# 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 November 2014

# 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:

Form 20-F x Form 40-F o

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 x

On November 10, 2014, the Registrant will issue a press release announcing its financial results for the three months and nine months ended September 30, 2014. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2014, and for the three months and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 10, 2014;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2014, and for the three months and nine months then ended;

Exhibit 3: Registrant's operating and financial review as of September 30, 2014, and for the three months and nine months then ended.

Pursuant to the requirements of the Securities Excha	ige Act of 1934, the Registrant ha	as duly caused this report to b	e signed on its behalf by	the undersigned
thereunto duly authorized.				

By: /s/ Philip Serlin

Philip Serlin Chief Financial and Operating Officer

Dated: November 10, 2014

### For immediate release

# **BioLineRx Reports Third Quarter 2014 Financial Results**

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

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

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

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

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

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

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

Sales and marketing expenses for the three months ended September 30, 2014 were NIS 1.1 million (\$0.3 million), an increase of NIS 0.4 million (\$0.1 million), or 46%, compared to NIS 0.7 million (\$0.2 million) for the three months ended September 30, 2013. The increase resulted primarily from professional fees related to increased business development activities. Sales and marketing expenses for the nine months ended September 30, 2014 were NIS 3.3 million (\$0.9 million), an increase of NIS 0.7 million (\$0.2 million), or 30%, compared to NIS 2.6 million (\$0.7 million) for the nine months ended September 30, 2013. The reason for the increase is similar to the one discussed above in the three-month comparison.

General and administrative expenses for the three months ended September 30, 2014 were NIS 2.8 million (\$0.8 million), substantially similar to the comparable period in 2013. General and administrative expenses for the nine months ended September 30, 2014 were NIS 9.1 million (\$2.5 million), a decrease of NIS 0.7 million (\$0.2 million), or 7%, compared to NIS 9.8 million (\$2.7 million) for the nine months ended September 30, 2013. The decrease resulted primarily from a one-time expense for professional services incurred in the 2013 period.

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

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

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

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

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

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

Net cash used in investing activities for the nine months ended September 30, 2014 was NIS 54.5 million (\$14.8 million), compared to net cash used in investing activities of NIS 17.5 million (\$4.7 million) for the nine months ended September 30, 2013. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

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

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

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

(Tables 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 completed a Phase 1/2 study.

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

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 17, 2014. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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Convenience

# CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

	December 31,	September 30,	translation into USD September 30,
	2013	2014	2014
	NIS in th	ousands	In thousands
Assets			
CURRENT ASSETS			
Cash and cash equivalents	30,888	17,379	4,703
Short-term bank deposits	32,345	91,936	24,881
Prepaid expenses	896	649	176
Other receivables	1,249	222	60
Total current assets	65,378	110,186	29,820
NON-CURRENT ASSETS			
Restricted deposits	573	611	165
Long-term prepaid expenses	169	133	36
Property and equipment, net	2,471	2,330	630
Intangible assets, net	878	837	227
Total non-current assets	4,091	3,911	1,058
Total assets	69,469	114,097	30,878
Liabilities and equity CURRENT LIABILITIES Accounts payable and accruals:			
Trade	7,945	5,607	1,517
Other	2,499	4,031	1,091
Total current liabilities	10,444	9,638	2,608
NON-CURRENT LIABILITIES			
Retirement benefit obligations	152	152	41
Warrants	18,187	5,296	1,433
Total non-current liabilities	18,339	5,448	1,474
COMMITMENTS AND CONTINGENT LIABILITIES			
Total liabilities	28,783	15,086	4,082
EQUITY			
Ordinary shares	2,414	3,411	923
Share premium	509,857	589,980	159,670
Capital reserve	34,192	35,425	9,587
Accumulated deficit	(505,777)	(529,805)	(143,384)
Total equity	40,686	99,011	26,796
Total liabilities and equity	69,469	114,097	30,878

# ${\bf BioLineRx\ Ltd.}$ CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

					Convenience into	
	Three mon Septemb		Nine mont Septemb		Three months ended September 30,	Nine months ended September 30,
	2013	2014	2013	2014	2014	2014
		NIS in tho	usands		USD in th	nousands
RESEARCH AND DEVELOPMENT EXPENSES, NET SALES AND MARKETING EXPENSES	(8,190) (731)	(10,440) (1,070)	(39,720) (2,565)	(29,627) (3,340)	(2,825) (290)	(8,018) (904)
GENERAL AND ADMINISTRATIVE	(/31)	(1,070)	(2,303)	(3,340)	(290)	(904)
EXPENSES	(2,663)	(2,779)	(9,789)	(9,130)	(752)	(2,471)
OPERATING LOSS	(11,584)	(14,289)	(52,074)	(42,097)	(3,867)	(11,393)
NON-OPERATING INCOME	(==,==,)	(= :,===)	(=_,; , )	( -, )	(=,==:)	(,)
(EXPENSES), NET	(4,627)	4,835	9,214	11,680	1,309	3,161
FINANCIAL INCOME	501	8,069	2,484	7,735	2,184	2,093
FINANCIAL EXPENSES	(1,956)	(1,122)	(5,698)	(1,346)	(303)	(364)
COMPREHENSIVE LOSS FOR THE PERIOD	(17,666)	(2,507)	(46,074)	(24,028)	(677)	(6,503)
		NIS			USD	
LOSS PER ORDINARY SHARE -						
BASIC AND DILUTED	(0.077)	(0.008)	(0.209)	(0.076)	(0.002)	(0.021)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF						
LOSS PER ORDINARY SHARE	230,871,411	341,150,506	220,559,858	317,253,636	341,150,506	317,253,636

# $\begin{tabular}{ll} \textbf{BioLineRx Ltd.} \\ \textbf{CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS} \\ \textbf{(UNAUDITED)} \end{tabular}$

Convenience translation

			into USD	
	Nine months ende	d September	Nine months ended September 30,	
	2013	2013 2014		
	NIS in thou	sands	In thousands	
CASH FLOWS - OPERATING ACTIVITIES				
Comprehensive loss for the period	(46,074)	(24,028)	(6,503)	
Adjustments required to reflect net cash used in operating activities (see appendix below)	(9,837)	(14,307)	(3,872)	
Net cash used in operating activities	(55,911)	(38,335)	(10,375)	
CASH FLOWS - INVESTING ACTIVITIES				
Investments in short-term deposits	(104,127)	(139,800)	(37,835)	
Maturities of short-term deposits	85,377	85,825	23,227	
Maturities of restricted deposits	1,550	-	-	
Additions to property and equipment	(196)	(545)	(148)	
Additions to intangible assets	(96)	(10)	(3)	
Net cash used in investing activities	(17,492)	(54,530)	(14,759)	
CASH FLOWS - FINANCING ACTIVITIES				
Repayments of bank loan	(127)	-	-	
Issuance of share capital and warrants, net	50,140	78,585	21,268	
Proceeds from exercise of employee stock options	*	*	*	
Net cash provided by financing activities	50,013	78,585	21,268	
DECREASE IN CASH AND CASH EQUIVALENTS	(23,390)	(14,280)	(3,866)	
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	68,339	30,888	8,360	
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(1,988)	771	209	

CASH AND CASH EQUIVALENTS - END OF PERIOD

42,961

17,379

# $\begin{tabular}{ll} \textbf{BioLineRx Ltd.} \\ \textbf{APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS} \\ \textbf{(UNAUDITED)} \\ \end{tabular}$

Convenience

			translation into USD
		Nine months ended September 30,	
	2013	2014	2014
	NIS in tho	usands	In thousands
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	870	737	200
Impairment of intangible assets	138	-	-
Long-term prepaid expenses	60	36	10
Exchange differences on cash and cash equivalents	1,988	(771)	(209)
Share-based compensation	2,400	2,727	737
Warrant issuance costs	470	-	-
Gain on adjustment of warrants to fair value	(10,191)	(12,891)	(3,489)
Commitment fee paid by issuance of share capital	-	1,041	282
Interest and exchange differences on short-term deposits	1,521	(5,616)	(1,520)
Interest and linkage on bank loan	(10)	-	-
Interest and exchange differences on restricted deposits	30	(38)	(10)
	(2,724)	(14,775)	(3,999)
Changes in operating asset and liability items:			
Decrease in trade accounts receivable and other receivables	1,374	1,274	345
Decrease in accounts payable and accruals	(8,487)	(806)	(218)
	(7,113)	468	127
	(9,837)	(14,307)	(3,872)
Supplementary information on interest received in cash	449	177	48
Supplementary intormation on interest received in cash		1//	40

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)  ${\rm AS\ OF\ SEPTEMBER\ 30,2014}$ 

# CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED) AS OF SEPTEMBER 30, 2014

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# CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (UNAUDITED)

Convenience translation into USD (Note 1b)

			(Note 1b)	
	December 31,	September 30,	September 30,	
	2013	2014	2014	
	NIS in th	nousands	In thousands	
Assets				
CURRENT ASSETS				
Cash and cash equivalents	30,888	17,379	4,703	
Short-term bank deposits	32,345	91,936	24,881	
Prepaid expenses	896	649	176	
Other receivables	1,249	222	60	
Total current assets	65,378	110,186	29,820	
NON-CURRENT ASSETS				
Restricted deposits	573	611	165	
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Property and equipment, net	2,471	2,330	630	
Intangible assets, net	878	837	227	
Total non-current assets	4,091	3,911	1,058	
Total assets	69,469	114,097	30,878	
Liabilities and equity				
CURRENT LIABILITIES				
Accounts payable and accruals:				
Trade	7,945	5,607	1,517	
Other	2,499	4,031	1,091	
Total current liabilities	10,444	9,638	2,608	
NON-CURRENT LIABILITIES				
Retirement benefit obligations	152	152	41	
Warrants	18,187	5,296	1,433	
Total non-current liabilities	18,339	5,448	1,474	
COMMITMENTS AND CONTINGENT LIABILITIES				
Total liabilities	28,783	15,086	4,082	
EQUITY				
Ordinary shares	2,414	3,411	923	
Share premium	509,857	589,980	159,670	
Capital reserve	34,192	35,425	9,587	
Accumulated deficit	(505,777)	(529,805)	(143,384)	
Total equity	40,686	99,011	26,796	
Total liabilities and equity	69,469	114,097	30,878	

# ${\bf BioLineRx\ Ltd.}$ CONDENSED CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

Convenience translation into USD (Note 1b)

						(Note 1D)	
	Three mont Septemb		Nine montl Septemb		Three months ended September 30,	Nine months ended September 30,	
	2013	2014	2013	2014	2014	2014	
		NIS in tho	usands		USD in tl	nousands	
RESEARCH AND DEVELOPMENT							
EXPENSES, NET	(8,190)	(10,440)	(39,720)	(29,627)	(2,825)	(8,018)	
SALES AND MARKETING EXPENSES	(731)	(1,070)	(2,565)	(3,340)	(290)	(904)	
GENERAL AND ADMINISTRATIVE							
EXPENSES	(2,663)	(2,779)	(9,789)	(9,130)	(752)	(2,471)	
OPERATING LOSS	(11,584)	(14,289)	(52,074)	(42,097)	(3,867)	(11,393)	
NON-OPERATING INCOME							
(EXPENSES), NET	(4,627)	4,835	9,214	11,680	1,309	3,161	
FINANCIAL INCOME	501	8,069	2,484	7,735	2,184	2,093	
FINANCIAL EXPENSES	(1,956)	(1,122)	(5,698)	(1,346)	(303)	(364)	
COMPREHENSIVE LOSS FOR THE							
PERIOD	(17,666)	(2,507)	(46,074)	(24,028)	(677)	(6,503)	
		NIS			USD	_	
LOSS PER ORDINARY SHARE -							
BASIC AND DILUTED	(0.077)	(0.008)	(0.209)	(0.076)	(0.002)	(0.021)	
WEIGHTED AVERAGE NUMBER OF							
SHARES USED IN CALCULATION OF							
LOSS PER ORDINARY SHARE	230,871,411	341,150,506	220,559,858	317,253,636	341,150,506	317,253,636	

# $\begin{tabular}{ll} \textbf{BioLineRx Ltd.} \\ \textbf{CONDENSED INTERIM STATEMENTS OF CHANGES IN EQUITY} \\ \textbf{(UNAUDITED)} \end{tabular}$

	Ordinary shares	Share premium	Capital reserve	Accumulated Deficit	Total
		N	IS in thousands		
BALANCE AT JANUARY 1, 2013	1,837	464,629	33,802	(444,339)	55,929
CHANGES FOR NINE MONTHS ENDED SEPTEMBER					
30, 2013:					
Issuance of share capital , net	518	37,202	-	-	37,720
Employee stock options exercised	*	1,457	(1,457)	-	-
Warrants exercised	2	257	-	-	259
Employee stock options forfeited and expired	-	764	(764)	-	-
Share-based compensation	-	-	2,400	-	2,400
Comprehensive loss for the period				(46,074)	(46,074)
BALANCE AT SEPTEMBER 30, 2013	2,357	504,309	33,981	(490,413)	50,234
	Ordinary	Share	Capital	Accumulated	
	Ordinary shares	premium	reserve	Accumulated Deficit	Total
	J	premium	-		Total
BALANCE AT JANUARY 1, 2014	J	premium	reserve		<b>Total</b> 40,686
BALANCE AT JANUARY 1, 2014 CHANGES FOR NINE MONTHS ENDED SEPTEMBER	shares	premium N	reserve IS in thousands	Deficit	
•	shares	premium N	reserve IS in thousands	Deficit	
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014: Issuance of share capital, net	shares	premium N	reserve IS in thousands	Deficit	
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014: Issuance of share capital, net Employee stock options exercised	2,414	premium N	reserve IS in thousands	Deficit	40,686
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014: Issuance of share capital, net Employee stock options exercised Employee stock options forfeited and expired	2,414 997	premium N 509,857	reserve IS in thousands 34,192	Deficit	40,686
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014: Issuance of share capital, net Employee stock options exercised	2,414 997	78,629	reserve IS in thousands 34,192 - (77)	Deficit	40,686 79,626 - 2,727
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014: Issuance of share capital, net Employee stock options exercised Employee stock options forfeited and expired	2,414 997	78,629	reserve  IS in thousands  34,192  - (77) (1,417)	Deficit	40,686 79,626 -

<sup>\*</sup> Represents an amount less than 1,000 NIS

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

	Ordinary shares	Share premium	Capital reserve	Accumulated deficit	Total
	Co	onvenience translat	tion into USD in th	ousands (Note 1b)	
BALANCE AT JANUARY 1, 2014	653	137,986	9,254	(136,881)	11,012
CHANGES FOR NINE MONTHS ENDED SEPTEMBER					
30, 2014:					
Issuance of share capital , net	270	21,280	-	-	21,550
Employee stock options exercised	*	21	(21)	-	-
Employee stock options forfeited and expired	-	383	(383)	-	-
Share-based compensation	-	-	737	-	737
Comprehensive loss for the period				(6,503)	(6,503)
BALANCE AT SEPTEMBER 30, 2014	923	159,670	9,587	(143,384)	26,796

<sup>\*</sup> Represents an amount less than \$1,000

# $\begin{tabular}{ll} \textbf{BioLineRx Ltd.} \\ \textbf{CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS} \\ \textbf{(UNAUDITED)} \end{tabular}$

Convenience translation into USD (Note 1b)

Nine months ended September

Nine months ended Sentember 30.

	30,		September 30,	
	2013	2014	2014	
	NIS in thousands		In thousands	
CASH FLOWS - OPERATING ACTIVITIES				
Comprehensive loss for the period	(46,074)	(24,028)	(6,503)	
Adjustments required to reflect net cash used in operating activities (see appendix below)	(9,837)	(14,307)	(3,872)	
Net cash used in operating activities	(55,911)	(38,335)	(10,375)	
CASH FLOWS - INVESTING ACTIVITIES				
Investments in short-term deposits	(104,127)	(139,800)	(37,835)	
Maturities of short-term deposits	85,377	85,825	23,227	
Maturities of restricted deposits	1,550	-	-	
Additions to property and equipment	(196)	(545)	(148)	
Additions to intangible assets	(96)	(10)	(3)	
Net cash used in investing activities	(17,492)	(54,530)	(14,759)	
CASH FLOWS - FINANCING ACTIVITIES				
Repayments of bank loan	(127)	-	-	
Issuance of share capital and warrants, net	50,140	78,585	21,268	
Proceeds from exercise of employee stock options	*	*	*	
Net cash provided by financing activities	50,013	78,585	21,268	
DECREASE IN CASH AND CASH EQUIVALENTS	(23,390)	(14,280)	(3,866)	
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	68,339	30,888	8,360	
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(1,988)	771	209	
CASH AND CASH EQUIVALENTS - END OF PERIOD	42,961	17,379	4,703	

<sup>\*</sup> Less than 1,000

# ${\bf BioLineRx\ Ltd.}$ APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

Convenience translation into USD (Note 1b) Nine months

ended

Nine months ended September

2013

30, September 30, 2014

	NIS in the	NIS in thousands	
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	870	737	200
Impairment of intangible assets	138	-	-
Long-term prepaid expenses	60	36	10
Exchange differences on cash and cash equivalents	1,988	(771)	(209)
Share-based compensation	2,400	2,727	737
Warrant issuance costs	470	-	-
Gain on adjustment of warrants to fair value	(10,191)	(12,891)	(3,489)
Commitment fee paid by issuance of share capital	-	1,041	282
Interest and exchange differences on short-term deposits	1,521	(5,616)	(1,520)
Interest and linkage on bank loan	(10)	-	-
Interest and exchange differences on restricted deposits	30	(38)	(10)
	(2,724)	(14,775)	(3,999)
Changes in operating asset and liability items:			
Decrease in trade accounts receivable and other receivables	1,374	1,274	345
Decrease in accounts payable and accruals	(8,487)	(806)	(218)
	(7,113)	468	127
	(9,837)	(14,307)	(3,872)
Supplementary information on interest received in cash	449	177	48

# BioLineRx Ltd. NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

#### **NOTE 1 – GENERAL INFORMATION**

#### a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Jerusalem, Israel, 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 pre-clinical-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 Ltd."). BIJ LP was established to operate a biotechnology incubator located in Jerusalem (the "Incubator") under an agreement with the State of Israel. The agreement with the State of Israel relating to the Incubator terminated on December 31, 2013, and the Company is currently in the process of winding down BIJ LP's operations. The Company expects to liquidate both BIJ LP and BIJ Ltd. during 2014.

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

The Company has been engaged in drug development since its incorporation. Although the Company has generated significant revenues from two out-licensing transactions, the Company cannot determine with reasonable certainty when and if the Company 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 September 30, 2014 have been translated into dollars, at the representative rate of exchange on September 30, 2014 (\$1 = NIS 3.695). 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 as of September 30, 2014, and for the three and nine months then ended, were approved by the Board of Directors on November 10, 2014, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.

# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

### NOTE 2 - BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of September 30, 2014 and for the three and nine 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, 2013 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 and nine months ended September 30, 2014 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, 2013 and for the year then ended.

# NOTE 4 – ISSUANCES OF SHARE CAPITAL AND WARRANTS

## a. Underwritten public offering of American Depositary Shares

In March 2014, the Company completed an underwritten public offering of 9,660,000 ADSs (including 1,260,000 ADSs resulting from exercise of the underwriters' overallotment option) at a public offering price of \$2.50 per ADS. The offering raised a total of \$24,150,000, with net proceeds of approximately \$22,300,000, after deducting fees and expenses.

## 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, 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 nine months ended September 30, 2014, BioLineRx sold a total of 151,164 ADSs to LPC for aggregate gross proceeds of \$400,000. In connection with these issuances, a total of 3,779 ADSs was issued to LPC as a commitment fee and a total of \$8,000 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 3,793,209 ADSs to LPC for aggregate gross proceeds of \$9,731,000. In connection with these issuances, a total of 94,832 ADSs was issued to LPC as a commitment fee and a total of \$195,000 was paid to Oberon Securities as a finder's fee.

# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

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

# b. Share purchase agreement with Lincoln Park Capital (cont.)

In May 2014, BioLineRx and LPC entered into a new \$20 million, 36-month purchase agreement, and terminated the previous \$15 million agreement. The terms of the new purchase agreement are substantially identical to the terms of the previous purchase agreement. Through the approval date of these financial statements, no sales of ADSs to LPC have been made under the new purchase agreement.

In consideration for entering into the new \$20 million purchase agreement, BioLineRx paid to LPC an initial commitment fee of \$300,000, paid via the issuance of 150,000 ADSs, and will pay a further commitment fee of up to \$500,000, pro rata, as the facility is used over time, which will be paid in ADSs valued based on the prevailing market prices of BioLineRx's ADSs at such time. The new purchase agreement may be terminated by BioLineRx at any time, at its sole discretion, without any cost or penalty.

In connection with the new purchase Agreement, BioLineRx agreed to pay an initial cash finder's fee to Oberon Securities of \$50,000, and will pay an additional cash finder's fee equal to 2.0% of the dollar amount of ADSs sold under the new agreement, up to an aggregate additional finder's fee of \$200,000. BioLineRx has no other obligations to Oberon Securities with respect to this or any other potential future agreement.

The initial commitment fee payable to LPC and the initial finder's fee payable to Oberon Securities, in the total aggregate amount of \$350,000, were recorded as a non-operating expense in the statement of comprehensive loss for the nine months ended September 30, 2014. Future commitment and finders fees payable, if and when the facility is used over time, will be recorded as issuance expenses against share premium on the statement of financial position.

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

In February 2013, the Company completed a direct placement to a 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.

# BioLineRx Ltd. NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

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

# c. Private placement of share capital and warrants to Orbimed (cont.)

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 reflected 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 during each reporting period, amounting to approximately \$2,040,000 and \$1,300,000 for the nine months ended September 30, 2013 and 2014, and approximately \$440,000 and \$400,000 for the three months ended September 30, 2013 and 2014, respectively, has been included in non-operating income on the statement of comprehensive loss.

# NOTE 5 - SHAREHOLDERS' EQUITY

As of September 30, 2014 and December 31, 2013, share capital is composed of ordinary shares, as follows:

	Number of ord	linary shares
	December 31, 2013	September 30, 2014
Authorized share capital	750,000,000	750,000,000
Issued and paid-up share capital	241,487,049	341,150,507
	In	NIS
	December 31,	September 30,
	2013	2014
Authorized share capital	7,500,000	7,500,000
Issued and paid-up share capital	2,414,870	3,411,505
11		

# NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 6 – NON-OPERATING INCOME, NET

		Three months ended September 30,		ıs ended er 30,	
	2013	2014	2013	2014	
	NIS in the	NIS in thousands		NIS in thousands	
Issuance costs	(320)	-	(977)	(1,212)	
Changes in fair value of warrants	(4,307)	4,835	10,191	12,892	
	(4,627)	4,835	9,214	11,680	

# NOTE 7 – EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

In November 2014, the Company's Board of Directors approved an increase from 3.3 million to 19.3 million in the number of authorized but unissued ordinary shares reserved for purposes of the Company's 2003 Share Incentive Plan (the "Plan") and any other present or future share incentive plans of the Company, subject to adjustments as provided in Section 14 of the Plan.

### **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 17, 2014 (the "Annual Report").

U.S. dollar amounts presented 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 September 30, 2014 (\$1 = NIS 3.695). 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:
- $\cdot \quad \text{the implementation of our business model, strategic plans for our business and the rapeutic candidates;}\\$
- 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
- 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 six clinical therapeutic candidates: BL-1040, BL-8040, BL-7010, BL-5010, BL-7040 and BL-8020. In addition, we have four 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. 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 six clinical therapeutic candidates:

- 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 agreement with Bellerophon BCM LLC, or Bellerophon, with respect to the development, manufacture and commercialization of BL-1040. In December 2011, Bellerophon commenced PRESERVATION I, a CE Mark registration clinical trial of BL-1040 (initially called IK-5001, and now called the "Bioabsorbable Cardiac Matrix" device, or BCM device). There are over 80 sites activated for this trial, 16 of which are in the United States. Over 280 patients have been enrolled in the trial, out of a total planned enrollment of approximately 300 patients.
- BL-8040 is a novel, short synthetic peptide that functions as a high-affinity, best-in-class antagonist for CXCR4, which we intend to develop for acute myeloid leukemia, or AML, stem cell mobilization and other hematological indications. In June 2013, we commenced a phase 2 trial for the treatment of AML, which is currently being conducted at three world-leading cancer research centers in the United States and at five premier sites in Israel. The trial is currently in the midst of the dose-escalation stage and when this stage is completed, will continue to the expansion stage at the optimal dose chosen during the dose escalation stage. In December 2013, we published early results from the dose-escalation stage showing that BL-8040 triggers substantial mobilization of cancer cells from the bone marrow to the peripheral blood, thereby increasing the vulnerability of the cells to chemotherapy treatment, as well as robust apoptosis of cancer cells in the higher doses tested to date. In September 2013, the U.S. Food & Drug Administration, or FDA, granted an Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to BL-8040 as a treatment for stem cell mobilization. In April 2014, we announced receipt of final regulatory approval for an investigator-initiated Phase 1/2 trial for BL-8040 as a treatment for chronic myeloid leukemia, or CML. Since the initiation of the study, there have been difficulties in enrolling patients, and therefore a decision was recently reached not to pursue this study. In September 2014, we announced the dosing of the first patient in a Phase 1 trial for the use of BL-8040 as a treatment for stem cell mobilization. In the same month, we announced positive preclinical results of BL-8040 as a novel treatment for a sub-population of AML patients with FLT3 mutations. This data was presented during the third quarter at the Society of Hematologic Oncology Annual Meeting, as well as at the Gordon Research Conference. In November 2014, we announced that in light of continued encouraging pharmacodynamic and excellent safety data from the ongoing Phase 2 clinical trial in AML, we filed with the FDA an amendment to the study protocol to test additional cohorts at higher doses in the current dose-escalation stage of the trial. The amendment also includes an increase in the total expected study enrollment, from up to 50 under the original protocol, to up to 70 patients.

- · BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease. In December 2013, we commenced a Phase 1/2 trial for BL-7010 at Tampere Hospital in Finland. In March 2014, we announced that BL-7010 successfully completed the single administration, dose-escalation stage of this study, and was safe and well tolerated at all doses tested. In July 2014, we announced that BL-7010 also successfully completed the repeated administration stage of the study, and we published unblinded results from both stages of the study. We also announced that we intend to further investigate lower repeated doses of BL-7010 in order to select the optimal dose for the upcoming efficacy study. In November 2014, we published positive final results of the full study. See "Recent Developments" below for further details regarding the final results of the study. In addition, we also announced that we are continuing to plan an efficacy study for BL-7010, which is expected to commence in the second half of 2015.
- BL-5010P is comprised of a customized, proprietary pen-like applicator containing a novel formulation of two acids (BL-5010), 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 (BSI) Notified Body of the regulatory pathway classification of both BL-5010 and BL-5010P as a Class 2a medical device. We are in advanced stages of discussions with potential partners for this asset regarding a number of potential indications. As a result of these discussions, we have delayed the commencement of a pivotal CE-Mark registration trial for seborrheic keratosis, or SK, that was scheduled to begin in the first half of 2014 and for which we received the necessary regulatory approval to commence the trial in January 2014. We are also continuing to assess the cost and feasibility of automated manufacturing processes to support full-scale production, since this has been an important aspect in our partnering discussions. Possible additional indications for this product include actinic keratosis and warts.
- 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 active ulcerative colitis (a type of IBD) at five medical centers in Israel. In November 2013, we announced additional results from this study showing significant improvement of disease measurements in biopsies taken from IBD patients treated with BL-7040. During the third quarter of 2014, we conducted a pharmacokinetic study which indicated that BL-7040 reaches the target organ (the colon) and appears to have a local, as opposed to systemic, effect. We are currently discussing this therapeutic candidate with a number of potential co-development partners, as well as planning the next stages of development.
- BL-8020 is an orally available treatment for the hepatitis C virus, or HCV, and other viral indications, with a unique mechanism of action involving the inhibition of virus-induced autophagy in host cells. In April 2013, we commenced a phase 1/2 clinical trial to evaluate the safety, tolerability and effectiveness of BL-8020 at two sites in France. In January 2014, we entered into a collaboration agreement with the licensors of the compound whereby, in consideration for the payment of future royalties to us, we terminated the license agreement, the licensors agreed to take over development of the compound and we agreed to supply, at the licensors' request and for full payment, the drug product needed for a clinical trial to be administered by the licensors. In August 2014, the licensors decided to terminate the ongoing phase 1/2 trial in HCV due to a very slow recruitment rate, and are now determining the next steps in the clinical development plan of the compound, including an assessment regarding potential additional viral indications for development.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing agreement with Bellerophon (formerly known as "Ikaria Development Subsidiary One LLC"). Under the agreement, we granted Bellerophon 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. Under the arrangement, Bellerophon 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, Bellerophon paid us a milestone payment of \$10.0 million in March 2010, and we are entitled to receive additional milestone payments upon the occurrence of certain events, as well as royalty payments on product sales, if any.

In June 2013, we signed an out-licensing agreement with CTTQ, the leading Chinese pharmaceutical company in the liver disease therapeutic area, for the development and commercialization of BL-8030, an orally available treatment for HCV. Under the terms of the agreement, we granted CTTQ exclusive rights to develop, manufacture and commercialize BL-8030 in China and Hong Kong. CTTQ paid us a small upfront license fee, and is obligated to pay future development, regulatory and commercialization milestones, for a total potential deal value of approximately \$30 million. In addition, we have the right to receive high single-digit royalties on future sales of the drug. We have retained the right to develop and commercialize BL-8030 in other parts of the world.

In January 2014, we signed a collaboration agreement with JHL Biotech, or JHL, a biopharmaceutical company that develops, manufactures, and commercializes biologic medicines. Pursuant to the agreement, we will collaborate with JHL in the development and commercialization of BL-9020, a novel monoclonal antibody in the preclinical development stage for the treatment of Type 1 diabetes. JHL will be responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and we will be responsible for all pre-clinical development of BL-9020. JHL will have global manufacturing rights to BL-9020, along with development and commercialization rights in China and Southeast Asia, and we will have development and commercialization rights in the rest of the world. In all development and manufacturing of BL-9020, JHL will adhere to FDA guidelines and regulations. Each party will have rights to all development and regulatory data generated under the agreement in order to commercialize BL-9020 in its respective territory. Each party will also be entitled to single-digit royalties on the sale of BL-9020 in the other party's respective territory.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the Office of the Chief Scientist of the Israeli Ministry of the Economy (OCS), payments received under out-licensing arrangements, 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 our existing out-licensing agreements, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. In March 2014, we completed an underwritten public offering for net proceeds of approximately \$22.3 million. As of September 30, 2014, we held approximately \$29.6 million of cash, cash equivalents and short-term bank deposits, based on the exchange rate reported by the Bank of Israel as of September 30, 2014.

### **Recent Company Developments**

Pre-Clinical and Clinical Development

### BL-8040

In September 2014, we announced the dosing of the first patient in a Phase 1 trial for BL-8040 as a novel treatment for the mobilization of stem cells from the bone marrow to the peripheral blood circulation. The study consists of two parts. Part 1 is a randomized, double-blind, placebo-controlled dose escalation study exploring the safety and tolerability of escalating repeated doses of BL-8040 in up to 32 healthy volunteers. Secondary objectives include assessment of the efficacy of BL-8040 in mobilizing stem cells as a stand-alone therapy, as well as determining the pharmacokinetic profile of the drug. Part 1 of the study will serve to select the optimal safe and efficacious dose of BL-8040 to be used as a stand-alone therapy in Part 2 of the study. Part 2 is an open-label study designed to assess BL-8040's stem cell mobilization capacity, as well as the yield of cells collected by apheresis. Secondary endpoints of the study include evaluation of the viability and biological activity of cells mobilized by BL-8040 and collected by apheresis. This part will be performed in a single cohort of eight healthy volunteers who will receive the selected dose regimen of BL-8040 based on the data from Part 1.

In November 2014, we announced that in light of encouraging pharmacodynamic and excellent safety data from the ongoing Phase 2 clinical trial of BL-8040 for AML, we filed with the FDA an amendment to the study protocol to test additional cohorts at higher doses in the current dose-escalation stage of the trial. The amendment also includes an increase in the total expected study enrollment, from up to 50 under the original protocol, to up to 70 patients. We also announced that BL-8040 was found to be safe at all doses tested to date, with no serious adverse events related to BL-8040, and that results from the trial to date continue to show substantial mobilization of leukemic cells from the bone marrow and robust induction of cancer cell apoptosis. The decision to add higher dosing cohorts, in order to determine the optimal dose to use in the upcoming expansion stage of the trial, was based on a unanimous recommendation from BL-8040's Clinical Advisory Board (CAB). We now expect to complete the dose escalation stage of the study by early next year, and the full study, following the expansion stage, in the second half of 2015.

# BL-7010

In July 2014, we announced unblinded results from our Phase 1/2 study for BL-7010, for the treatment of celiac disease. The Phase 1/2 study, taking place at Tampere Hospital in Finland, a world-leading site for celiac disease research, is a two-part (single and repeated administration), double-blind, placebo-controlled, dose escalation study of BL-7010 in up to 32 well-controlled celiac patients. The primary objective of the study is to assess the safety of single and repeated ascending doses of BL-7010. Secondary objectives include an assessment of the systemic exposure, if any, of BL-7010. The study was conducted based on a device pre-clinical submission package under an approval from the Finnish National Supervisory Authority for Welfare and Health (Valvira).

During the single-administration part of the study, six dose levels of BL-7010 were evaluated compared to placebo in a 6+2 standard design, with six patients on BL-7010 and two patients on placebo. This escalation stage reached the highest planned dose with no serious or dose-limiting adverse events. All planned doses were safe and well-tolerated with all patients completing this part of the study. During the second, repeated-administration part of the study, each patient received either 3 grams of BL-7010 or placebo for 14 days, three times per day, in the same 6+2 standard design. BL-7010 was well-tolerated over 14 days of treatment, with only one patient not completing the 14-day treatment period. Gastrointestinal-related adverse events (primarily diarrhea) were reported in six out of eight patients, though none were considered serious or dose-limiting and were also observed in one of the two patients on placebo. In light of these findings, and based on pre-clinical studies where the efficacious dose is predicted to be lower than the dose tested in the repeated administration stage of the study, we filed an amendment to further investigate lower repeated doses of BL-7010 in this study in order to select the optimal dose for the upcoming efficacy study, which is expected to commence in the second half of 2015.

In November 2014, we reported the final results of the study, including the results of the additional cohort tested. The final results of the study fully confirmed the positive unblinded results previously reported in July, and showed a substantially reduced level of gastrointestinal-related adverse events. Based on these results, we selected the dosing regimen of one gram, three times per day, of BL-7010 as the optimal repeated dose for the upcoming efficacy study. Importantly, pharmacokinetic analyses revealed no systemic exposure of BL-7010 in plasma and urine samples from all patients at all doses and time points tested, both in the single- and repeated-dose regimens. Based on previous communications with a Notified Body in the European Union, we believe the lack of systemic exposure will likely support a medical-device classification in Europe for BL-7010.

**Out-Licensing Arrangements** 

# BL-1040

We continue to be engaged in discussions with Bellerophon relating to its performance under our license agreement with it. We believe that Bellerophon has breached the license agreement in several ways, and we also disagree with Bellerophon about the timing of a \$12.5 million milestone payment that Bellerophon would owe to us in the future based upon progress in the BL-1040 clinical development program. During the last few months, we have had several additional discussions with Bellerophon on these issues and these discussions are continuing. Although we hope we can resolve the outstanding issues with Bellerophon amicably, if we are unable to reach agreement with Bellerophon on these issues, we would consider all other remedies available to us.

#### Patent Protection

In August 2014, we announced that we received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent claiming the use of BL-7010. This patent, when issued, will be valid until at least 2026. Additional patents claiming the BL-7010 composition and use thereof are granted or pending in the United States, Europe, Japan, Canada, Israel, India, China, Brazil, Russia, Australia, South Africa and Hong Kong.

Bellerophon recently informed us that a Notice of Opposition to our European patents covering BL-1040 has been filed with the European Patent Office. We believe we were properly granted the patents and that the patents remain valid. Bellerophon has indicated to us that it intends to defend the patents vigorously and that it will file a response to the opposition in the near future. At this time, given the early stage of this matter, we cannot make any assessment regarding the claims made in the Notice of Opposition, or the ability to prevail in defending the patents.

## 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. During the quarter, we neither added nor terminated any therapeutic candidates to or from our pipeline.

### Stock Option Plan

In November 2014, our Board of Directors approved an increase from 3.3 million to 19.3 million in the number of authorized but unissued ordinary shares reserved for purposes of our 2003 Share Incentive Plan and any other present or future share incentive plans, subject to adjustments as provided in Section 14 of the plan.

### Revenues

Our revenues to date have been generated primarily from milestone payments under our license agreement with Bellerophon and the amounts we received from Cypress Bioscience. We entered into a license agreement with Bellerophon in 2009, in respect of which Bellerophon paid us an up-front payment of \$7.0 million. In addition, upon successful completion of the phase 1/2 clinical trial, Bellerophon 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 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 Bellerophon, in addition to the payments mentioned above, the maximum amount of 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 Bellerophon 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 Bellerophon 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 in-licensors 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 out-licensing and other collaboration arrangements, including future royalties on product sales. Furthermore, we may receive payments under future out-licensing and collaboration agreements.

# **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 expense 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:

Project	Status	Expected or Recent Near Term Milestones
BL-1040	CE mark registration pivotal trial (conducted by Bellerophon)	Completion of patient enrollment for PRESERVATION I study expected by end of 2014; study completion expected around mid-2015
BL-8040	<ol> <li>Phase 2 study for AML</li> <li>Phase 1 study in stem cell mobilization</li> </ol>	<ol> <li>Completion of dose-escalation stage of study in early 2015; final results of study in H2 2015</li> <li>Final results of phase 1 study for stem cell mobilization in late 2014 or early 2015</li> </ol>
BL-7010	Completed phase 1/2 study	Randomized, controlled efficacy study expected to commence in H2 2015
BL-5010	Completed phase 1/2 pilot study; received regulatory approval for pivotal CE Mark registration trial; completed development of customized, proprietary pen-like applicator prototype	Potential partnering transaction and decision regarding commencement of pivotal CE mark registration trial in seborrheic keratosis, or in another indication as agreed with potential partner
BL-7040	Phase 2a trial completed	Potential co-development collaboration or licensing transaction; additional pre- clinical development to support further clinical studies
BL-8020	Phase 1/2 clinical development (in collaboration with licensors)	Decision by licensors on direction of clinical development plan, as well as determination of potential additional indications

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-8030	Small molecule	Heneritie	Preclinical studies; in collaboration with CTTQ for China and Hong Kong
BL-9010	Bi-specific antibody	Severe allergies/asthma	Preclinical studies
BL-9020	Monoclonal antibody	Type 1 diabetes	Preclinical studies and optimization of antibody; in collaboration with JHL Biotech for China and Southeast Asia
BL-1110	Small molecule	Neuropathic pain	Preclinical studies

Set forth below is a summary of the costs allocated to our main projects on an individual basis, as well as the costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2011, 2012 and 2013; for the nine months ended September 30, 2014; and on an aggregate basis since project inception. Certain of such costs were covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

			Nine Months Ended September 30,	Total Costs Since Project
2011	2012	2013	2014	Inception
	(in the	ou <mark>sands of U.S. d</mark> olla	ars)	
3	-	-	-	10,227
_	723	3,910	2,978	7,611
274	560	1,905	2,925	5,664
94	132	251	886	3,273
465	500	650	281	1,896
_	794	918	164	1,876
6,219	10,017	3,529	846	87,171
7,055	12,726	11,163	8,080	117,718
	2011 3 - 274 94 465 - 6,219	2011     2012       (in the       3     -       -     723       274     560       94     132       465     500       -     794       6,219     10,017	(in thousands of U.S. dollars)  3	Year Ended December 31,       Ended September 30,         2011       2012       2013       2014         (in thous/U.S. doll/U.S. dol

(1) Does not include indirect project costs and overhead for years prior to 2013, 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 for such years.

From our inception through September 30, 2014, we have incurred research and development expense of approximately NIS 587.8 million (\$159.1 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 share purchase agreements with Lincoln Park Capital, or LPC, and an at-the-market equity offering sales agreement with Stifel, Nicolaus & Company, Incorporated. The at-the-market equity offering sales agreement was terminated in March 2014.

### **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, 2013.

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 and 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 and judgments, 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 form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

#### Revenues

We did not record any revenues during each of the three-month or nine-month periods ended September 30, 2014 and 2013.

#### Cost of revenues

We did not record any cost of revenues during each of the three-month or nine-month periods ended September 30, 2014 and 2013.

# 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 2013, we added two new compounds to our pipeline and discontinued the development of six compounds from the pipeline, so that our drug development pipeline as of December 31, 2013 consisted of ten therapeutic candidates. Subsequent to December 31, 2013, we added a new compound to our pipeline and discontinued the development of one compound from the pipeline, so that our drug development pipeline as of the date of this report consists of ten 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 months ended September 30,			Nine mo	nths ended Septem	ber 30,
			Increase			Increase
	2013	2014	(decrease)	2013	2014	(decrease)
			(in thousands	s of NIS)		
Research and development expenses, net	8,190	10,440	2,250	39,720	29,627	(10,093)
One-time reversal of liability to the OCS in						
respect of BL-1020	<u> </u>			5,993		(5,993)
"Normalized" research and development						
expenses, net	8,190	10,440	2,250	45,713	29,627	(16,086)

# Comparison of three-month periods ending September 30, 2014 and 2013

Research and development expenses for the three months ended September 30, 2014 were NIS 10.4 million (\$2.8 million), an increase of NIS 2.2 million (\$0.6 million), or 27%, compared to NIS 8.2 million (\$2.2 million) for the three months ended September 30, 2013. The increase resulted primarily from an increase in spending on BL-8040 in the 2014 period, as well as the reversal of an accrual for project termination costs related to BL-1020 that was recorded in the 2013 period.

# Comparison of nine-month periods ending September 30, 2014 and 2013

Research and development expenses for the nine months ended September 30, 2014 were NIS 29.6 million (\$8.0 million), a decrease of NIS 16.1 million (\$4.4 million), or 35%, compared to NIS 45.7 million (\$12.4 million) for the nine months ended September 30, 2013. The decrease resulted primarily from termination of the BL-1020 CLARITY clinical trial in March 2013 and certain one-time costs associated with several clinical-stage projects in 2013, partially offset by increased spending on BL-7010 in the 2014 period.

# Sales and marketing expenses

	Three mo	Three months ended September 30,			nths ended Septem	ber 30,
			Increase			Increase
	2013	2014	(decrease)	2013	2014	(decrease)
			(in thousands	s of NIS)		
Sales and marketing expenses	731	1,070	339	2,565	3,340	775

# Comparison of three-month periods ending September 30, 2014 and 2013

Sales and marketing expenses for the three months ended September 30, 2014 were NIS 1.1 million (\$0.3 million), an increase of NIS 0.4 million (\$0.1 million), or 46%, compared to NIS 0.7 million (\$0.2 million) for the three months ended September 30, 2013. The increase resulted primarily from professional fees related to increased business development activities.

# Comparison of nine-month periods ending September 30, 2014 and 2013

Sales and marketing expenses for the nine months ended September 30, 2014 were NIS 3.3 million (\$0.9 million), an increase of NIS 0.7 million (\$0.2 million), or 30%, compared to NIS 2.6 million (\$0.7 million) for the nine months ended September 30, 2013. The reason for the increase is similar to the one discussed above in the three-month comparison.

### General and administrative expenses

	Three months ended September 30,			Nine mor	nths ended Septem	ber 30,
			Increase			Increase
	2013	2014	(decrease)	2013	2014	(decrease)
			(in thousand	s of NIS)		
General and administrative expenses	2,663	2,779	116	9,789	9,130	(659)

# Comparison of three-month periods ending September 30, 2014 and 2013

General and administrative expenses for the three months ended September 30, 2014 were NIS 2.8 million (\$0.8 million), substantially similar to the comparable period in 2013.

# Comparison of nine-month periods ending September 30, 2014 and 2013

General and administrative expenses for the nine months ended September 30, 2014 were NIS 9.1 million (\$2.5 million), a decrease of NIS 0.7 million (\$0.2 million), or 7%, compared to NIS 9.8 million (\$2.7 million) for the nine months ended September 30, 2013. The decrease resulted primarily from a one-time expense for professional services incurred in the 2013 period.

## Non-operating income (expenses), net

	Three months ended September 30,			Nine mon	ths ended Septeml	ber 30,
	2013	2014	2013	2014	Increase (decrease)	
		_	(in thousands	of NIS)	_	
Non-operating income (expenses), net	(4,627)	4,835	9,462	9,214	11,680	2,466

# Comparison of three-month periods ending September 30, 2014 and 2013

We recognized net non-operating income of NIS 4.8 million (\$1.3 million) for the three months ended September 30, 2014, a change of NIS 9.4 million (\$2.6 million), compared to net non-operating expenses of NIS 4.6 million (\$1.3 million) for the three months ended September 30, 2013. Non-operating income for both periods primarily relates to fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements 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).

# Comparison of nine-month periods ending September 30, 2014 and 2013

We recognized net non-operating income of NIS 11.7 million (\$3.2 million) for the nine months ended September 30, 2014, an increase of NIS 2.5 million (\$0.7 million), compared to net non-operating income of NIS 9.2 million (\$2.5 million) for the nine months ended September 30, 2013. The reason for the increase is similar to the one discussed above in the three-month comparison.

#### Financial income (expenses), net

	Three months ended September 30,			Nine mor	nths ended Septeml	ber 30,
	Increase					Increase
	2013	2014	(decrease)	2013	2014	(decrease)
	(in thousands of NIS)					
Financial income	501	8,069	7,568	2,484	7,735	5,251
Financial expenses	(1,956)	(1,122)	834	(5,698)	(1,346)	4,352
Net financial income (expenses)	(1,455)	6,947	8,402	(3,214)	6,389	9,603

# Comparison of three-month periods ending September 30, 2014 and 2013

We recognized net financial income of NIS 7.0 million (\$1.9 million) for the three months ended September 30, 2014, a change of NIS 8.4 million (\$2.3 million), compared to net financial expenses of NIS 1.4 million (\$0.4 million) for the three months ended September 30, 2013. Net financial income and expenses result primarily from changes in the average exchange rate of the dollar in relation to the NIS during the respective periods, which have a direct effect on our net assets denominated in dollars.

# Comparison of nine-month periods ending September 30, 2014 and 2013

We recognized net financial income of NIS 6.4 million (\$1.7 million) for the nine months ended September 30, 2014, a change of NIS 9.6 million (\$2.6 million), compared to net financial expenses of NIS 3.2 million (\$0.9 million) for the nine months ended September 30, 2013. The reason for the change is similar to the one discussed above in the three-month comparison.

# **Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, funding from the OCS, and payments received under our strategic licensing arrangements. In March 2014, we closed an underwritten public offering of our ADSs for gross proceeds of \$24.1 million and net proceeds of \$22.3 million, after deducting fees and expenses. At September 30, 2014, we held NIS 109.3 million (\$29.6 million) in cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

Pursuant to the share purchase agreement signed with LPC in May 2014, we may sell, from time to time, and at our discretion, up to \$20 million of our ADSs to LPC during the 36-month term of the purchase agreement. As of the date of this report, we have not yet sold any ADSs to LPC under the purchase agreement.

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

Net cash used in investing activities for the nine months ended September 30, 2014 was NIS 54.5 million (\$14.8 million), compared to net cash used in investing activities of NIS 17.5 million (\$4.7 million) for the nine months ended September 30, 2013. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

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

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 through 2016, 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.