

---

**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 2017*

\_\_\_\_\_

**BioLineRx Ltd.**

(Translation of Registrant's name into English)

\_\_\_\_\_

**2 HaMa'ayan Street**

**Modi'in 7177871, 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** ☒

---

On November 21, 2017, the Registrant will issue a press release announcing its financial results for the three and nine months ended September 30, 2017. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2017 and for the three and nine months then ended. Attached hereto are the following exhibits:

[Exhibit 1: Registrant's press release dated November 21, 2017;](#)

[Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2017 and for the three and nine months then ended; and](#)

[Exhibit 3 - Registrant's operating and financial review as of September 30, 2017 and for the three and nine months then ended.](#)

This Form 6-K, including all exhibits hereto, is hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

---

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 Executive Officer

Dated: November 21, 2017

---



### **BioLineRx Reports Third Quarter 2017 Financial Results**

Tel Aviv, Israel, November 21, 2017 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the third quarter ended September 30, 2017.

#### **Highlights and achievements during the third quarter 2017 and to date:**

Continued execution on multiple clinical development programs for the Company's lead program, BL-8040:

Announced initiation of two additional Phase 1b/2 studies under collaboration with Genentech, following the first study which was initiated in July 2017. All studies are exploring the combination of BL-8040 with Tecentriq (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy agent.

- o Phase 1b/2 trial for the maintenance treatment of patients with intermediate- and high-risk acute myeloid leukemia (AML) who have achieved a complete response (CR) following induction and consolidation therapy.
- o Phase 1b/2 trial for the treatment of gastric cancer. This study is conducted as part of MORPHEUS, Roche's Novel Cancer Immunotherapy Development Platform;

Announced completion of enrollment to the COMBAT study, which is investigating the combination of BL-8040 and Merck's PD-1 inhibitor, Keytruda, in the treatment of pancreatic cancer patients.

Announced regulatory submission to initiate Phase 3 pivotal study with BL-8040 as novel stem cell mobilization treatment for autologous bone-marrow transplantation by the end of 2017, following receipt of regulatory approvals; and

Announced several abstracts accepted to key scientific conferences:

- o Oral presentation at the 59<sup>th</sup> American Society of Hematology (ASH) in December 2017 of pre-clinical data supporting BL-8040 as a robust mobilizer of hematopoietic stem cells (HSC) associated with long-term engraftment.
  - o Poster presentation to the ASCO GI conference of partial results from the COMBAT study. This abstract will be published prior to the conference in January 2018, and will include monotherapy data of BL-8040 from this study.
-

**Expected significant upcoming milestones for 2017 and 2018:**

Partial results from immuno-oncology Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA®, expected in January 2018 at ASCO GI conference; top line results expected in H2 2018;

Initiation of Phase 3 pivotal study for BL-8040 in stem-cell mobilization for autologous transplantation, expected by the end of 2017;

Initiation of Phase 1b/2 immuno-oncology study for BL-8040 in combination with Genentech's atezolizumab in non-small cell lung cancer, expected by end of 2017. Partial results in Phase 1b/2 solid tumors and AML trials in collaboration with Genentech are expected in H2 2018;

Initiation of Phase 1 immuno-oncology study for AGI-134 in several solid tumor indications expected in H1 2018;

Top-line results of Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by mid-2018.

Philip A. Serlin, Chief Executive Officer of BioLineRx, remarked, "We are pleased to report third quarter-to-date activities that continue to demonstrate clinical and regulatory execution on our multiple programs. This included timely initiation of the studies under our cancer immunotherapy collaboration with Genentech for gastric cancer and AML, as well as finalization of all preparations for initiation of our Phase 3 GENESIS study in stem cell mobilization. We are also very excited about the completion of enrollment to the COMBAT study, which will allow us to report topline results as planned in H2 2018. By year-end 2017, we remain on track to have one Phase 3 and seven Phase 2 or 1b/2 clinical trials up and running, and in January 2018 we plan to announce partial results from our Phase 2 study in pancreatic cancer under our immunotherapy collaboration with Merck."

### Financial Results for the Third Quarter Ended September 30, 2017

Research and development expenses for the three months ended September 30, 2017 were \$5.7 million, an increase of \$2.7 million, or 91.4%, compared to \$3.0 million for the three months ended September 30, 2016. The increase resulted primarily from spending on the recently acquired AGI-134 near-clinical project and from higher expenses in 2017 associated with new BL-8040 studies commenced during the third quarter of 2016 and during 2017. Research and development expenses for the nine months ended September 30, 2017 were \$13.3 million, an increase of \$5.1 million, or 61.6%, compared to \$8.2 million for the nine months ended September 30, 2016. The reason for the increase is the same as that presented in the three-month comparison above.

Sales and marketing expenses for the three months ended September 30, 2017 were \$0.2 million, a decrease of \$0.2 million, or 39.1%, compared to \$0.4 million for the three months ended September 30, 2016. The decrease resulted primarily from market research activities related to BL-8040, as well as legal expenses related to business development collaborations and in-licensing activities, in the 2016 period. Sales and marketing expenses for the nine months ended September 30, 2017 were \$1.2 million, an increase of \$0.3 million, or 31.2%, compared to \$0.9 million for the nine months ended September 30, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

General and administrative expenses for the three months ended September 30, 2017 were \$1.1 million, similar to the comparable period in 2016. General and administrative expenses for the nine months ended September 30, 2017 were \$3.0 million, similar to the comparable period in 2016.

The Company's operating loss for the three months ended September 30, 2017 amounted to \$7.1 million, compared with an operating loss of \$4.5 million for the corresponding 2016 period. The Company's operating loss for the nine months ended September 30, 2017 amounted to \$17.6 million, compared with an operating loss of \$12.1 million for the corresponding 2016 period. The increase in operating loss reflects a significant increase in research and development expenses for the respective periods.

Non-operating income (expenses) for the three and nine months ended September 30, 2017 and 2016 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. Non-operating expenses for the three-month and nine-month periods ended September 30, 2017 primarily result from a \$0.3 million fair-value adjustment of derivative liabilities on account of the warrants issued in the direct placement conducted in July 2017. These fair-value adjustments are highly influenced by the Company's share price at each period end (revaluation date).

Net financial income amounted to \$0.2 million for the three months ended September 30, 2017, similar to the comparable period in 2016. Net financial income amounted to \$0.9 million for the nine months ended September 30, 2017 compared to net financial income of \$0.4 million for the nine months ended September 30, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

The Company's net loss for the three months ended September 30, 2017 amounted to \$7.2 million, compared with a net loss of \$4.3 million for the corresponding 2016 period. The Company's net loss for the nine months ended September 30, 2017 amounted to \$17.0 million, compared with a net loss of \$11.6 million for the corresponding 2016 period.

The Company held \$55.0 million in cash, cash equivalents and short-term bank deposits as of September 30, 2017.

Net cash used in operating activities was \$14.2 million for the nine months ended September 30, 2017, compared with net cash used in operating activities of \$10.4 million for the nine months ended September 30, 2016. The \$3.8 million increase in net cash used in operating activities during the nine-month period in 2017, compared to the nine-month period in 2016, was primarily the result of increased research and development expenses in the 2017 period.

Net cash used in investing activities for the nine months ended September 30, 2017 was \$19.5 million, compared to net cash provided by investing activities of \$7.3 million for the nine months ended September 30, 2016. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the acquisition of Agalimmune and investment in iPharma.

Net cash provided by financing activities for the nine months ended September 30, 2017 was \$37.7 million, compared to net cash provided by financing activities of \$1.5 million for the nine months ended September 30, 2016. The increase in cash flows from financing activities primarily reflects our public offering completed in April 2017 and the registered direct placement completed in July 2017.

## Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 21, 2017, at 10:00 a.m. EST. To access the conference call, please dial 1-888-407-2553 from the U.S. or +972-3-918-0664 internationally. The call will also be available via webcast and can be accessed through the [Investor Relations](#) page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call at the [Investor Relations](#) page of BioLineRx's website. A dial-in replay of the call will be available until November 24, 2017; please dial 1-866-500-4953 from the U.S. or +972-3-925-5946 internationally.

(Tables follow)

## About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and is expected to initiate a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is expected to initiate a first-in-man study in the first half of 2018. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the US and Canada), on the basis of which the Company has initiated a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

For additional information on BioLineRx, please visit the Company's website at [www.bioglinrx.com](http://www.bioglinrx.com), where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).



*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, 2017. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.*

**Contact:**

PCG Advisory  
Vivian Cervantes  
Investor Relations  
646-863-6274  
[vivian@pcgadvisory.com](mailto:vivian@pcgadvisory.com)

or

Tsipi Haitovsky  
Public Relations  
+972-52-598-9892  
[tsipihai5@gmail.com](mailto:tsipihai5@gmail.com)

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

	December 31,	September 30,
	2016	2017
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	6,712
Short-term bank deposits	33,154	48,295
Prepaid expenses	255	282
Other receivables	223	558
Total current assets	36,101	55,847
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	60
Long-term investment	-	1,000
Property and equipment, net	2,605	2,365
Intangible assets, net	181	6,855
Total non-current assets	2,838	10,280
Total assets	38,939	66,127
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	4,349
Other	978	1,084
Total current liabilities	3,661	5,526
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	180
Warrants	1	1,396
Total non-current liabilities	251	1,576
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,912	7,102
EQUITY		
Ordinary shares	1,513	2,809
Share premium	199,567	239,606
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,569	10,227
Accumulated deficit	(175,206)	(192,201)
Total equity	35,027	59,025
Total liabilities and equity	38,939	66,127

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2017	2016	2017
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,954)	(5,654)	(8,233)	(13,306)
SALES AND MARKETING EXPENSES	(409)	(249)	(928)	(1,218)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,125)	(1,154)	(2,968)	(3,028)
OPERATING LOSS	(4,488)	(7,057)	(12,129)	(17,552)
NON-OPERATING INCOME (EXPENSES), NET	(14)	(333)	182	(342)
FINANCIAL INCOME	172	153	403	914
FINANCIAL EXPENSES	(4)	(6)	(12)	(15)
NET LOSS AND COMPREHENSIVE LOSS	(4,334)	(7,243)	(11,556)	(16,995)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.08)	(0.07)	(0.21)	(0.20)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	56,426,202	101,874,372	55,912,486	85,106,723

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

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other comprehensive loss</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2016</b>	1,455	196,201	(1,416)	10,735	(159,365)	47,610
<b>CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2016:</b>						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options exercised	1	128	-	(128)	-	1
Employee stock options forfeited and expired	-	460	-	(460)	-	-
Share-based compensation	-	-	-	959	-	959
Comprehensive loss for the period	-	-	-	-	(11,556)	(11,556)
<b>BALANCE AT SEPTEMBER 30, 2016</b>	<u>1,460</u>	<u>198,380</u>	<u>(1,416)</u>	<u>11,106</u>	<u>(170,921)</u>	<u>38,609</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Other comprehensive loss</u>	<u>Capital reserve</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2017</b>	1,513	199,567	(1,416)	10,569	(175,206)	35,027
<b>CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2017:</b>						
Issuance of share capital, net	1,295	38,388	-	-	-	39,683
Employee stock options exercised	1	326	-	(326)	-	1
Employee stock options forfeited and expired	-	1,325	-	(1,325)	-	-
Share-based compensation	-	-	-	1,309	-	1,309
Comprehensive loss for the period	-	-	-	-	(16,995)	(16,995)
<b>BALANCE AT SEPTEMBER 30, 2017</b>	<u>2,809</u>	<u>239,606</u>	<u>(1,416)</u>	<u>10,227</u>	<u>(192,201)</u>	<u>59,025</u>

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

	Nine months ended September 30,	
	2016	2017
	in USD thousands	
<b>CASH FLOWS - OPERATING ACTIVITIES</b>		
Comprehensive loss for the period	(11,556)	(16,995)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,128	2,772
Net cash used in operating activities	(10,428)	(14,223)
<b>CASH FLOWS - INVESTING ACTIVITIES</b>		
Long-term investment	-	(1,000)
Investments in short-term deposits	(28,978)	(48,029)
Maturities of short-term deposits	36,480	33,327
Purchase of property and equipment	(164)	(109)
Purchase of intangible assets	(24)	(3,721)
Net cash provided by (used in) investing activities	7,314	(19,532)
<b>CASH FLOWS - FINANCING ACTIVITIES</b>		
Issuance of share capital and warrants, net of issuance costs	1,595	37,761
Repayments of bank loan	(72)	(70)
Proceeds from exercise of employee stock options	1	-
Net cash provided by financing activities	1,524	37,691
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(1,590)	3,936
<b>CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD</b>	5,544	2,469
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	60	307
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	4,014	6,712

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

	Nine months ended September 30,	
	2016	2017
	in USD thousands	
<b>Adjustments required to reflect net cash used in operating activities:</b>		
Income and expenses not involving cash flows:		
Depreciation and amortization	368	381
Long-term prepaid expenses	4	(8)
Interest and exchange rate differences on short-term deposits	(277)	(439)
Share-based compensation	959	1,309
Warrant issuance costs	-	17
Exchange differences on cash and cash equivalents	(60)	(307)
Loss (gain) on adjustment of warrants to fair value	(179)	316
	815	1,269
Changes in operating asset and liability items:		
Decrease (Increase) in prepaid expenses and other receivables	14	(362)
Increase in accounts payable and accruals	299	1,865
	313	1,503
	1,128	2,772
Supplementary information on interest received in cash	310	378
Supplementary non-cash investment (see Note 4b)	-	2,985

**BioLineRx Ltd.**  
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS  
(UNAUDITED)  
AS OF SEPTEMBER 30, 2017

---

**BioLineRx Ltd.**  
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS  
(UNAUDITED)  
AS OF SEPTEMBER 30, 2017

TABLE OF CONTENTS

	<u>Page</u>
<a href="#"><u>Condensed consolidated interim statements of financial position</u></a>	1
<a href="#"><u>Condensed consolidated interim statements of comprehensive loss</u></a>	2
<a href="#"><u>Condensed consolidated interim statements of changes in equity</u></a>	3
<a href="#"><u>Condensed consolidated interim cash flow statements</u></a>	4-5
<a href="#"><u>Notes to the condensed consolidated interim financial statements</u></a>	6-10

---



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

	December 31,	September 30,
	2016	2017
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	2,469	6,712
Short-term bank deposits	33,154	48,295
Prepaid expenses	255	282
Other receivables	223	558
Total current assets	36,101	55,847
NON-CURRENT ASSETS		
Long-term prepaid expenses	52	60
Long-term investment	-	1,000
Property and equipment, net	2,605	2,365
Intangible assets, net	181	6,855
Total non-current assets	2,838	10,280
Total assets	38,939	66,127
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	2,590	4,349
Other	978	1,084
Total current liabilities	3,661	5,526
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	250	180
Warrants	1	1,396
Total non-current liabilities	251	1,576
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,912	7,102
EQUITY		
Ordinary shares	1,513	2,809
Share premium	199,567	239,606
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,569	10,227
Accumulated deficit	(175,206)	(192,201)
Total equity	35,027	59,025
Total liabilities and equity	38,939	66,127

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2017	2016	2017
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,954)	(5,654)	(8,233)	(13,306)
SALES AND MARKETING EXPENSES	(409)	(249)	(928)	(1,218)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,125)	(1,154)	(2,968)	(3,028)
OPERATING LOSS	(4,488)	(7,057)	(12,129)	(17,552)
NON-OPERATING INCOME (EXPENSES), NET	(14)	(333)	182	(342)
FINANCIAL INCOME	172	153	403	914
FINANCIAL EXPENSES	(4)	(6)	(12)	(15)
NET LOSS AND COMPREHENSIVE LOSS	(4,334)	(7,243)	(11,556)	(16,995)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.08)	(0.07)	(0.21)	(0.20)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	56,426,202	101,874,372	55,912,486	85,106,723

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

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

	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2016</b>	1,455	196,201	(1,416)	10,735	(159,365)	47,610
<b>CHANGES FOR NINE MONTHS ENDED</b>						
<b>SEPTEMBER 30, 2016:</b>						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options exercised	1	128	-	(128)	-	1
Employee stock options forfeited and expired	-	460	-	(460)	-	-
Share-based compensation	-	-	-	959	-	959
Comprehensive loss for the period	-	-	-	-	(11,556)	(11,556)
<b>BALANCE AT SEPTEMBER 30, 2016</b>	<u>1,460</u>	<u>198,380</u>	<u>(1,416)</u>	<u>11,106</u>	<u>(170,921)</u>	<u>38,609</u>
	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
<b>BALANCE AT JANUARY 1, 2017</b>	1,513	199,567	(1,416)	10,569	(175,206)	35,027
<b>CHANGES FOR NINE MONTHS ENDED</b>						
<b>SEPTEMBER 30, 2017:</b>						
Issuance of share capital, net	1,295	38,388	-	-	-	39,683
Employee stock options exercised	1	326	-	(326)	-	1
Employee stock options forfeited and expired	-	1,325	-	(1,325)	-	-
Share-based compensation	-	-	-	1,309	-	1,309
Comprehensive loss for the period	-	-	-	-	(16,995)	(16,995)
<b>BALANCE AT SEPTEMBER 30, 2017</b>	<u>2,809</u>	<u>239,606</u>	<u>(1,416)</u>	<u>10,227</u>	<u>(192,201)</u>	<u>59,025</u>

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

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

	Nine months ended September 30,	
	2016	2017
	in USD thousands	
<b>CASH FLOWS - OPERATING ACTIVITIES</b>		
Comprehensive loss for the period	(11,556)	(16,995)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,128	2,772
Net cash used in operating activities	(10,428)	(14,223)
<b>CASH FLOWS - INVESTING ACTIVITIES</b>		
Long-term investment	-	(1,000)
Investments in short-term deposits	(28,978)	(48,029)
Maturities of short-term deposits	36,480	33,327
Purchase of property and equipment	(164)	(109)
Purchase of intangible assets	(24)	(3,721)
Net cash provided by (used in) investing activities	7,314	(19,532)
<b>CASH FLOWS - FINANCING ACTIVITIES</b>		
Issuance of share capital and warrants, net of issuance costs	1,595	37,761
Repayments of bank loan	(72)	(70)
Proceeds from exercise of employee stock options	1	-
Net cash provided by financing activities	1,524	37,691
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(1,590)	3,936
<b>CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD</b>	5,544	2,469
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	60	307
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	4,014	6,712

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

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

	Nine months ended September 30,	
	2016	2017
	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	368	381
Long-term prepaid expenses	4	(8)
Interest and exchange rate differences on short-term deposits	(277)	(439)
Share-based compensation	959	1,309
Warrant issuance costs	-	17
Exchange differences on cash and cash equivalents	(60)	(307)
Loss (gain) on adjustment of warrants to fair value	(179)	316
	<u>815</u>	<u>1,269</u>
<b>Changes in operating asset and liability items:</b>		
Decrease (Increase) in prepaid expenses and other receivables	14	(362)
Increase in accounts payable and accruals	299	1,865
	<u>313</u>	<u>1,503</u>
	<u>1,128</u>	<u>2,772</u>
<b>Supplementary information on interest received in cash</b>	<u>310</u>	<u>378</u>
<b>Supplementary non-cash investment (see Note 4b)</b>	<u>-</u>	<u>2,985</u>

The accompanying notes are an integral part of these unaudited condensed consolidated 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. BioLineRx and its subsidiaries (collectively, the “Company”) are engaged in the development of therapeutics, from pre-clinical development to advanced clinical trials, primarily in the fields of oncology and immunology.

In February 2007, BioLineRx listed its ordinary shares 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 been traded on the NASDAQ Capital Market.

In March 2017, the Company acquired Agalimmune Ltd. (“Agalimmune”), a privately-held company incorporated in the United Kingdom focusing on the field of immuno-oncology. See Notes 4b and 6.

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 in the past, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

**b. Approval of financial statements**

The condensed consolidated interim financial statements of the Company as of September 30, 2017, and for the three and nine months then ended, were approved by the Board of Directors on November 21, 2017, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

**NOTE 2 – BASIS OF PREPARATION**

The Company’s condensed consolidated interim financial statements as of September 30, 2017 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 fair statement 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, 2016 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, 2017 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, 2016 and for the year then ended.

**NOTE 4 – ISSUANCES OF SHARE CAPITAL AND WARRANTS**

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

In May 2014, BioLineRx and Lincoln Park Capital Fund (“LPC”) entered into a \$20 million, 36-month purchase 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, 2017, BioLineRx issued a total of 2,124,952 ADSs to LPC for aggregate gross proceeds of \$2,130,000. In connection with these issuances, a total of 53,124 ADSs was issued to LPC as a commitment fee and a total of \$43,000 was paid to Oberon Securities as a finder’s fee. The purchase agreement with LPC expired in accordance with its terms on July 1, 2017.

**b. Share issuance to Agalimmune shareholders**

In March 2017, in connection with the Agalimmune acquisition, the Company issued 2,550,935 ADSs to the shareholders of Agalimmune. See Note 7.

**c. Underwritten public offering**

In April 2017, the Company completed an underwritten public offering of approximately 33.8 million ADSs at a public offering price of \$0.85 per ADS. The offering raised a total of \$28.8 million, with net proceeds of approximately \$26.2 million, after deducting fees and expenses.

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

**NOTE 4 – ISSUANCES OF SHARE CAPITAL AND WARRANTS (cont.)**

**d. Direct placement of share capital and warrants to BVF**

In July 2017, the Company completed a direct placement to BVF Partners L.P., its largest shareholder, for aggregate gross proceeds of \$9.6 million. The placement consisted of 8,495,575 ADSs, Series A warrants to purchase an additional 2,973,451 ADSs and Series B warrants to purchase an additional 2,973,451 ADSs. The Series A warrants have an exercise price of \$2.00 per ADS and are exercisable for a term of four years. The Series B warrants have an exercise price of \$4.00 per ADS and are also exercisable for a term of four years. Net proceeds from the transaction were approximately \$9.5 million, after deducting fees and expenses.

The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability is initially recognized at its fair value on the date the contract is entered into and subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the then current price of an ADS, a risk-free interest rate of 1.66% and an average standard deviation of 57.8%. The fair value of the warrants as of September 30, 2017 was based on the then current price of an ADS, a risk-free interest rate of 1.79% and an average standard deviation of 57.5%.

The amount of the direct placement consideration initially allocated to the warrants was approximately \$1.1 million. Total issuance costs allocable to the warrants was not material. The change in fair value from the date of issuance through September 30, 2017, amounting to approximately \$0.3 million, has been recorded as non-operating expense on the statement of comprehensive loss.



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

**NOTE 5 – SHAREHOLDERS' EQUITY**

As of December 31, 2016 and September 30, 2017, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31,	September 30,
	2016	2017
Authorized share capital	150,000,000	250,000,000
Issued and paid-up share capital	57,033,355	104,115,833
	In USD and NIS	
	December 31,	September 30,
	2016	2017
Authorized share capital (in NIS)	15,000,000	25,000,000
Issued and paid-up share capital (in NIS)	5,703,336	10,411,583
Issued and paid-up share capital (in USD)	1,513,294	2,809,076

**NOTE 6 – LONG-TERM INVESTMENT**

The long-term investment represents the Company's \$1.0 million investment, completed in September 2017, in iPharma (H.K.) Limited ("iPharma"), a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China. iPharma is focusing on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. iPharma expects to raise the funds needed to develop its pipeline primarily from third-party investors.

**NOTE 7 – AGALIMMUNE ACQUISITION**

In March 2017, the Company acquired substantially all the outstanding shares of Agalimmune Ltd. for initial consideration of approximately \$6.0 million, of which \$3.0 million was in cash and the remainder in the Company's ADSs. The acquisition expanded the Company's pipeline to include Agalimmune's primary asset, AGI-134, a novel immuno-oncology agent for various cancer indications at the near-clinical stage of development. Due in part to the early stage of development of AGI-134 and other elements evaluated by the Company's management as required by IFRS, the acquisition has been accounted for in the Company's financial statements as an asset transaction. Total costs associated with bringing the asset into the Company's pipeline include additional expenses of approximately \$0.7 million, resulting in a total increase in intangibles reflected in the Company's financial statements of approximately \$6.7 million as of September 30, 2017.

Additional consideration may be due to Agalimmune shareholders based on certain development and commercial milestones, including future sales of Agalimmune products.

**BioLineRx Ltd.**

NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS  
(UNAUDITED)

**NOTE 8 – EVENT SUBSEQUENT TO THE BALANCE SHEET DATE**

In October 2017, the Company entered into an at-the-market (“ATM”) sales agreement with BTIG, LLC (“BTIG”), pursuant to which the Company may, at its sole discretion, offer and sell through BTIG, acting as sales agent, ADSs having an aggregate offering price of up to \$30 million throughout the period during which the ATM facility remains in effect. The Company will pay BTIG a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. As of the date of these financial statements, the available balance under the facility is \$30 million.

**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, 2017 (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;
  - our ability to integrate new therapeutic candidates and new personnel
  - 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 and 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.
-

## Overview

### *General*

We are a clinical-stage biopharmaceutical development company focused on oncology and immunology. Our current development and commercialization pipeline consists of a clinical-stage therapeutic candidate, BL-8040; a near-clinical therapeutic candidate, AGI-134; and one commercialized product, BL-5010. In addition, we have four other therapeutic candidates in clinical and 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. Although our focus is principally on the therapeutic areas of oncology and immunology, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

### *Main Therapeutic Candidates*

The following is a description of our main programs:

- BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we are developing for the treatment of solid tumors, acute myeloid leukemia, or AML, and stem-cell mobilization for bone-marrow transplantation.

#### *Solid tumors*

- Ø In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT study, focusing on evaluating the safety and efficacy of BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in up to 30 patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity. Partial results will be presented at the 2018 ASCO Gastrointestinal Cancers Symposium (ASCO GI) in January 2018, with top-line results expected in the second half of 2018.
- Ø In August 2016, in the framework of an agreement with MD Anderson Cancer Center, we entered into an additional collaboration for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, is the mechanism-of-action by which both drugs might synergize, as well as multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We are supplying BL-8040 for this Phase 2b study, which commenced in January 2017. Data from this study will be presented at the 2018 ASCO GI in January 2018.
- Ø In September 2016, we entered into a collaboration with Genentech, Inc., a member of the Roche Group, in the framework of which both companies would carry out Phase 1b/2 studies investigating BL-8040 in combination with atezolizumab (TECENTRIQ®), Genentech's anti-PDL1 cancer immunotherapy, in various solid tumors and hematologic malignancies. Genentech commenced a Phase 1b/2 study for the treatment of pancreatic cancer in July 2017, as well as a Phase 1b/2 study in gastric cancer in October 2017. Genentech expects to commence an additional Phase 1b/2 study in lung cancer by early 2018. In September 2017, we initiated a Phase 1b/2 study under this collaboration in acute myeloid leukemia (AML). These studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters.

## AML

- Ø During 2016, we completed and reported on a Phase 2a proof-of-concept trial for the treatment of relapsed or refractory acute myeloid leukemia (r/r AML) which was conducted on 42 patients at six world-leading cancer research centers in the U.S. and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. At the annual meetings of SOHO and ASH in September and December 2016, respectively, we presented detailed, positive safety and response rate data relating to the study. We continue to monitor long-term survival data for patients in the dose expansion phase of the study.
- Ø We are currently investigating BL-8040 as a consolidation treatment together with cytarabine (the current standard of care) for AML patients who have responded to standard induction treatment and are in complete remission and, in this regard, are running a significant Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group. 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 194 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 considering carrying out an interim analysis on this study in the second half of 2018, with top-line results expected in 2020.

## Stem-cell mobilization

- Ø In March 2015, we reported successful top-line safety and efficacy results from a Phase 1 safety and efficacy trial for the use of BL-8040 as a novel stem-cell mobilization treatment for allogeneic bone marrow transplantation at Hadassah Medical Center in Jerusalem.
- Ø In March 2016, we initiated a Phase 2 trial for BL-8040 for allogeneic stem-cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. Initial results of this study announced in March 2017 show that a single injection of BL-8040 mobilized sufficient amounts of cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care. Topline results of this study are now expected in mid-2018, as a result of certain delays in study recruitment in connection with the addition of two sites to the study and the regulatory filings associated therewith.
- Ø In August 2017, following a successful meeting with the FDA, we announced the filing of regulatory submissions required to commence a randomized, controlled Phase 3 registrational trial of BL-8040 for the mobilization of hematopoietic stem cells, or HSCs, for autologous transplantation in patients with multiple myeloma. The trial is expected to commence by the end of 2017.
- Ø In November 2017, we disclosed preclinical data supporting BL-8040 as robust mobilizer of hematopoietic stem cells, or HSCs, associated with long-term engraftment. The data will be presented as an oral presentation at the 59th American Society of Hematology (ASH) Annual Meeting and Exhibition in Atlanta, GA, taking place in December 2017.

#### *Other matters*

- Ø In addition to the above, we are currently conducting, or planning to conduct, a number of investigator-initiated, open-label studies in a variety of indications, to support the interest of the scientific and medical communities in exploring additional uses for BL-8040. These studies serve to further elucidate the mechanism of action for BL-8040.
- Ø In September 2013, the 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 January 2015, the FDA modified this Orphan Drug Designation for BL-8040 for use either as a single agent or in combination with G-CSF.
- AGI-134, a near-clinical therapeutic candidate in-licensed by our subsidiary, Agalimmune Ltd., or Agalimmune, is a synthetic alpha-Gal glycolipid immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-Gal antibodies to induce a hyper-acute, systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. AGI-134 has completed numerous proof-of-concept studies, demonstrating robust protection against the development of secondary tumors in a model of melanoma with a single dose only. Synergy has also been demonstrated in the same model when combined with a PD-1 immune checkpoint inhibitor, offering the potential to broaden the utility of such immunotherapies and improve the rate and duration of responses in multiple cancer types. A 28-day, repeated-administration GLP toxicology study in monkeys with AGI-134 has also been successfully completed. We expect to commence a first-in-man study using AGI-134 in patients with solid tumors in the first half of 2018.
- 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 2014, we entered into an exclusive out-licensing arrangement with a subsidiary of Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of this first OTC indication (warts/verruca) commenced in Europe in the second quarter of 2016 and sales are expected to slowly ramp up over the next 2-3 years.

#### *Principal Partnering and Collaboration Agreements*

In December 2014, we entered into a strategic collaboration with 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. We are currently developing two pre-clinical projects – BL-1220 and BL-1230 – in the framework of this collaboration, with the ongoing scientific support of Novartis. The companies are continually evaluating late pre-clinical and early clinical projects, with the goal of bringing additional projects into our pipeline during the next six to 12 months.

In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo for the rights to BL-5010 for over-the-counter or OTC indications in the territory of Europe, Australia and additional selected countries. We retain all OTC rights to BL-5010 in the United States and the rest of the world, as well as all non-OTC rights on a global basis. Under our out-licensing arrangement with Perrigo, it 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, Perrigo will sponsor and manufacture BL-5010 in the relevant regions. Perrigo will pay us an agreed amount for each unit sold, and we will be entitled to certain commercial milestone payments. We will have full access to all clinical and research and development data, as well as manufacturing 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.

For information on our collaborations with Merck, Genentech and MD Anderson Cancer Center, see “— *Main Therapeutic Candidates*” above.

#### *Other Partnering and Collaboration Agreements*

In August 2016, we announced the establishment of a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China. The joint venture, named iPharma, is focusing on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. In accordance with the terms of the joint venture agreement, each partner has provided seed capital of \$1 million to the venture. As of the date of this report, iPharma has licensed exclusive worldwide rights to one clinical-stage asset and one pre-clinical stage asset. The clinical-stage asset, licensed from Boehringer Ingelheim, is a focal adhesion kinase inhibitor (FAKi), being developed for multiple solid tumors. Additional therapeutic candidates for indications that are of special interest for the Chinese population are being screened and, if found suitable, will be in-licensed by iPharma for further development and commercialization in China and possibly in other countries as well. iPharma expects to raise the funds needed to develop its pipeline primarily from third-party investors. In this regard, we do not expect to invest material additional capital in iPharma.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Bellerophon. 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.

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 which 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 Biotech is responsible for all process development and manufacturing of BL-9020 during its pre-clinical and clinical development stages, and we are responsible for all pre-clinical development of BL-9020.

#### *Funding*

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from a government body which previously was called the Office of the Chief Scientist of the Israeli Ministry of the Economy (OCS) (and which in 2016 was replaced by the newly established Israel Innovation Authority), 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, 2017, we held \$55.0 million of cash, cash equivalents and short-term bank deposits.

#### **Recent Company Developments**

##### *Pre-Clinical and Clinical Development*

## **BL-8040**

In July 2017, Genentech initiated a Phase 1b/2 study for BL-8040 in combination with atezolizumab in pancreatic cancer. In October 2017, Genentech initiated a Phase 1b/2 study for BL-8040 in combination with atezolizumab in gastric cancer. Up to 40 patients are planned to be enrolled in each of these multicenter, randomized, controlled, open-label studies. These clinical study collaborations between BioLineRx and Genentech are part of MORPHEUS, a phase 1b/2 adaptive platform to assess the efficacy and safety of combination cancer immunotherapies.

In August 2017, we filed the regulatory submissions required to commence a randomized, controlled Phase 3 registrational trial of BL-8040 for the mobilization of hematopoietic stem cells, or HSCs, for autologous transplantation in patients with multiple myeloma. The trial, named GENESIS, is expected to commence by the end of 2017. The trial is aimed at evaluating the efficacy, safety and tolerability of the combination treatment of BL-8040 and granulocyte colony-stimulating factor (G-CSF), as compared to the control arm of placebo and G-CSF.

In September 2017, we initiated a Phase 1b/2 study for BL-8040 in combination with Genentech's atezolizumab in AML. The trial, known as the BATTLE study, will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response (CR) following induction and consolidation therapy, and who are not fit for bone-marrow transplantation. Up to 60 patients are planned to be enrolled in this multicenter, single arm, open-label study to evaluate the relapse-free survival, minimal residual disease status and overall survival, as well as the safety and tolerability of the combination of BL-8040 and atezolizumab. The trial is planned to take place at approximately 22 sites in the US, Europe and Israel.

In November 2017, we disclosed preclinical data supporting BL-8040 as robust mobilizer of HSCs associated with long-term engraftment. The data demonstrate that human CD34+ cells purified from BL-8040-mobilized grafts contain high numbers of a specific type of HSC (CD34+CD38-CD45RA-CD90+ CD49f+) associated with long-term engraftment, compared to cells mobilized by G-CSF. The study further showed that BL-8040-mobilized HSCs can successfully engraft the bone marrow and spleen of immunodeficient mice. In addition, a robust long-term engraftment of BL-8040-mobilized human CD34+ cells was seen in these mice. The data will be presented in an oral presentation at the 59<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exhibition in Atlanta, Georgia, taking place in December 2017.

### *Capital Resources*

In July 2017, we completed a direct placement to BVF Partners L.P., our largest shareholder, of 8,495,575 ADSs and 5,946,902 warrants to purchase an additional 5,946,902 ADSs, at a unit price of \$1.13. The warrants were issued in two series: 2,973,451 Series A warrants with an exercise price of \$2.00 per ADS and exercisable for a term of four years; and 2,973,451 Series B warrants with an exercise price of \$4.00 per ADS and exercisable for a term of four years. The offering raised gross proceeds of \$9.6 million, with net proceeds of approximately \$9.5 million after deducting fees and expenses.

In October 2017, we entered into an at-the-market sales agreement with BTIG, LLC, or BTIG, whereby we may, in our discretion and at such times as we shall determine from time to time, offer and sell through BTIG, acting as sales agent, up to \$30 million of our ADSs throughout the period during which the sales agreement remains in effect (the "ATM Program"). As of the date of this report, the available balance under the facility is \$30 million.

### **Revenues**

Our revenues to date have been generated primarily from milestone payments under current and previously existing out-licensing agreements.

We expect our revenues for the next several years to be derived primarily from future payments under our current out-licensing agreement with Perrigo, our collaboration agreement with Novartis and other potential collaboration arrangements, including future royalties on product sales.



## 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 Near Term Milestones
BL-8040	<ol style="list-style-type: none"> <li>1. Phase 2a study for relapsed or refractory AML completed</li> <li>2. Phase 2b consolidation treatment for AML ongoing</li> <li>3. Phase 2 study in stem cell mobilization ongoing</li> <li>4. Phase 2a study in pancreatic cancer, in collaboration with Merck, ongoing</li> <li>5. Phase 2a study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, ongoing</li> <li>6. Phase 1b/2 study in AML, in collaboration with Genentech, commenced</li> <li>7. Phase 1b/2 studies in various solid tumors, in collaboration with Genentech; pancreatic and gastric cancer studies commenced</li> <li>8. Phase 3 registration study in autologous stem cell mobilization, regulatory submissions made</li> </ol>	<ol style="list-style-type: none"> <li>1. Follow-up for overall survival is ongoing</li> <li>2. Completion of enrollment and possible interim results expected in H2 2018; top-line results expected in 2020</li> <li>3. Top-line results expected in mid-2018</li> <li>4. Partial results to be presented at ASCO GI in January 2018; top-line results expected in H2 2018</li> <li>5. Top-line results expected in H2 2018</li> <li>6. Top-line results expected in 2019</li> <li>7. Commencement of additional study in lung cancer expected by early 2018; top-line results expected in 2019</li> <li>8. Commencement of study expected by end of 2017</li> </ol>
AGI-134	Near-clinical development studies	Commencement of first-in-man study expected in H1 2018
BL-5010	Out-licensed to Perrigo; CE mark approval obtained; commercial launch of first OTC indication in Europe commenced	Gradual full roll-out of commercial launch over next 2-3 years; pursuit of potential out-licensing partner(s) for OTC and non-OTC rights still held by us

In addition to the projects set forth above, we have four additional projects in clinical and pre-clinical stages of development (BL-9020, BL-1220, BL-1230 and BL-1040) that are significantly less material to the Company's ongoing research and development expenditures.

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, 2014, 2015 and 2016; for the nine months ended September 30, 2017; and on an aggregate basis since project inception.

	Year Ended December 31,			Nine Months Ended September 30,	Total Costs Since Project Inception
	2014	2015	2016	2017	
	<i>(in thousands of U.S. dollars)</i>				
BL-8040	4,698	7,045	8,281	8,351	33,008
AGI-134	-	-	-	2,694	2,694
BL-5010	1,282	400	75	18	4,162
Other projects	5,293	3,573	2,647	1,732	115,863
<b>Total gross direct project costs</b>	<b>11,273</b>	<b>11,018</b>	<b>11,003</b>	<b>12,795</b>	<b>155,727</b>

From our inception through September 30, 2017, we have incurred research and development expenses of approximately \$190.4 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 and the direct placement we conducted in July 2017. 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.

#### **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. In addition, it may also include gains/losses on foreign exchange hedging transactions, which we carry out from time to time to protect against a portion of our NIS-denominated expenses (primarily compensation) in relation to the dollar.

#### **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, 2016.

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- or nine-month periods ended September 30, 2017 and 2016.

### Cost of revenues

We did not record any cost of revenues during each of the three- or nine-month periods ended September 30, 2017 and 2016.

### Research and development expenses

At December 31, 2013, our drug development pipeline consisted of 10 therapeutic candidates. During 2014, we added a new compound to our pipeline and discontinued the development of two compounds from the pipeline, so that our drug development pipeline as of December 31, 2014 consisted of nine therapeutic candidates. During 2015, we did not add any new compounds to our pipeline and we discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2015 consisted of eight therapeutic candidates. During 2016, we added three compounds to our pipeline and discontinued the development of three compounds in our pipeline, so that our drug development pipeline as of December 31, 2016 consisted of eight therapeutic candidates. Subsequent to December 31, 2016, we terminated two therapeutic candidates in our pipeline, and added one therapeutic candidate to the pipeline, so that our drug development pipeline as of the date of this report consists of seven 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,		
	2016	2017	Increase (decrease)	2016	2017	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Research and development expenses, net	2,954	5,654	2,700	8,233	13,306	5,073

### Comparison of three-month periods ending September 30, 2017 and 2016

Research and development expenses for the three months ended September 30, 2017 were \$5.7 million, an increase of \$2.7 million, or 91.4%, compared to \$3.0 million for the three months ended September 30, 2016. The increase resulted primarily from spending on our new AGI-134 near-clinical project and from higher expenses in 2017 associated with new BL-8040 studies commenced during the third quarter of 2016 and during 2017.

### Comparison of nine-month periods ending September 30, 2017 and 2016

Research and development expenses for the nine months ended September 30, 2017 were \$13.3 million, an increase of \$5.1 million, or 61.6%, compared to \$8.2 million for the nine months ended September 30, 2016. The reason for the increase is the same as that presented in the three-month comparison above.

**Sales and marketing expenses**

	Three months ended September 30,			Nine months ended September 30,		
	2016	2017	Increase (decrease)	2016	2017	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Sales and marketing expenses	409	249	(160)	928	1,218	290

**Comparison of three-month periods ending September 30, 2017 and 2016**

Sales and marketing expenses for the three months ended September 30, 2017 were \$0.2 million, a decrease of \$0.2 million, or 39.1%, compared to \$0.4 million for the three months ended September 30, 2016. The decrease resulted primarily from market research activities related to BL-8040, as well as legal expenses related to business development collaborations and in-licensing activities, in the 2016 period.

**Comparison of nine-month periods ending September 30, 2017 and 2016**

Sales and marketing expenses for the nine months ended September 30, 2017 were \$1.2 million, an increase of \$0.3 million, or 31.2%, compared to \$0.9 million for the nine months ended September 30, 2016. The increase resulted primarily from one-time legal fees related to AGI-134.

**General and administrative expenses**

	Three months ended September 30,			Nine months ended September 30,		
	2016	2017	Increase (decrease)	2016	2017	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
General and administrative expenses	1,125	1,154	99	2,968	3,028	60

**Comparison of three-month periods ending September 30, 2017 and 2016**

General and administrative expenses for the three months ended September 30, 2017 were \$1.1 million, similar to the comparable period in 2016.

**Comparison of nine-month periods ending September 30, 2017 and 2016**

General and administrative expenses for the nine months ended September 30, 2017 were \$3.0 million, similar to the comparable period in 2016.

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

	Three months ended September 30,			Nine months ended September 30,		
	2016	2017	Increase (decrease)	2016	2017	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Non-operating income (expenses), net	(14)	(333)	(319)	182	(342)	(524)

**Comparison of three-month and nine-month periods ending September 30, 2017 and 2016**

Non-operating income (expenses) for the three and nine months ended September 30, 2017 and 2016 are primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. Non-operating expenses for the three-month and nine-month periods ended September 30, 2017 primarily result from a \$0.3 million fair-value adjustment of derivative liabilities on account of the warrants issued in the direct placement conducted in July 2017. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date).

**Financial income (expenses), net**

	Three months ended September 30,			Nine months ended September 30,		
	2016	2017	Increase (decrease)	2016	2017	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Financial income	172	153	(19)	403	914	511
Financial expenses	(4)	(6)	(2)	(12)	(15)	(3)
Net financial income (expense)	168	147	(21)	391	899	508

**Comparison of three-month periods ending September 30, 2017 and 2016**

We recognized net financial income of \$0.2 million for the three months ended September 30, 2017, similar to the comparable period in 2016.

**Comparison of nine-month periods ending September 30, 2017 and 2016**

We recognized net financial income of \$0.9 million for the nine months ended September 30, 2017 compared to net financial income of \$0.4 million for the nine months ended September 30, 2016. The increase in net financial income relates primarily to gains recorded on foreign currency hedging transactions and higher investment income due to higher levels of cash and short-term bank deposits.

**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, 2017, we held \$55.0 million in cash, cash equivalents and short-term bank deposits. We have invested substantially all our available cash funds in short-term bank deposits.

Pursuant to the sales agreement signed with BTIG in October 2017, we may sell, from time to time, and at our discretion, up to \$30 million of our ADSs through BTIG during the term of the sales agreement. As of the date of this report, we have an available balance under the facility of \$30 million.

Net cash used in operating activities was \$14.2 million for the nine months ended September 30, 2017, compared with net cash used in operating activities of \$10.4 million for the nine months ended September 30, 2016. The \$3.8 million increase in net cash used in operating activities during the nine-month period in 2017, compared to the nine-month period in 2016, was primarily the result of increased research and development expenses in the 2017 period.

Net cash used in investing activities for the nine months ended September 30, 2017 was \$19.5 million, compared to net cash provided by investing activities of \$7.3 million for the nine months ended September 30, 2016. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the acquisition of Agalimmune and investment in iPharma.

Net cash provided by financing activities for the nine months ended September 30, 2017 was \$37.7 million, compared to net cash provided by financing activities of \$1.5 million for the nine months ended September 30, 2016. The increase in cash flows from financing activities primarily reflects our public offering completed in April 2017 and the registered direct placement completed in July 2017.

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 2019, 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.