260
Employee stock options forfeited and expired	-	355	(355)	-	-
Share-based compensation	-	-	999	-	999
Comprehensive loss for the period			-	(12,840)	(12,840)
BALANCE AT MARCH 31, 2013	2,225	494,749	34,222	(457,179)	74,017

The accompanying notes are an integral part of these condensed financial statements.

## BioLineRx Ltd. CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

	Ordinary shares	Share premium	Capital reserve	Accumulated deficit	Total
	Co	nvenience translat	ion into USD in th	ousands (Note 1b)	
BALANCE AT JANUARY 1, 2013	504	127,366	9,266	(121,805)	15,331
CHANGES FOR THREE MONTHS ENDED MARCH 31,					
2013:					
Issuance of share capital , net	106	8,027	-	-	8,133
Employee stock options exercised	*	61	(61)	-	-
Warrants exercised	*	71	-	-	71
Employee stock options forfeited and expired	-	97	(97)	-	-
Share-based compensation	-	-	273	-	273
Comprehensive loss for the period				(3,519)	(3,519)
BALANCE AT MARCH 31, 2013	610	135,622	9,381	(125,324)	20,289

\* Represents an amount less than 1,000.

The accompanying notes are an integral part of these condensed financial statements.

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

	Three months endo	ed March 31,	Convenience translation into USD (Note 1b) Three months ended March 31,
	2012	2013	2013
	NIS in thou	sands	In thousands
CASH FLOWS - OPERATING ACTIVITIES			
Comprehensive loss for the period	(17,932)	(12,840)	(3,519)
Adjustments required to reflect net cash used in operating activities (see appendix below)	5,012	(6,353)	(1,741)
Net cash used in operating activities	(12,920)	(19,193)	(5,260)
CASH FLOWS - INVESTING ACTIVITIES			
	(22.072)	(E6 60E)	(15 5 4 2)
Investments in short-term deposits Maturities of short-term deposits	(22,872) 45,338	(56,695) 11,412	(15,542) 3,128
Maturities of restricted deposits	45,550	1,550	425
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EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(836)	(718)	(197)
CASH AND CASH EQUIVALENTS - END OF PERIOD	93,749	46,638	12,785

\* Represents an amount less than 1,000.

The accompanying notes are an integral part of the financial statements.

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

	Three months end 2012 NIS in tho	2013	Convenience translation into USD (Note 1b) Three months ended March 31, 2013 In thousands
Adjustments required to reflect net cash used in operating activities:			in thousands
Income and expenses not involving cash flows:			
Depreciation and amortization	406	304	83
Long-term prepaid expenses	(1)	12	3
Exchange differences on cash and cash equivalents	836	718	197
Interest and exchange differences on short-term deposits	1,904	937	257
Interest and linkage on bank loan	(5)	(7)	(2)
Share-based compensation	965	999	273
Warrant issuance costs	1,204	470	130
Gain on adjustment of warrants to fair value	(4,023)	(12,732)	(3,490)
Interest and exchange differences on restricted deposits	4	13	4
	1,290	(9,286)	(2,545)
Changes in operating asset and liability items:			
Decrease (increase) in trade accounts receivable and other receivables	1,673	(366)	(100)
Increase in accounts payable and accruals	2,049	3,299	904
increase in accounts phyable and accruais	3,722	2,933	804
	5,012	(6,353)	(1,741)
Supplementary information on interest received in cash	601	316	87

The accompanying notes are an integral part of the financial statements.

## NOTE 1 – GENERAL INFORMATION

### a. General

BioLineRx Ltd. ("BioLineRx") was incorporated and commenced operations in April 2003.

Since incorporation, BioLineRx has been engaged, both independently and through its consolidated entities (collectively, the "Company"), in the development of therapeutics, from early-stage development to advanced clinical trials, for a wide range of medical needs.

In December 2004, BioLineRx registered a limited partnership, BioLine Innovations Jerusalem L.P. ("BIJ LP"), which commenced operations in January 2005. BioLineRx holds a 99% interest in BIJ LP, with the remaining 1% held by a wholly owned subsidiary of BioLineRx, BioLine Innovations Ltd. BIJ LP was established to operate a biotechnology incubator located in Jerusalem under an agreement with the State of Israel.

In February 2007, BioLineRx listed its securities on the Tel Aviv Stock Exchange ("TASE") and they have traded on the TASE since that time. Since July 2011, BioLineRx's American Depositary Shares ("ADSs") have also traded on the NASDAQ Capital Market.

In January 2008, BioLineRx established a wholly owned subsidiary, BioLineRx USA Inc. ("BioLineRx USA"), which served as the Company's business development arm in the United States. During 2011, the Company transferred its business development activities to Israel, and BioLineRx USA is no longer active.

The Company has been engaged in drug development since its incorporation. Although the Company has generated revenues from two outlicensing transactions, the Company cannot determine with reasonable certainty if and when it will have sustainable profits.

## b. Convenience translation into US dollars ("dollars" or "USD")

For the convenience of the reader, the reported New Israeli Shekel ("NIS") amounts as of March 31, 2013 have been translated into dollars, at the representative rate of exchange on March 31, 2013 (\$1 = NIS 3.648). The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

**c.** The condensed consolidated interim financial statements of the Company for the three months ended March 31, 2013 were approved by the Board of Directors on May 7, 2013, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.



## NOTE 2 – BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of March 31, 2013 and for the three months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a complete presentation of financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2012 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The results of operations for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

### NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2012 and for the year then ended.

#### NOTE 4 - ISSUANCES OF SHARE CAPITAL AND WARRANTS

## a. Private placement of share capital and warrants to Orbimed

In February 2013, the Company completed a direct placement to leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC. The placement consisted of 2,666,667 ADSs and 1,600,000 warrants to purchase an additional 1,600,000 ADSs, at a unit price of \$3.00. The warrants have an exercise price of \$3.94 per ADS and are exercisable for a term of five years. The offering raised a total of \$8,000,000, with net proceeds of approximately \$7,700,000, after deducting fees and expenses.

The warrants are exercisable over a period of five years from the date of their issuance. Since the exercise price was not deemed to be fixed, the warrants are not qualified for classification as an equity instrument and have therefore been classified as a non-current derivative financial liability. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

The amount of the direct placement consideration allocated to the warrants was approximately \$3,400,000, as calculated on the basis of the Black-Scholes model, which reflects their fair value as of the issuance date. The portion of total issuance costs allocable to the warrants, in the amount of approximately \$130,000, was recorded as non-operating expense on the statement of comprehensive loss. The change in fair value from the date of issuance through March 31, 2013, amounting to approximately \$2,300,000, has been recorded as non-operating income on the statement of comprehensive loss.

## NOTE 4 - ISSUANCES OF SHARE CAPITAL AND WARRANTS (cont.)

## b. Share purchase agreement with Lincoln Park Capital

In September 2012, BioLineRx and Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("LPC"), entered into a \$15 million purchase agreement (the "Purchase Agreement"), together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to \$15 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the Purchase Agreement.

During the three months ended March 31, 2013, BioLineRx sold a total of 1,168,848 ADSs to LPC for aggregate gross proceeds of \$3,700,000. In connection with these issuances, a total of 29,222 ADSs was issued to LPC as a commitment fee and a total of \$74,000 was paid to Oberon Securities as a finder's fee.

On a cumulative basis, from the effective date of the Purchase Agreement through the approval date of these financial statements, BioLineRx has sold a total of 2,035,177 ADSs to LPC for aggregate gross proceeds of \$5,873,000. In connection with these issuances, a total of 50,880 ADSs was issued to LPC as a commitment fee and a total of \$117,000 was paid to Oberon Securities as a finder's fee.

### NOTE 5 – SHAREHOLDERS' EQUITY

As of March 31, 2013 and December 31, 2012, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares
	December 31, March 31,
	2012 2013
Authorized share capital	750,000,000 750,000,000
Issued and paid-up share capital	183,713,197 222,553,868
	In NIS
	December
	<u> </u>
	2012 2015
Authorized share capital	7,500,000 7,500,000
Issued and paid-up share capital	1 007 100 0 005 00
	1,837,132 2,225,539

## NOTE 6 - RESEARCH AND DEVELOPMENT

Changes in fair value of warrants

- **a.** In March 2013, the Company decided to terminate the CLARITY study in connection with its BL-1020 therapeutic candidate for schizophrenia. As a result of the study termination, the Company reversed the remaining liability to repay grants previously received from the OCS in respect of BL-1020, amounting to NIS 6,148,000, since it became more likely than not that such liability would not be repaid. This amount is reflected in research and development expenses.
- **b.** Trade accounts payable and accruals as of March 31, 2013 reflect an accrual of NIS 14,200,000 related to activities in respect of the CLARITY study, including study termination costs. This amount is reflected in research and development expenses.
- c. Research and development expenses are reflected net of research grants received from an interested (related) party of the Company, pursuant to a research funding arrangement for early development stage projects, as follows:

	Three months ended March 31,	
	2012 NIS in the	2013 Dusands
Grants received from an interested party, offset against research and development expenses	898	842
NOTE 7 – NON-OPERATING INCOME, NET		
	Three mon March	
	2012	2013
	NIS in the	ousands
Issuance costs allocated to warrants	1,204	470

10

1,615

2,819

11,792

12,262

### **OPERATING AND FINANCIAL REVIEW**

You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this 6-K, as well as in our Annual Report on Form 20-F filed on March 12, 2013 (the "Annual Report").

U.S. dollar amounts herein (other than amounts that were originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of March 31, 2013 (\$1 = NIS 3.648). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

## **Forward Looking Statements**

The following discussion contains "forward-looking statements", including statements regarding expectations, beliefs, intentions or strategies for the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions, and are subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those listed below as well as those discussed in the Annual Report (particularly those in "Item 3. Key Information – Risk Factors"). Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the initiation, timing, progress and results of our preclinical studies, clinical trials, and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization, and market acceptance of our therapeutic candidates;
- · our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;

- · competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business.

#### Overview

We are a clinical stage biopharmaceutical development company dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of seven clinical therapeutic candidates: BL-1020, BL-1040, BL-5010, BL-7040, BL-8040, BL-1021 and BL-8020. In addition, we have five therapeutic candidates in pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. We also operate, with financial support of the Office of the Chief Scientist of the Israeli Ministry of Trade and Industry (OCS), a biotechnology incubator to evaluate therapeutic candidates. As of March 31, 2013, we have received approximately NIS 53.7 million (\$14.7 million) in funding from the OCS to operate the incubator, which does not include NIS 22.3 million (\$6.1 million) in funding we have received from the OCS outside of the incubator agreement as of that date. Such amounts include aggregate funding of approximately NIS 36.5 million (\$10.0 million) for terminated programs. We are not required to repay funds received for terminated programs. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently.

The following is a description of our seven clinical therapeutic candidates:

- BL-1020 is an orally available drug in development for the treatment of schizophrenia. In March 2013, we announced that results from an interim analysis of the phase 2/3 CLARITY trial indicated that the trial would not meet its pre-specified primary efficacy endpoint. Based on these results, we discontinued the study, and are currently in the process of reviewing and cleaning the study data. We expect to receive a full analysis of the unblinded study data on all study patients in the third quarter of 2013, at which point we will make a decision about the future of this therapeutic candidate.
- BL-1040 is a novel resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. BL-1040 is being developed as a medical device. In March 2010, we announced encouraging results from a phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing arrangement with Ikaria, Inc., or Ikaria, with respect to the development, manufacture and commercialization of BL-1040. In December 2011, Ikaria commenced PRESERVATION 1, a CE Mark registration clinical trial of BL-1040 (now called the "Bioabsorbable Cardiac Matrix" device, or BCM device, by Ikaria).
- BL-5010 comprises a customized, proprietary pen-like applicator (BL-5010P) containing a novel formulation of two acids, which is being developed for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a phase 1/2 clinical trial of BL-5010. We have received European confirmation from the British Standards Institution Notified Body in the UK of the regulatory pathway classification of BL-5010 as a Class IIa medical device. We are planning to commence a pivotal CE-Mark registration trial for European approval in the second half of 2013.
- BL-7040 is an orally available synthetic oligonucleotide which we are developing for the treatment of inflammatory bowel disease, or IBD. In April 2013, we announced positive results from a phase 2a proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel.
- BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for acute myeloid leukemia, or AML, and other hematological cancers. We plan to commence a phase 2 clinical trial in the second quarter of 2013.



- BL-1021 is a new chemical entity in development for the treatment of neuropathic pain. We are currently evaluating potential development collaborations with other parties in order to continue development of this compound.
- BL-8020 is an orally available treatment for hepatitis C, or HCV, with a unique mechanism of action involving the inhibition of HCV-induced autophagy in host cells. We have recently commenced a phase 1/2 clinical trial to evaluate the safety, tolerability and effectiveness of BL-8020 at two sites in France.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Ikaria. Under the agreement, we granted Ikaria an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart following AMI. Under the arrangement, Ikaria is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment of \$7.0 million upon the execution of the license agreement. Upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment of \$10.0 million in March 2010, and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

In June 2010, we entered into an exclusive, royalty-bearing out-licensing arrangement with Cypress Bioscience with regard to BL-1020, covering the United States, Canada and Mexico, which became effective in August 2010. We received an upfront fee of \$30.0 million from Cypress Bioscience upon the effectiveness of the agreement. In May 2011, following the acquisition of Cypress Bioscience by Royalty Pharma earlier in the year, we reacquired all of the rights to develop and commercialize BL-1020 from Cypress Bioscience and currently hold full global rights to the product. We commenced the phase 2/3 CLARITY trial in June 2011 and in March 2013, we announced that results from an interim analysis of the phase 2/3 CLARITY trial indicated that the trial would not meet its pre-specified primary efficacy endpoint. Based on these results, we discontinued the study, and are currently in the process of reviewing and cleaning the study data. We expect to receive a full analysis of the un-blinded study data on all study patients in the third quarter of 2013, at which point we will make a decision about the future of BL-1020.

We have funded our operations primarily through the sale of equity securities (both in private placements and in three public offerings on the TASE), funding received from the OCS, payments received under the licensing arrangements with Ikaria and Cypress Bioscience, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone payments that we expect to receive from Ikaria, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of March 31, 2013, we held \$28.1 million of cash, cash equivalents and short-term bank deposits, based on the exchange rate reported by the Bank of Israel as of March 31, 2013.

#### **Recent Company Developments**

#### Clinical and Pre-Clinical Development

In March 2013, we announced the discontinuation of the Phase 2/3 CLARITY trial of BL-1020 after the results from an interim analysis indicated that the trial would not meet the pre-specified primary efficacy endpoint. As a result of the CLARITY study termination, we anticipate that planned research and development expenses will decrease for the remainder of 2013 and part of 2014 by approximately \$6 to \$7 million, thus allowing our current cash reserves of approximately \$28 million to fund our expected operations into 2015.

In April 2013, we announced positive Phase 2a results for BL-7040. The study showed that BL-7040 is safe and effective in treating ulcerative colitis, a form of IBD. The Phase 2a trial was an open-label, proof-of-concept study to evaluate the efficacy, safety and tolerability of BL-7040 in patients with moderately active ulcerative colitis. Patients who completed the study were treated for five weeks with BL-7040: 12 mg/day for up to three weeks, followed by 40 mg/day for two additional weeks. The clinical trial was carried out at five leading medical centers in Israel.

Sixteen of the 22 patients who were enrolled in the clinical trial completed the full five-week course of treatment and two-week follow-up. Of the six patients who did not complete the study, five came from one particular site and that site recruited only five patients. The primary clinical endpoint in the study - a reduction in the Mayo score between baseline and completion of treatment – was achieved. Fifty percent of patients (8 patients) met the primary endpoint, while the remaining 8 patients demonstrated a stable clinical condition or minor improvement. Fifty-six percent of patients (9 patients) demonstrated decreases of at least 1 point in the rectal-bleeding sub-score and 69% (11 patients) had rectal-bleeding sub-scores of  $\leq 1$  (6 of the 11 patients demonstrated complete remission of rectal bleeding).

Fifty percent of the patients completing study treatment also met certain secondary endpoints, such as a partial Mayo score reduction and mucosal healing evaluated by endoscopy sub-score measurements. Additional secondary endpoints in the study were the IBD Quality-of-Life Questionnaire, and the serum CRP and fecal calprotectin measurements. The results of these additional secondary endpoints were not conclusive, although certain positive trends were noted.

BL-7040 was highly safe and well tolerated by the study participants, with a very low incidence of drug related, mild-to-moderate adverse events (AEs), as well as one serious adverse event (SAE) not related to the treatment. Both patients and investigators were very satisfied with the safety and tolerability profile of the treatment and, in particular, emphasized the ease of oral administration.

In April 2013, we announced that we received all necessary regulatory approvals in the U.S. to commence a Phase 2a trial for BL-8040. The study is a multicenter, open-label study under an IND, designed to evaluate the safety and efficacy profile of repeated escalating doses of BL-8040 in adult subjects with relapsed/refractory AML. The primary endpoints of the study are the safety and tolerability of the drug. Secondary endpoints will include the pharmacokinetic profile of the drug and an efficacy evaluation, as assessed by various parameters, such as the response rate by bone marrow biopsy. The study is also designed in a way that will enable the investigators to evaluate the capabilities of BL-8040 in mobilizing cancer cells from the bone marrow to the peripheral blood, and in inducing their cell death. The study is expected to be conducted in the U.S. and Israel, and will enroll up to 50 patients.

In March 2013, we announced that we received approval from the French regulatory authorities to commence a Phase 1/2 trial for BL-8020, an orally available, interferon-free treatment for the Hepatitis C virus (HCV). The study is an open-label trial to evaluate the efficacy, safety and tolerability of BL-8020 in patients infected with HCV. It will be conducted at two clinical sites in France and will include HCV-infected patients of any genotype who have previously failed or relapsed following treatment with the standard-of-care. In April 2013, we announced the enrollment of the first patient in the trial.

In February 2013, we announced that following promising pre-clinical data, EDP-14, for the treatment of severe and persistent asthma, was added to our main therapeutic pipeline under the name BL-9010. Previously, the project was developed under our Early Development Program. BL-9010 is a novel bi-specific antibody treatment for severe and persistent asthma. It targets and links together two immunological modulators - IgE and CD300a. Allergen-bound IgE activates cells involved in allergic responses, such as mast cells, while CD300a inhibits immune responses. In murine models of experimental asthma, BL-9010 significantly blocked allergic responses. Importantly, this could be reproduced in human mast cells, where BL-9010 was shown to inhibit the allergic reaction of these cells in-vitro.

### Addition and Termination of Therapeutic Candidates

As part of our business strategy, we continue to actively source, rigorously evaluate and in-license selected therapeutic candidates. As noted above, in February 2013, we added BL-9010 to our clinical pipeline. In March 2013, we terminated three projects for scientific considerations in light of experimental results: BL-6030/1, BL-7020 and BL-8010. BL-6030/1 was intended to treat bacterial infection; BL-7020, psoriasis; and BL-8010, retinopathy. Until their termination, BL-6030/1 and BL-7020 were conducted by our incubator, and BL-8010 was partially funded in the framework of our Early Development Program.

#### Capital Raisings

In February 2013, we completed a direct placement to leading healthcare investor, OrbiMed Israel Partners Limited Partnership, an affiliate of OrbiMed Advisors LLC, or OrbiMed, of 2,666,667 ADSs and 1,600,000 warrants to purchase an additional 1,600,000 ADSs, at a unit price of \$3.00. The offering raised \$8.0 million, with net proceeds of approximately \$7.7 million after deducting fees and expenses.

In September 2012, we entered into a \$15 million purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or LPC, whereby LPC agreed to purchase, from time to time, up to \$15 million of our ADSs, subject to certain limitations, during the 36-month term of the Purchase Agreement.

During the three months ended March 31, 2013, we sold a total of 1,168,848 ADSs to LPC for aggregate gross proceeds of \$3,700,000. In connection with these issuances, a total of 29,222 ADSs was issued to LPC as a commitment fee and a total of \$74,000 was paid to Oberon Securities as a finder's fee.

On a cumulative basis, from the effective date of the Purchase Agreement through the approval date of these financial statements, we have sold a total of 2,035,177 ADSs to LPC for aggregate gross proceeds of \$5,873,000. In connection with these issuances, a total of 50,880 ADSs was issued to LPC as a commitment fee and a total of \$117,000 was paid to Oberon Securities as a finder's fee.

#### Other Developments

In March 2013, we announced that on March 4, 2013, Yakov Friedman, a director, resigned from the Company's Board.

#### Revenues

Our revenues to date have been generated primarily from milestone payments under our licensing arrangements with Ikaria and the amounts we received from Cypress Bioscience. We entered into a license and collaboration agreement with Ikaria in 2009, in respect of which Ikaria paid us an up-front payment of \$7.0 million. In addition, upon successful completion of the phase 1/2 clinical trial, Ikaria paid us a milestone payment of \$10.0 million, which was subject to a 15% withholding tax in the United States. We received a full refund of the tax withheld from the U.S. Internal Revenue Service in the third quarter of 2011. In June 2010, we entered into a license agreement with Cypress Bioscience. Under the terms of the license agreement, we received an upfront fee of \$30.0 million. The license agreement with Cypress Bioscience was terminated, effective as of May 31, 2011.

Under the terms of our agreement with Ikaria, in addition to the payments mentioned above, the maximum future development-related payments to which we are entitled is \$115.5 million. We are also entitled to maximum commercialization milestone payments of \$150.0 million, subject to the terms and conditions of the license agreement. Certain payments we have received from Ikaria have been subject to a 15% withholding tax in the United States, and certain payments we may receive in the future, if at all, may also be subject to a 15% withholding tax in the United States. Receipt of any milestone payment under the Ikaria agreement depends on many factors, some of which are beyond our control. We cannot assure you that we will receive any of these future payments. We believe that we may be entitled to a refund of withholding taxes paid in connection with future payments from the U.S. government but there can be no assurance that we will be able to obtain such a refund. In addition, we may be able to use U.S. taxes withheld from future payments to us as credits against Israeli corporate income tax when we have income, if at all, but there can be no assurance that we will be able to realize the credits. Our payments to our inlicensors are to be made from the net consideration received from our out-licensees.

We expect our revenues for the next several years to be derived primarily from payments under our current agreement with Ikaria with regard to BL-1040, as well as additional collaborations that we may enter into in the future, including with regard to BL-1020, BL-5010, BL-7040, BL-8040, BL-1021, BL-8020 or other therapeutic candidates. Furthermore, we may receive future royalties on product sales, if any, under our agreement with Ikaria with regard to BL-1040, as well as under any future agreement relating to BL-1020, BL-5010, BL-8020 or other compounds.

#### **Research and Development**

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

<u>Project</u>	<u>Status</u>	Expected or Recent Near Term Milestone
BL-1020	Phase 2/3 CLARITY trial discontinued	Completion of full analysis of un-blinded study data on all study patients; final decision about future of therapeutic candidate
BL-1040	CE registration pivotal trial (conducted by Ikaria)	Study results in 2014
BL-5010	Completed phase 1/2	Completion of unique applicator prototype by second quarter of 2013; commencement of pivotal CE Mark registration trial in second half of 2013
BL-7040	Phase 2 trial completed	Clinical and business evaluation, including examination of potential additional indications; potential co-development collaboration or licensing transaction
BL-8040	Regulatory approval for phase 2 study received in the U.S.	Phase 2 study expected to commence during the second quarter of 2013; partial study results by end of 2013
BL-1021	Completed phase 1a	Potential co-development collaboration
BL-8020	Commenced phase 1/2	Partial study results expected by end of 2013

In addition to the projects set forth above, the following table identifies our current portfolio of projects that are in the preclinical stages of development. Such projects have significantly lower costs due to their stage of development.

Project	Description	Indication	Status
BL-7010	Polymer	Celiac disease	Preclinical studies
BL-5040	Protein	Cachexia	Preclinical studies
BL-7060/EDP 29	Peptide	Inflammatory diseases	Preclinical studies
BL-8030	Small molecule	Hepatitis C	Preclinical studies
BL-9010	Bi-specific antibody	Severe allergies/Asthma	Preclinical studies

Set forth below is a summary of the gross direct costs allocated to our main projects on an individual basis, as well as the gross direct costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2010, 2011 and 2012; for the three months ended March 31, 2013; and on an aggregate basis since project inception. Certain of such costs are covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

				Three Months	
				Ended March	Total Costs
	Year l	Ended December 3	51,	31,	Since Project
	2010	2011	2012	2013	Inception
		(in thou	isands of U.S. dolla	ars)	
BL-1020	450	2,765	7,448	4,381	55,939
BL-1040	167	3	_	-	10,227
BL-5010	384	94	132	26	2,162
BL-7040	-	465	500	79	1,044
BL-8040	-	-	723	763	1,486
BL-1021	924	466	68	2	7,129
BL-8020	-	_	794	122	916
Other projects	1,704	3,262	3,061	333	25,278
Total gross direct project costs <sup>(1)</sup>	3,629	7,055	12,726	5,706	104,181

(1) Does not include indirect project costs and overhead, including payroll and related expenses (including stock-based compensation), facilities, depreciation and impairment of intellectual property, which are included in total research and development expenses in our financial statements. Certain of such costs are also covered by OCS funding.

As indicated in the above table, a significant portion of our research and development costs have been incurred in connection with our BL-1020 project. As a result of the CLARITY study termination, it is likely that we will no longer incur significant additional costs in connection with the project, other than costs related to termination of various project activities.

From our inception through March 31, 2013, we have incurred research and development expense of approximately NIS 533.5 million (\$146.2 million). We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to remain our most significant cost as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

### Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

#### **Non-Operating Expense and Income**

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the placements related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder's fees, as well as other one-time expenses, associated with the initial set-up of the Lincoln Park Capital share purchase agreement.

#### **Financial Expense and Income**

Financial expense and income consists of interest earned on our cash, cash equivalents and short-term bank deposits; bank fees and other transactional costs; and expense or income resulting from fluctuations of the dollar and other currencies, in which a portion of our assets and liabilities are denominated, against the NIS (our functional currency).

#### **Significant Accounting Policies and Estimates**

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2012.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates using assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which impact the carrying value of our assets and liabilities that are not readily apparent from other sources. Actual results will differ from these estimates and such differences may be significant.

#### **Results of Operations – Overview**

#### Revenues

We did not record any revenues during each of the three-month periods ended March 31, 2013 and 2012.

#### Cost of revenues

We did not record any cost of revenues during each of the three-month periods ended March 31, 2013 and 2012.

#### **Research and development expenses**

At December 31, 2011, our drug development pipeline consisted of 15 therapeutic candidates. During 2012, we added four new compounds to our pipeline and discontinued the development of five compounds from the pipeline, so that our drug development pipeline as of December 31, 2012 consisted of 14 therapeutic candidates. During the first three months of 2013, we added one new compound to our pipeline and discontinued the development of three additional compounds from the pipeline, so that our drug development pipeline as of 12 therapeutic candidates.

#### **Operating Results Comparison between Periods**

## **Revenues and cost of revenues**

See discussion under "Results of Operations - Overview" above.

#### **Research and development expenses**

	Three mor	Three months ended March 31,		
		Increase		
	2012	2013	(decrease)	
	(in th	(in thousands of NIS)		
Research and development expenses, net	14,675	19,443	4,768	

Research and development expenses for the three months ended March 31, 2013 were NIS 19.4 million (\$5.3 million), an increase of NIS 4.7 million (\$1.3 million) or 32% compared to NIS 14.7 million (\$4.0 million) for the three months ended March 31, 2012. In March 2013, due to the BL-1020 CLARITY study termination, we reversed the remaining liability to repay grants previously received from the OCS in respect of BL-1020, as it became more likely than not that such liability would not be repaid. As a result, we recorded a one-time credit to research and development expenses in the amount of NIS 6.0 million during the quarter. Without regard to this one-time credit, research and development expenses increased by NIS 10.8 million compared to the first quarter of 2012. The primary reason for this increase is significantly higher expenses in 2013 associated with the CLARITY clinical trial, as well as a ramp-up in spending on other clinical-stage projects introduced during 2012.

#### Sales and marketing expenses

	Three mor	Three months ended March 31,		
	2012	2012 2012		
	2012	2013	(decrease)	
	(in th	(in thousands of NIS)		
Sales and marketing expenses	766	771	5	

Sales and marketing expenses for the three months ended March 31, 2013 were NIS 0.8 million (\$0.2 million), similar to the three months ended March 31, 2012.

#### General and administrative expenses

	Three mo	Three months ended March 31,		
	Increa		Increase	
	2012	2013	(decrease)	
	(in thousands of NIS)		NIS)	
General and administrative expenses	3,525	3,522	(3)	

General and administrative expenses for the three months ended March 31, 2013 were NIS 3.5 million (\$1.0 million), similar to the three months ended March 31, 2012.

	Three mor	Three months ended March 31,		
		Increase		
	2012	2013	(decrease)	
	(in th	(in thousands of NIS)		
Non-operating income, net	2,819	12,262	9,443	

We recognized net non-operating income of NIS million 12.3 (\$3.4 million) for the three months ended March 31, 2013, an increase of NIS 9.4 million (\$2.6 million), compared to net non-operating income of NIS 2.8 million (\$0.8 million) for the three months ended March 31, 2012. 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 which we conducted in February 2012 and 2013. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

#### Financial income (expense), net

	Three mor	Three months ended March 31,		
		Increase 2012 2013 (decrease		
	2012			
	(in th	(in thousands of NIS)		
Financial income	446	663	217	
Financial expenses	(2,231)	(2,029)	(202)	
Net financial expenses	(1,785)	(1,366)	419	

We recognized net financial expenses of NIS million 1.4 (\$0.4 million) for the three months ended March 31, 2013, a decrease of NIS 0.4 million (\$0.1 million), compared to net financial expenses of NIS 1.8 million (\$0.5 million) for the three months ended March 31, 2012. Net financial expenses for both periods result primarily from changes in the average exchange rate of the dollar in relation to the NIS, which had a negative effect on our net assets denominated in dollars.

### Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public (in Israel) and private offerings of our equity securities, grants and loans from the OCS, and payments received under our strategic licensing arrangements. At March 31, 2013, we held NIS 102.4 million (\$28.1 million) in cash, cash equivalents and short-term bank deposits.

In February 2013, we completed a direct placement to OrbiMed. The placement consisted of 2,666,667 ADSs and warrants to purchase an additional 1,600,000 ADSs, at a unit price of \$3.00. The warrants have an exercise price of \$3.94 per ADS and are exercisable for a term of five years. The offering raised a total of \$8,000,000, with net proceeds of approximately \$7,700,000, after deducting fees and expenses.

Pursuant to the share purchase agreement with LPC signed in September 2012, we may sell, from time to time, and at our discretion, up to \$15 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through May 7, 2013, we have sold an aggregate of approximately \$5.9 million of our ADSs to LPC, leaving an available balance under the facility of approximately \$9.1 million.

Net cash used in operating activities was NIS 19.2 million (\$5.3 million) for the three months ended March 31, 2013, compared with net cash used in operating activities of NIS 12.9 million (\$3.5 million) for the three months ended March 31, 2012. The NIS 6.3 million (\$1.8 million) increase in net cash used in operating activities during the three-month period in 2013, compared to the three-month period in 2012, was primarily the result of increased research and development spending.

Net cash used in investing activities for the three months ended March 31, 2013 was NIS 43.8 million (\$12.0 million), compared to net cash provided by investing activities of NIS 22.1 million (\$6.1 million) for the three months ended March 2012. The cash flows related to investing activities relate primarily to investments in, and maturities of, our short-term bank deposits during the respective quarters.

Net cash provided by financing activities for the three months ended March 31, 2013 was NIS 42.0 million (\$11.5 million), compared to net cash provided by financing activities of NIS 52.4 million (\$14.4 million) for the three months ended March 2012. The cash flows from financing activities primarily reflect the direct and private placements that we completed in February 2013 and 2012.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2015, we will require significant additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- · the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- · any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- · payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

#### **Off-Balance Sheet Arrangements**

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.