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**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 2015*

**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       Form 40-F

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

Yes       No

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On November 16, 2015, the Registrant will issue a press release announcing its financial results for the three and nine months ended September 30, 2015. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2015, and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 16, 2015;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2015, and for the three and nine months and then ended;

Exhibit 3 - Registrant's operating and financial review as of September 30, 2015, and for the three and nine months then ended.

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

**BioLineRx Ltd.**

By: /s/ Philip Serlin  
Philip Serlin  
Chief Financial and Operating Officer

Dated: November 16, 2015

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For immediate release

### BioLineRx Reports Third Quarter 2015 Financial Results

**Tel Aviv, Israel - November 16, 2015** - BioLineRx Ltd. (NASDAQ/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, 2015.

Kinneret Savitsky, Ph.D., CEO of BioLineRx, remarked, "Our focus during the third quarter of 2015 was on continued clinical execution, primarily for BL-8040, our lead platform for the treatment of acute myeloid leukemia (AML) and other oncology and hematology indications. While we continued to advance the development of BL-8040 for the treatment of relapsed or refractory AML, as well as stem cell mobilization for transplantation purposes, in August we initiated a clinical study for BL-8040 as a novel consolidation treatment for AML, and we expect to initiate clinical studies in two additional indications in the upcoming months. We are also currently performing an extensive evaluation of BL-8040's potential in the exciting immuno-oncology space, expanding upon our unique oncology platform. CXCR4 antagonists have been identified as potentially synergistic with immune checkpoint inhibitors. In this regard, we believe BL-8040's best-in-class qualities make it a great candidate to explore such combinations."

"Earlier this month we reported positive results from the dose-escalation part of BL-8040's Phase 2 clinical trial in relapsed or refractory AML, including clinical response (remission) data. The encouraging composite response rate of 38%, which will be presented for the first time at the upcoming American Society of Hematology (ASH) Annual Meeting, together with continued robust mobilization and apoptotic effects, strongly suggest that BL-8040 has potent anti-leukemic activity and, in combination with Ara-C, may improve the response typically achieved in this advanced AML population. We are looking forward to reporting top-line results from this study in early 2016. With regard to BL-8040 as a novel stem cell mobilization treatment, last month we held a meeting with the FDA, which has provided us with substantial clarification regarding the future development plan for this indication. We are gearing up to start a Phase 2 study in stem cell mobilization in the first quarter of 2016."

Dr. Savitsky continued, "After successfully completing a Phase 1/2 study for BL-7010 for the treatment of celiac disease, we are waiting for a response from the EU regulatory authorities regarding classification of BL-7010 as a medical device in Europe. Contingent upon this decision, we are planning to start the next efficacy study in celiac disease in the first half of 2016. In parallel, we are investing considerable efforts in examining alternative development and commercialization pathways for this promising product, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity, which also has a significantly shorter time to market, especially in the US."

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“Our partner Omega Pharma, now part of Perrigo, is swiftly progressing in the development of BL-5010 as an OTC solution for the non-surgical removal of benign skin lesions. In September, they submitted an application for CE Mark designation for this product. Assuming successful completion of the CE Mark registration process, we expect the first sales in Europe to begin in 2016.”

Dr. Savitsky concluded, “We continue to pursue various collaboration agreements to maximize the value of our current pipeline assets, including discussions with additional partners for the purpose of monetizing some of our non-core programs. In parallel to our internal pipeline development, we continue to screen potential assets to develop under our strategic partnership with Novartis, and we look forward to in-licensing promising therapeutic candidates for development under the collaboration in the near future. Finally, with over \$50 million on our balance sheet, we remain well capitalized to execute on our development program and to achieve significant milestones across our expanded therapeutic pipeline well into 2018, and we look forward to demonstrating our enhanced value proposition over the coming months.”

#### **Financial Results for Quarter and Nine Months Ended September 30, 2015**

Research and development expenses for the three months ended September 30, 2015 were \$2.6 million, a decrease of \$0.4 million, or 13.4%, compared to \$3.0 million for the three months ended September 30, 2014. The decrease resulted primarily from decreased spending on BL-1110, BL-7010 and BL-5010 in the 2015 period, partially offset by increased spending on BL-8040. Research and development expenses for the nine months ended September 30, 2015 were \$8.7 million, an increase of \$0.2 million, or 2.3%, compared to \$8.5 million for the nine months ended September 30, 2014. The small increase resulted primarily from increased spending on BL-8040 in the 2015 period, partially offset by decreased spending on BL-7010, BL-7040, BL-5010 and BL-8020.

Sales and marketing expenses for the three months ended September 30, 2015 were \$0.3 million, substantially similar to the comparable period in 2014. Sales and marketing expenses for the nine months ended September 30, 2015 were \$0.8 million, a decrease of \$0.1 million, or 13.9%, compared to \$0.9 million for the nine months ended September 30, 2014. The decrease resulted primarily from significant professional fees related to a number of material business development activities carried out during the nine-month period in 2014, which resulted in collaboration and outlicensing agreements.

General and administrative expenses for the three months ended September 30, 2015 were \$0.8 million, substantially similar to the comparable period in 2014. General and administrative expenses for the nine months ended September 30, 2015 were \$2.6 million, substantially similar to the comparable period in 2014.

The Company's operating loss for the three months ended September 30, 2015 amounted to \$3.6 million, compared with an operating loss of \$4.1 million for the corresponding 2014 period. The Company's operating loss for the nine months ended September 30, 2015 amounted to \$12.1 million, substantially similar to the corresponding 2014 period.

Net non-operating income amounted to \$2.0 million for the three months ended September 30, 2015, an increase of \$0.6 million, compared to net non-operating income of \$1.4 million for the three months ended September 30, 2014. Net non-operating income amounted to \$1.1 million for the nine months ended September 30, 2015, a decrease of \$2.3 million, compared to net non-operating income of \$3.4 million for the nine months ended September 30, 2014. Non-operating income (expenses) for both periods primarily relate 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).

Net financial income was immaterial for the three months ended September 30, 2015, compared to net financial income of \$2.0 million for the three months ended September 30, 2014. Net financial income amounted to \$0.3 million for the nine months ended September 30, 2015, compared to net financial income of \$1.8 million for the nine months ended September 30, 2014. Net financial income (expenses) for the 2015 period primarily relates to investment income earned on our bank deposits, as well as banking fees. The 2014 period also includes significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate.

The Company's net loss for the three months ended September 30, 2015 amounted to \$1.6 million, compared with a net loss of \$0.7 million for the corresponding 2014 period. The Company's net loss for the nine months ended September 30, 2015 amounted to \$10.7 million, compared with a net loss of \$6.9 million for the corresponding 2014 period.

The Company held \$50.7 million in cash, cash equivalents and short-term bank deposits as of September 30, 2015.

Net cash used in operating activities was \$11.0 million for the nine months ended September 30, 2015, substantially similar to the comparable period in 2014.

Net cash used in investing activities for the nine months ended September 30, 2015 was \$18.7 million, compared to net cash used in investing activities of \$15.6 million for the nine months ended September 30, 2014. 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, 2015 was \$29.3 million, compared to net cash provided by financing activities of \$22.6 million for the nine months ended September 30, 2014. The cash flows from financing activities primarily reflect the underwritten public offerings of our ADSs in March 2015 and 2014.

## Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its third quarter 2015 results today, November 16, 2015, at 10:00 a.m. EST. To access the conference call, please dial 1-888-668-9141 from the U.S. or +972-3-918-0609 internationally. The call will also be available via live webcast through BioLineRx's website. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-888-254-7270 from the U.S. or +972-3-925-5928 internationally. The replay will be available through November 19, 2015.

(Tables follow)

### About BioLineRx

BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory acute myeloid leukemia (AML), has recently initiated a Phase 2b study as an AML consolidation treatment, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study.

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

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

*Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 23, 2015. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.*

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

	<u>December 31,</u> <u>2014</u>	<u>September 30,</u> <u>2015</u>
<u>in USD thousands</u>		
<b>Assets</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	5,790	5,320
Short-term bank deposits	28,890	45,387
Prepaid expenses	221	186
Other receivables	257	992
Total current assets	<u>35,158</u>	<u>51,885</u>
<b>NON-CURRENT ASSETS</b>		
Restricted deposits	166	-
Long-term prepaid expenses	49	56
Property and equipment, net	721	2,962
Intangible assets, net	117	128
Total non-current assets	<u>1,053</u>	<u>3,146</u>
<b>Total assets</b>	<u>36,211</u>	<u>55,031</u>
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES</b>		
Current maturities of long-term bank loan	-	93
Accounts payable and accruals:		
Trade	1,654	2,349
Other	1,252	1,148
Total current liabilities	<u>2,906</u>	<u>3,590</u>
<b>NON-CURRENT LIABILITIES</b>		
Long-term bank loan, net of current maturities	-	366
Warrants	1,500	404
Total non-current liabilities	<u>1,500</u>	<u>770</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
Total liabilities	<u>4,406</u>	<u>4,360</u>
<b>EQUITY</b>		
Ordinary shares	1,055	1,450
Share premium	167,331	195,950
Other reserves	(1,416)	(1,416)
Capital reserve	9,800	10,400
Accumulated deficit	(144,965)	(155,713)
Total equity	<u>31,805</u>	<u>50,671</u>
<b>Total liabilities and equity</b>	<u>36,211</u>	<u>55,031</u>

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2015	2014	2015
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,975)	(2,576)	(8,486)	(8,678)
SALES AND MARKETING EXPENSES	(305)	(265)	(957)	(824)
GENERAL AND ADMINISTRATIVE EXPENSES	(791)	(762)	(2,615)	(2,594)
OPERATING LOSS	(4,071)	(3,603)	(12,058)	(12,096)
NON-OPERATING INCOME, NET	1,380	1,983	3,346	1,096
FINANCIAL INCOME	1,991	85	2,216	363
FINANCIAL EXPENSES	-	(91)	(386)	(111)
NET LOSS	(700)	(1,626)	(6,883)	(10,748)
OTHER COMPREHENSIVE LOSS:				
CURRENCY TRANSLATION DIFFERENCES	(2,027)	-	(1,739)	-
COMPREHENSIVE LOSS	(2,727)	(1,626)	(8,622)	(10,748)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.03)	(0.22)	(0.21)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	34,115,051	54,632,788	31,725,364	50,306,892

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

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2015</b>
	<b>in USD thousands</b>	
<b>CASH FLOWS - OPERATING ACTIVITIES</b>		
Comprehensive loss for the period	(6,883)	(10,748)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(4,094)	(232)
Net cash used in operating activities	<u>(10,977)</u>	<u>(10,980)</u>
<b>CASH FLOWS - INVESTING ACTIVITIES</b>		
Investments in short-term deposits	(40,045)	(51,262)
Maturities of short-term deposits	24,584	34,878
Maturities of restricted deposits	-	166
Purchase of property and equipment	(156)	(2,466)
Purchase of intangible assets	(3)	(22)
Net cash used in investing activities	<u>(15,620)</u>	<u>(18,706)</u>
<b>CASH FLOWS - FINANCING ACTIVITIES</b>		
Issuances of share capital, net	22,612	28,844
Proceeds of bank loan	-	467
Repayments of bank loan	-	(8)
Net cash provided by financing activities	<u>22,612</u>	<u>29,303</u>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,985)</b>	<b>(383)</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD</b>	<b>8,899</b>	<b>5,790</b>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<b>(211)</b>	<b>(87)</b>
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	<b><u>4,703</u></b>	<b><u>5,320</u></b>

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

	Nine months ended September 30,	
	2014	2015
	in USD thousands	
<b>Adjustments required to reflect net cash used in operating activities:</b>		
<b>Income and expenses not involving cash flows:</b>		
Depreciation and amortization	211	322
Long-term prepaid expenses	10	(7)
Interest on restricted deposits	(11)	-
Interest and exchange rate differences on short-term deposits	(1,609)	(113)
Share-based compensation	781	770
Exchange differences on cash and cash equivalents	(220)	87
Gain on adjustment of warrants to fair value	(3,693)	(1,096)
Commitment fee paid by issuance of share capital	303	-
	(4,228)	(37)
<b>Changes in operating asset and liability items:</b>		
Decrease (increase) in trade accounts receivable and other receivables	365	(700)
Increase (decrease) in accounts payable and accruals	(231)	505
	134	(195)
	(4,094)	(232)
<b>Supplementary information on investing activities not involving cash flows:</b>		
Property and equipment acquired on supplier trade credit	-	228
<b>Supplementary information on interest received in cash</b>	51	105

**BioLineRx Ltd.**  
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS  
(UNAUDITED)  
AS OF SEPTEMBER 30, 2015

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**BioLineRx Ltd.**  
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS  
(UNAUDITED)  
AS OF SEPTEMBER 30, 2015

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

	<u>December 31,</u> <u>2014</u>	<u>September 30,</u> <u>2015</u>
	<u>in USD thousands</u>	
<b>Assets</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	5,790	5,320
Short-term bank deposits	28,890	45,387
Prepaid expenses	221	186
Other receivables	257	992
Total current assets	<u>35,158</u>	<u>51,885</u>
<b>NON-CURRENT ASSETS</b>		
Restricted deposits	166	-
Long-term prepaid expenses	49	56
Property and equipment, net	721	2,962
Intangible assets, net	117	128
Total non-current assets	<u>1,053</u>	<u>3,146</u>
<b>Total assets</b>	<u>36,211</u>	<u>55,031</u>
<b>Liabilities and equity</b>		
<b>CURRENT LIABILITIES</b>		
Current maturities of long-term bank loan	-	93
Accounts payable and accruals:		
Trade	1,654	2,349
Other	1,252	1,148
Total current liabilities	<u>2,906</u>	<u>3,590</u>
<b>NON-CURRENT LIABILITIES</b>		
Long-term bank loan, net of current maturities	-	366
Warrants	1,500	404
Total non-current liabilities	<u>1,500</u>	<u>770</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
Total liabilities	<u>4,406</u>	<u>4,360</u>
<b>EQUITY</b>		
Ordinary shares	1,055	1,450
Share premium	167,331	195,950
Other reserves	(1,416)	(1,416)
Capital reserve	9,800	10,400
Accumulated deficit	(144,965)	(155,713)
Total equity	<u>31,805</u>	<u>50,671</u>
<b>Total liabilities and equity</b>	<u>36,211</u>	<u>55,031</u>

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2015	2014	2015
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,975)	(2,576)	(8,486)	(8,678)
SALES AND MARKETING EXPENSES	(305)	(265)	(957)	(824)
GENERAL AND ADMINISTRATIVE EXPENSES	(791)	(762)	(2,615)	(2,594)
OPERATING LOSS	(4,071)	(3,603)	(12,058)	(12,096)
NON-OPERATING INCOME, NET	1,380	1,983	3,346	1,096
FINANCIAL INCOME	1,991	85	2,216	363
FINANCIAL EXPENSES	-	(91)	(386)	(111)
NET LOSS	(700)	(1,626)	(6,883)	(10,748)
OTHER COMPREHENSIVE LOSS:				
CURRENCY TRANSLATION DIFFERENCES	(2,027)	-	(1,739)	-
COMPREHENSIVE LOSS	(2,727)	(1,626)	(8,622)	(10,748)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.03)	(0.22)	(0.21)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	34,115,051	54,632,788	31,725,364	50,306,892

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

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

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other reserves</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2014</b>	640	134,390	1,418	9,163	(133,889)	11,722
<b>CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2014:</b>						
Issuance of share capital , net	287	22,628	-	-	-	22,915
Employee stock options exercised	-	22	-	(22)	-	-
Employee stock options forfeited and expired	-	396	-	(396)	-	-
Share-based compensation	-	-	-	781	-	781
Other comprehensive loss	-	-	(1,739)	-	-	(1,739)
Loss for the period	-	-	-	-	(6,883)	(6,883)
<b>BALANCE AT SEPTEMBER 30, 2014</b>	<u>927</u>	<u>157,436</u>	<u>(321)</u>	<u>9,526</u>	<u>(140,772)</u>	<u>26,796</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other reserves</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2015</b>	1,055	167,331	(1,416)	9,800	(144,965)	31,805
<b>CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2015:</b>						
Issuance of share capital , net	395	28,449	-	-	-	28,844
Employee stock options forfeited and expired	-	170	-	(170)	-	-
Share-based compensation	-	-	-	770	-	770
Comprehensive loss for the period	-	-	-	-	(10,748)	(10,748)
<b>BALANCE AT SEPTEMBER 30, 2015</b>	<u>1,450</u>	<u>195,950</u>	<u>(1,416)</u>	<u>10,400</u>	<u>(155,713)</u>	<u>50,671</u>

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

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

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2015</b>
	<b>in USD thousands</b>	
<b>CASH FLOWS - OPERATING ACTIVITIES</b>		
Comprehensive loss for the period	(6,883)	(10,748)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(4,094)	(232)
Net cash used in operating activities	<u>(10,977)</u>	<u>(10,980)</u>
<b>CASH FLOWS - INVESTING ACTIVITIES</b>		
Investments in short-term deposits	(40,045)	(51,262)
Maturities of short-term deposits	24,584	34,878
Maturities of restricted deposits	-	166
Purchase of property and equipment	(156)	(2,466)
Purchase of intangible assets	(3)	(22)
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<b>CASH FLOWS - FINANCING ACTIVITIES</b>		
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Repayments of bank loan	-	(8)
Net cash provided by financing activities	<u>22,612</u>	<u>29,303</u>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,985)</b>	<b>(383)</b>
<b>CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD</b>	<b>8,899</b>	<b>5,790</b>
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	<b>(211)</b>	<b>(87)</b>
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	<b><u>4,703</u></b>	<b><u>5,320</u></b>

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

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

Nine months ended  
September 30,  
2014                      2015  
in USD thousands

<b>Adjustments required to reflect net cash used in operating activities:</b>		
<b>Income and expenses not involving cash flows:</b>		
Depreciation and amortization	211	322
Long-term prepaid expenses	10	(7)
Interest on restricted deposits	(11)	-
Interest and exchange rate differences on short-term deposits	(1,609)	(113)
Share-based compensation	781	770
Exchange differences on cash and cash equivalents	(220)	87
Gain on adjustment of warrants to fair value	(3,693)	(1,096)
Commitment fee paid by issuance of share capital	303	-
	<u>(4,228)</u>	<u>(37)</u>
<b>Changes in operating asset and liability items:</b>		
Decrease (increase) in trade accounts receivable and other receivables	365	(700)
Increase (decrease) in accounts payable and accruals	(231)	505
	<u>134</u>	<u>(195)</u>
	<u>(4,094)</u>	<u>(232)</u>
<b>Supplementary information on investing activities not involving cash flows:</b>		
Property and equipment acquired on supplier trade credit	-	228
<b>Supplementary information on interest received in cash</b>		
	<u>51</u>	<u>105</u>

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

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

**NOTE 1 – GENERAL INFORMATION**

**a. General**

BioLineRx Ltd. (“BioLineRx”), headquartered in Modi’in, Israel, was incorporated and commenced operations in April 2003.

Since incorporation, BioLineRx and its consolidated entities (collectively, the “Company”) have been engaged in the development of therapeutics, from pre-clinical-stage development to advanced clinical trials, for a wide range of medical needs.

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”) have also been 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 a number of out-licensing transactions, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

**b. Change in functional and reporting currency**

Effective January 1, 2015, the Company changed its functional currency to the U.S. dollar (“dollar”, “USD” or “\$”) from the New Israeli Shekel (“NIS”). This change was based on an assessment by Company management that the dollar is the primary currency of the economic environment in which the Company operates. Accordingly, the functional and reporting currency of the Company in these financial statements is the U.S. dollar.

In determining the appropriate functional currency to be used, the Company followed the guidance in International Accounting Standard (IAS) 21, which states that economic factors relating to sales, costs and expenses, financing activities and cash flows, as well as other potential factors, should be considered both individually and collectively. In this regard, a significant element in the Company’s decision to effect the functional currency change resulted from the strategic collaboration agreement that it entered into with Novartis in December 2014, which will be managed solely in dollars. In addition, the Company expects a significant increase in expenses denominated in dollars relating to advanced clinical trials. These changes, as well as the fact that the Company’s principal source of financing is the U.S. capital market, and all of the Company’s budgeting and planning is conducted solely in dollars, led to the decision to make the change in functional currency as of January 1, 2015, as indicated above.

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

**NOTE 1 – GENERAL INFORMATION (cont.)**

**b. Change in functional and reporting currency (cont.)**

In effecting the change in functional currency to the dollar, as of January 1, 2015, all assets and liabilities of the Company were translated using the current rate method, using the dollar exchange rate as of December 31, 2014, and equity was translated using historical exchange rates at the relevant transaction dates. The resulting amounts translated into dollars for non-monetary items have been treated as their historical cost. Translation differences resulting from the change in functional currency have been reported as a component of shareholders' equity.

For presentation purposes, comparative figures in these financial statements have been translated into dollars on the following basis: (i) assets and liabilities have been translated using the exchange rate prevailing at December 31, 2014; (ii) the statement of comprehensive loss has been translated at the average exchange rate for the reporting period; and (iii) the results of translation differences have been recorded as "currency translation differences" within other comprehensive income (loss).

**c. Reverse split of ordinary shares**

In June 2015, BioLineRx effected a 1:10 reverse split of its ordinary shares. All share and per share amounts in these financial statements have been retroactively adjusted to reflect the reverse split as if it had been effected prior to the earliest financial statement period included herein. Following the reverse split, one ordinary share traded on the TASE is equivalent to one ADS traded on NASDAQ (prior to the split, the ratio of ordinary shares to ADSs was 10:1). In connection with the reverse split, shareholders also approved an increase in BioLineRx's authorized share capital to 150,000,000 ordinary shares, NIS 0.10 par value each.

**d. Approval of financial statements**

The condensed consolidated interim financial statements of the Company as of September 30, 2015, and for the three and nine months ended September 30, 2015, were approved by the Board of Directors on November 16, 2015, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial and Operating Officer.

**NOTE 2 – BASIS OF PREPARATION**

The Company's condensed consolidated interim financial statements as of September 30, 2015 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, 2014 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, 2015 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

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

**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, 2014 and for the year then ended, other than the change in functional and reporting currency, as described above.

**NOTE 4 – ISSUANCES OF SHARE CAPITAL**

**a. Underwritten public offerings of American Depositary Shares**

In March 2014, the Company completed an underwritten public offering of 9,660,000 ADSs at a public offering price of \$2.50 per ADS. The offering raised a total of \$24.2 million, with net proceeds of approximately \$22.3 million, after deducting fees and expenses.

In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of \$2.00 per ADS. The offering raised a total of \$28.8 million, with net proceeds of approximately \$26.4 million, after deducting fees and expenses.

**b. Share purchase agreement with Lincoln Park Capital**

In May 2014, BioLineRx and Lincoln Park Capital Fund (“LPC”), entered into a \$20 million purchase agreement, together with a registration rights agreement, whereby LPC agreed to purchase, from time to time, up to \$20 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, 2015, BioLineRx sold a total of 1,129,469 ADSs to LPC for aggregate gross proceeds of \$2,433,000. In connection with these issuances, a total of 28,237 ADSs was issued to LPC as a commitment fee and a total of \$49,000 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 1,136,351 ADSs to LPC for aggregate gross proceeds of \$2,443,000. In connection with these issuances, a total of 28,409 ADSs was issued to LPC as a commitment fee and a total of \$49,000 was paid to Oberon Securities as a finder’s fee.

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

**NOTE 5 – SHAREHOLDERS' EQUITY**

As of September 30, 2015 and December 31, 2014, share capital is composed of ordinary shares, as follows:

	<b>Number of ordinary shares</b>	
	<b>December 31,</b>	<b>September 30,</b>
	<b>2014</b>	<b>2015</b>
Authorized share capital	75,000,000	150,000,000
Issued and paid-up share capital	39,115,051	54,647,757
	<b>In NIS/USD</b>	
	<b>December 31,</b>	<b>September 30,</b>
	<b>2014</b>	<b>2015</b>
Authorized share capital (in NIS)	7,500,000	15,000,000
Issued and paid-up share capital (in NIS)	3,911,505	5,464,776
Issued and paid-up share capital (in USD)	1,054,851	1,450,030

**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 23, 2015 (the "Annual Report").*

**Forward Looking Statements**

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

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

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

### General

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-8040, BL-7010, BL-5010, BL-7040, BL-8020 and BL-1040. In addition, we have three 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.

### Clinical-Stage Pipeline

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

- BL-8040 is a novel, short peptide that functions as a high-affinity 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 relapsed or refractory AML, which is currently being conducted at five world-leading cancer research centers in the U.S. and at five premier sites in Israel. In May 2015, we announced successful completion of the dose escalation stage of this study and commencement of the expansion stage at the optimal dose of 1.5 mg/kg. In November 2015, we announced positive results from the dose escalation stage of this study, including clinical response data. Top-line results of the study are expected in early 2016.
  - In September 2014, we commenced a Phase 1 safety and efficacy trial for the use of BL-8040 as a novel treatment for stem cell mobilization at Hadassah Medical Center in Jerusalem. In March 2015 we reported successful top-line safety and efficacy results from this study. More comprehensive data from this study was reported at the European Hematology Association (EHA) Conference in June 2015. In October 2015, we held a “Type B” meeting with the FDA to discuss the next steps in the clinical development plan for stem cell mobilization, and expect to commence a Phase 2 trial in stem cell mobilization in the first quarter of 2016.
  - In August 2015, we initiated a Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, as a consolidation treatment for AML patients who have responded to standard induction treatment. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 200 patients will be enrolled in the trial. The primary endpoint of the study is to compare the relapse free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization;
  - We are also planning to commence the following trials for BL-8040 in the near future:
    - a Phase 2a trial, in collaboration with the MD Anderson Cancer Center, for BL-8040 as a treatment for hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (AA). The regulatory submissions necessary to commence the trial have been filed and the trial is expected to commence shortly after receipt of regulatory approval, anticipated by end of this year; and
    - a Phase 2a trial, also in collaboration with the MD Anderson Cancer Center, for the treatment of AML patients with the FLT3-ITD mutation, expected to commence in the first half of 2016.

- 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.
- 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, a leading site for celiac research. This study was conducted based on an initial medical device submission, under a conditional approval received from the regulatory authorities. In November 2014, we reported the final results of the study. BL-7010 was found to be safe and well tolerated in both single- and repeated-dose administrations. 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 next efficacy study in celiac disease, which we hope to commence during the first half of 2016. Currently, we are in the process of communicating with the notified body in Europe regarding the regulatory pathway classification of BL-7010 as a medical device, a process that we hope to complete in the next few months. Commencement of the efficacy study is contingent on finalizing the regulatory pathway classification process. In addition to the celiac disease pathway, we are currently investing considerable efforts in examining alternative development and commercialization pathways for this product, including as a food supplement, in order to potentially address the multi-billion dollar market for gluten sensitivity, which we believe may also have a shorter time to market than drug or device pathways.
- BL-5010 is a customized, proprietary, pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a Phase 1/2 clinical trial of BL-5010. We have received European confirmation from the British Standards Institution Notified Body in the UK of the regulatory pathway classification of BL-5010 as a Class 2a medical device. In December 2014, we entered into an exclusive out-licensing agreement with Omega Pharma (now a subsidiary of Perrigo Company plc), for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. In September 2015, we reported that Omega Pharma submitted an application for CE marking for BL-5010. Earlier this year, Omega Pharma conducted a 30-patient, open-label clinical study in Turkey to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. The commercial launch of the first OTC indication for this product is expected during 2016.
- BL-7040 is an orally available synthetic oligonucleotide which we are developing for the treatment of inflammatory bowel disease, or IBD. In April 2013, we announced positive results from a Phase 2a proof-of-concept study to evaluate the effectiveness of BL-7040 for the treatment of IBD at five sites in Israel. 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.
- 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 HCV-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 whereby, among other things, the licensors agreed to take over the development of the drug and we agreed to supply, at the licensors' request, the drug 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.
- BL-1040 is a novel, resorbable polymer solution for use in the prevention of ventricular remodeling that may occur in patients who have suffered an acute myocardial infarction, or AMI. BL-1040 is being developed as a medical device. In March 2010, we announced encouraging results from a Phase 1/2 clinical trial. We have entered into an exclusive, worldwide, royalty-bearing out-licensing arrangement with 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 "Bioabsorbable Cardiac Matrix" device, or BCM device). Enrollment for this trial was completed in December 2014, with 303 AMI patients having been recruited and treated. In July 2015, Bellerophon reported top-line results from PRESERVATION I, showing no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints of the study. We have not yet received any notification from Bellerophon about their plans regarding the future of this program.

#### *Partnering and Collaboration Agreements*

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. Additionally, in April 2015, Bellerophon reimbursed us for certain legal fees in the amount of \$250,000.

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.

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

In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma for the rights to BL-5010 for OTC indications in the territory of Europe, Australia and additional selected countries. We will retain the rights to BL-5010 in the United States and the rest of the world. Under our out-licensing arrangement with Omega Pharma, Omega Pharma is obligated to use commercially reasonable best efforts to obtain regulatory approval in the licensed territory for at least two OTC indications and to commercialize BL-5010 for those two OTC indications. In addition, Omega Pharma will sponsor and manufacture BL-5010 in the relevant regions. Omega Pharma will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. In addition, we will have full access to all clinical and research and development data generated during the performance of the development plan and may use these data in order to develop or license the product in other territories and fields of use where we retain the rights.

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding previously 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 and royalty payments that we may 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. As of September 30, 2015, we held approximately \$50.7 million of cash, cash equivalents and short-term bank deposits.

## Recent Company Developments

### *Pre-Clinical and Clinical Development*

#### BL-8040

In August 2015, we initiated a Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, as a consolidation treatment for AML patients who have responded to standard induction treatment. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. The primary endpoint of the study is to compare the relapse free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. In addition, pharmacodynamic measurements will be conducted in order to assess the minimal residual disease, and biomarker analyses will be performed to identify predictors of BL-8040 response. The study will enroll up to 194 patients at up to 25 sites in Germany. AML patients between 18 and 75 years of age with documented first remission will be randomized in a 1:1 ratio to receive high dose Cytarabine, either with BL-8040 or with a matching placebo, as consolidation therapy.

In September 2015, we announced that we had filed the regulatory submissions required to commence a Phase 2 trial for BL-8040, in combination with standard-of-care immunosuppressive therapy, as a novel treatment for two bone marrow failure conditions: hypoplastic myelodysplastic syndrome (hMDS) and aplastic anemia (AA). The open-label trial will be conducted in collaboration with MD Anderson Cancer Center in Houston and is expected to enroll up to 25 patients. The trial is expected to commence shortly after receipt of regulatory approval, anticipated in the next few months. It will examine BL-8040's ability to improve bone marrow cellularity and peripheral blood counts in patients suffering from these bone marrow failure conditions.

In November 2015, we announced positive results from the dose escalation part of BL-8040's Phase 2 clinical trial for the treatment of relapsed or refractory AML. Results showed that BL-8040, as a single agent and in combination with Cytarabine (Ara-C), was safe and well tolerated at all doses tested up to and including the highest dose level of 1.5 mg/kg, with no major adverse events. The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving only one cycle of BL-8040 treatment at doses of 1 mg/kg and higher (n=16). Patients included in this part of the study were patients that had undergone a significant number of prior treatment cycles or that were refractory to induction treatment. These results will be presented at the American Society of Hematology (ASH) Annual Meeting, to be held in December 2015 in Orlando, Florida.

#### BL-5010

In September 2015, we announced that our licensee, Omega Pharma, submitted an application for CE mark designation for BL-5010. Assuming successful completion of the CE mark registration process, the first sales in Europe of BL-5010 are expected during 2016.

#### BL-1040

In July 2015, Bellerophon reported top-line results from PRESERVATION I, showing no statistically significant difference between patients treated with BCM versus placebo for both the primary and the secondary endpoints of the study. We have not yet received any notification from Bellerophon about their plans regarding the future of this program.

#### *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. In line with our business strategy, during the period beginning July 1, 2015 through the date of this announcement, we terminated one project during its early pre-clinical stage (BL-9010) due to lack of efficacy or other scientific considerations. BL-9010 was intended to treat severe allergies and asthma.

#### **Revenues**

Our revenues to date have been generated primarily from upfront and milestone payments under our license agreement with Bellerophon and the amounts we received from Cypress Bioscience.

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, 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 Milestone
BL-8040	<ol style="list-style-type: none"> <li>1. Phase 2 study for AML; dose expansion stage ongoing</li> <li>2. Phase 1 study in stem cell mobilization completed; Type B (end of Phase 1 meeting) with FDA conducted</li> <li>3. Phase 2b consolidation treatment for AML initiated</li> <li>4. Phase 2a study for hMDS and AA in final planning stages; submissions filed</li> <li>5. Phase 2a study for AML patients with FLT3-ITD mutation in final planning stages</li> </ol>	<ol style="list-style-type: none"> <li>1. Top-line results expected in early 2016</li> <li>2. Phase 2 trial expected to commence in Q1 2016</li> <li>3. Top-line results expected in 2018</li> <li>4. Commencement of study expected by end of 2015</li> <li>5. Commencement of study expected in H1 2016</li> </ol>
BL-7010	Completed Phase 1/2 study	Determination by notified body in Europe regarding regulatory pathway classification of BL-7010 as a medical device; randomized controlled efficacy study in celiac disease expected to commence in first half of 2016; feasibility evaluation and determination of alternative development pathways, including as a food supplement for the gluten sensitivity market
BL-5010	Out-licensed to Omega Pharma; application for CE mark submitted in Q3 2015	CE mark approval; commercial launch of first OTC indication in Europe during 2016
BL-7040	Phase 2 trial completed	Potential co-development collaboration or licensing transaction; or project termination
BL-8020	Phase 1/2 development (collaboration with Licensors)	Determination by Licensors of next steps in clinical development plan of the compound, including assessment regarding potential additional viral indications for development.
BL-1040	Completed CE registration pivotal trial (conducted by Bellerophon); primary and secondary study endpoints not achieved	Notification from Bellerophon about their plans regarding the future of this program.

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	Hepatitis C	Preclinical studies; in collaboration with CTTQ for China and Hong Kong
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/scleroderma	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, 2012, 2013 and 2014; for the nine months ended September 30, 2015; 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.

	Year Ended December 31,			Nine Months Ende	Total Costs Since
	2012	2013	2014	September 30,	Project
	<i>(in thousands of U.S. dollars)</i>				Inception
BL-8040	723	3,910	4,698	5,364	14,695
BL-7010	560	1,905	3,756	1,602	8,097
BL-5010	132	251	1,282	367	4,036
BL-7040	500	650	287	35	1,937
BL-8020	794	918	160	4	1,876
BL-1040	-	-	-	-	10,227
Other projects	10,017	3,529	1,090	1,484	88,899
Total gross direct project costs <sup>(1)</sup>	<u>12,726</u>	<u>11,163</u>	<u>11,273</u>	<u>8,856</u>	<u>129,767</u>

(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, 2015, we have incurred research and development expense of approximately \$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 a share purchase agreement with Lincoln Park Capital, or LPC.

## **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.

## **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, 2014.

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.

## **Functional and Presentation Currency**

From the Company's inception through December 31, 2014, the Company's functional and presentation currency was the NIS. Effective January 1, 2015, as a result of a number of factors, including the strategic collaboration agreement with Novartis that will be managed solely in U.S. dollars, as well as expectations regarding a significant increase in expenses denominated in U.S. dollars relating to advanced clinical trials, the Company's functional and presentation currency was changed to the U.S. dollar. See Note 1b to the Company's September 30, 2015 interim financial statements included elsewhere in this 6-K.

## **Results of Operations – Overview**

### *Revenues*

We did not record any revenues during each of the nine-month periods ended September 30, 2015 and 2014.

### *Cost of revenues*

We did not record any cost of revenues during each of the nine-month periods ended September 30, 2015 and 2014.

### *Research and development expenses*

At December 31, 2012, our drug development pipeline 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 10 therapeutic candidates. During 2014, 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 December 31, 2014 consisted of 10 therapeutic candidates. Subsequent to December 31, 2014, we terminated one therapeutic candidate in our pipeline, so that our drug development pipeline of the date of this report consists of 9 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 months ended September 30,		
	2014	2015	Increase (decrease)	2014	2015	Increase (decrease)
Research and development expenses, net	2,975	2,576	(399)	8,486	8,678	192

#### Comparison of three-month periods ending September 30, 2015 and 2014

Research and development expenses for the three months ended September 30, 2015 were \$2.6 million, a decrease of \$0.4 million, or 13.4%, compared to \$3.0 million for the three months ended September 30, 2014. The decrease resulted primarily from decreased spending on BL-1110, BL-7010 and BL-5010 in the 2015 period, partially offset by increased spending on BL-8040.

#### Comparison of nine-month periods ending September 30, 2015 and 2014

Research and development expenses for the nine months ended September 30, 2015 were \$8.7 million, an increase of \$0.2 million, or 2.3%, compared to \$8.5 million for the nine months ended September 30, 2014. The small increase resulted primarily from increased spending on BL-8040 in the 2015 period, partially offset by decreased spending on BL-7010, BL-7040, BL-5010 and BL-8020.

### Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2014	2015	Increase (decrease)	2014	2015	Increase (decrease)
Sales and marketing expenses	305	265	(40)	957	824	(133)

#### Comparison of three-month periods ending September 30, 2015 and 2014

Sales and marketing expenses for the three months ended September 30, 2015 were \$0.3 million, substantially similar to the comparable period in 2014.

#### Comparison of nine-month periods ending September 30, 2015 and 2014

Sales and marketing expenses for the nine months ended September 30, 2015 were \$0.8 million, a decrease of \$0.1 million, or 13.9%, compared to \$0.9 million for the nine months ended September 30, 2014. The decrease resulted primarily from significant professional fees related to a number of material business development activities carried out during the nine-month period in 2014, which resulted in collaboration and outlicensing agreements.

### General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2014	2015	Increase (decrease)	2014	2015	Increase (decrease)
General and administrative expenses	791	762	(29)	2,615	2,594	(21)

#### *Comparison of three-month periods ending September 30, 2015 and 2014*

General and administrative expenses for the three months ended September 30, 2015 were \$0.8 million, substantially similar to the comparable period in 2014.

#### *Comparison of nine-month periods ending September 30, 2015 and 2014*

General and administrative expenses for the nine months ended September 30, 2015 were \$2.6 million, substantially similar to the comparable period in 2014.

### Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2014	2015	Increase (decrease)	2014	2015	Increase (decrease)
Non-operating income (expenses), net	1,380	1,983	603	3,346	1,096	(2,250)

#### *Comparison of three-month periods ending September 30, 2015 and 2014*

We recognized net non-operating income of \$2.0 million for the three months ended September 30, 2015, an increase of \$0.6 million, compared to net non-operating income of \$1.4 million for the three months ended September 30, 2014. Non-operating income (expenses) for both periods primarily relate 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, 2015 and 2014*

We recognized net non-operating income \$1.1 million for the nine months ended September 30, 2015, a decrease of \$2.3 million, compared to net non-operating income of \$3.4 million for the nine months ended September 30, 2014. The reason for the decrease is similar to the one discussed above in the three-month comparison.

### Financial income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2014	2015	Increase (decrease)	2014	2015	Increase (decrease)
Financial income	1,991	85	(1,906)	2,216	363	(1,853)
Financial expenses	-	(91)	(91)	(386)	(111)	275
Net financial income (expense)	1,991	(6)	(1,997)	1,830	252	(1,578)

*Comparison of three-month periods ending September 30, 2015 and 2014*

We recognized an immaterial amount of net financial income for the three months ended September 30, 2015, compared to net financial income of \$2.0 million for the three months ended September 30, 2014. Net financial income (expenses) for the 2015 period primarily relates to investment income earned on our bank deposits, as well as banking fees. The 2014 period also includes significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate.

*Comparison of nine-month periods ending September 30, 2015 and 2014*

We recognized net financial income \$0.3 million for the nine months ended September 30, 2015, compared to net financial income of \$1.8 million for the nine months ended September 30, 2014. Net financial income (expenses) for the 2015 period primarily relates to investment income earned on our bank deposits, as well as banking fees. The 2014 period also includes significant exchange rate differences primarily relating to changes in the USD/NIS exchange rate.

**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. At September 30, 2015, we held \$50.7 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. From the effective date of the purchase agreement through the date of this report, we have sold an aggregate of approximately \$2.4 million of our ADSs to LPC, leaving an available balance under the facility of approximately \$17.6 million.

Net cash used in operating activities was \$11.0 million for the nine months ended September 30, 2015, substantially similar to the comparable period in 2014.

Net cash used in investing activities for the nine months ended September 30, 2015 was \$18.7 million, compared to net cash used in investing activities of \$15.6 million for the nine months ended September 30, 2014. 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, 2015 was \$29.3 million, compared to net cash provided by financing activities of \$22.6 million for the nine months ended September 30, 2014. The cash flows from financing activities primarily reflect the underwritten public offerings of our ADSs in March 2015 and 2014.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2018, 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.