
**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 August 2018

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 August 13, 2018, the registrant will issue a press release announcing its financial results for the three and six months ended June 30, 2018. The registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of June 30, 2018, and for the three and six months then ended. Attached hereto are the following exhibits:

[Exhibit 1: Registrant's press release dated August 13, 2018;](#)

[Exhibit 2: Registrant's condensed consolidated interim financial statements as of June 30, 2018, and for the three and six months and then ended; and](#)

[Exhibit 3 - Registrant's operating and financial review as of June 30, 2018, and for the three and six months then ended.](#)

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

BioLineRx Ltd.

By: /s/ Philip Serlin
Philip Serlin
Chief Executive Officer

Dated: August 13, 2018



For Immediate Release

BioLineRx Reports Second Quarter 2018 Financial Results

Tel Aviv, Israel, August 13, 2018 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the second quarter ended June 30, 2018.

Highlights and achievements during the second quarter 2018 and to date:

Continued progress made on multiple clinical trials for the Company's lead oncology program, BL-8040:

Positive data from successful completion of first lead-in patient cohort of the GENESIS trial, a double-blind, placebo-controlled, Phase 3 trial comparing BL-8040 in combination with granulocyte colony-stimulating factor (G-CSF), to G-CSF alone, for the mobilization of hematopoietic stem cells (HSCs) used for autologous transplantation in multiple myeloma patients. Results from first 11 patients prompted Data Monitoring Committee (DMC) to recommend early continuation to randomized placebo-controlled part 2 of trial; data show that 9/11 patients (82%) reached primary endpoint threshold of $\geq 6 \times 10^6$ CD34 cells/kg with only one dose of BL-8040 and in up to 2 apheresis sessions;

Expansion of immuno-oncology collaboration with Merck & Co., Inc., Kenilworth, N.J. (Merck), supporting a Phase 2a program investigating BL-8040 in combination with KEYTRUDA in pancreatic cancer patients. Under the expansion, a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy will be added to the ongoing COMBAT/KEYNOTE-202 study, with a specific focus on second line patients;

Presentation at the 2018 European Hematology Association (EHA) Conference of very encouraging long-term overall survival results in Phase 2a trial in relapsed/refractory AML, demonstrating that the combination of BL-8040 with high-dose Cytarabine (HiDAC) significantly improved overall survival, compared with historical data for HiDAC monotherapy;

Grant of European patent covering use of BL-8040 with Cytarabine for treating AML; valid through March 2034 with up to five years' patent term extension.

The Company also announced advancements made in its second immuno-oncology compound, AGI-134:

Initiation of multicenter, open-label Phase 1/2a study in the UK and Israel, with possible expansion to the US and additional countries in Europe in 2019; study will evaluate the safety and tolerability of AGI-134, as a monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors.

Expected significant milestones in next 18 months:

Top-line results in immuno-oncology Phase 2a COMBAT study in pancreatic cancer for BL-8040 in combination with KEYTRUDA, under collaboration with Merck, to be presented at the European Society for Medical Oncology (ESMO) Congress in October 2018;

Partial results in Phase 1b/2 study in pancreatic cancer under Genentech immuno-oncology collaboration, investigating BL-8040 in combination with Genentech's atezolizumab, expected in H2 2018;

Potential interim analysis of Phase 2b BLAST study in AML consolidation in mid-2019;

Results from additional cohort in Phase 2a COMBAT study under expansion of Merck collaboration, investigating triple combination of BL-8040, KEYTRUDA and chemotherapy in pancreatic cancer, by end of 2019;

"We are very encouraged by the clinical results achieved to-date in the major indications being developed under our BL-8040 platform, as we continue to advance the asset towards registration," stated Philip A. Serlin, Chief Executive Officer of BioLineRx. "Specifically, positive results from the initial lead-in cohort in the Phase 3 GENESIS trial, and the resulting DMC recommendation for an early continuation to the randomized, double-blind, placebo-controlled part of the trial, is an important clinical achievement for BL-8040. The data continue to demonstrate BL-8040's robust efficacy in stem-cell mobilization for autologous transplantation, including the potential to reduce the number of required apheresis sessions to one session in the majority of patients, versus multiple sessions under current practice. Building on this success, data from our ongoing COMBAT Phase 2a immuno-oncology trial support continued development in pancreatic cancer, as we expand our collaboration with Merck, with the addition to the existing study of a new cohort with 30-50 patients investigating the triple combination of BL-8040, KEYTRUDA and chemotherapy. The new cohort will focus on second-line pancreatic cancer patients and we are hopeful for significant synergies from the triple drug combination in this very difficult-to-treat population."

Mr. Serlin added, “In addition, we are excited about the data we continue to accumulate from our Phase 2a study in relapsed/refractory AML, with further significant improvement in overall survival data recently presented at EHA. We are focused on determining the appropriate next clinical development steps for this indication, in light of this very encouraging data. With regard to our second main asset, AGI-134, we were pleased to initiate a Phase 1/2a study in multiple solid tumors. AGI-134 represents a new mechanistic class of cancer immunotherapies with a unique and highly differentiated mode of action, and we are pleased to begin our clinical evaluation of its potential.”

“Over the next few quarters, we look forward to reporting on key milestones. These include top line results in our Phase 2a COMBAT study, partial results in the Phase 1b/2 pancreatic cancer trial under our collaboration with Genentech, and a potential interim analysis on the Phase 2b BLAST study in AML consolidation therapy,” concluded Mr. Serlin.

Financial Results for the Second Quarter Ended June 30, 2018

Research and development expenses for the three months ended June 30, 2018 were \$4.5 million, an increase of \$0.4 million, or 10.4%, compared to \$4.1 million for the three months ended June 30, 2017. The increase resulted primarily from higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230. Research and development expenses for the six months ended June 30, 2018 were \$9.6 million, an increase of \$1.9 million, or 24.9%, compared to \$7.7 million for the six months ended June 30, 2017. The increase resulted primarily from higher expenses associated with new BL-8040 clinical studies commenced during 2017, as well as higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230.

Sales and marketing expenses for the three months ended June 30, 2018 were \$0.4 million, an increase of \$0.1 million, or 25%, compared to \$0.3 million for the three months ended June 30, 2017. The increase resulted primarily from one-time consulting fees related to market research in the 2018 period. Sales and marketing expenses for the six months ended June 30, 2018 were \$0.9 million, a decrease of \$0.1 million, or 12.9%, compared to \$1.0 million for the six months ended June 30, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 paid in the 2017 period.

General and administrative expenses for the three months ended June 30, 2018 were \$0.9 million, similar to the comparable period in 2017. General and administrative expenses for the six months ended June 30, 2018 were \$1.9 million, similar to the comparable period in 2017.

The Company's operating loss for the three months ended June 30, 2018 amounted to \$5.7 million, compared with an operating loss of \$5.2 million for the corresponding 2017 period. The Company's operating loss for the six months ended June 30, 2018 amounted to \$12.4 million, compared with an operating loss of \$10.5 million for the corresponding 2017 period.

Non-operating income (expenses) for the three and six months ended June 30, 2018 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet and the capital gain from realization of the investment in iPharma. Non-operating income (expenses) for the three and six months ended June 30, 2017 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial income amounted to \$0.3 million for the three months ended June 30, 2018, similar to the comparable period in 2017. Net financial income for both periods relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits. Net financial income amounted to \$0.3 million for the six months ended June 30, 2018, compared to net financial income of \$0.8 million for the six months ended June 30, 2017. Net financial income for the 2018 period primarily relates to investment income earned on bank deposits, offset by losses recorded on foreign currency hedging transactions. Net financial income for the 2017 period relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on bank deposits.

The Company's net loss for the three months ended June 30, 2018 amounted to \$4.8 million, compared with a net loss of \$4.9 million for the corresponding period. The Company's net loss for the six months ended June 30, 2018 amounted to \$11.0 million, compared with a net loss of \$9.8 million for the corresponding 2017 period.

The Company held \$41.1 million in cash, cash equivalents and short-term bank deposits as of June 30, 2018.

Net cash used in operating activities was \$13.0 million for the six months ended June 30, 2018, compared with net cash used in operating activities of \$8.0 million for the six months ended June 30, 2017. The \$5.0 million increase in net cash used in operating activities during the six-month period in 2018, compared to the six-month period in 2017, was the result of increased research and development expenses in the 2018 period, as well as a decrease in accounts payable and accruals.

Net cash provided by investing activities was \$10.8 million for the six months ended June 30, 2018, compared to net cash used in investing activities of \$16.0 million for the six months ended June 30, 2017. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the investment in Agalimmune in 2017 and realization of the investment in iPharma in 2018.

Net cash provided by financing activities was \$2.8 million for the six months ended June 30, 2018, compared to net cash provided by financing activities of \$28.3 million for the six months ended June 30, 2017. The decrease in cash flows from financing activities reflects the public offering completed in April 2017.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, August 13, 2018 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 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 on the [Investor Relations](#) page of BioLineRx's website. A dial-in replay of the call will be available until August 16, 2018; please dial +1-877-456-0009 from the U.S. or +972-3-925-5937 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 has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. 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 is conducting 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.biolinerx.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 6, 2018. 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)

	December 31,	June 30,
	2017	2018
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,110	5,789
Short-term bank deposits	44,373	35,339
Prepaid expenses	307	1,231
Other receivables	586	438
Total current assets	50,376	42,797
NON-CURRENT ASSETS		
Long-term prepaid expenses	61	63
Long-term investment	1,000	-
Property and equipment, net	2,505	2,318
Intangible assets, net	7,023	7,035
Total non-current assets	10,589	9,416
Total assets	60,965	52,213
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	4,128
Other	1,113	1,117
Total current liabilities	6,722	5,338
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	109
Warrants	1,205	580
Total non-current liabilities	1,362	689
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	6,027
EQUITY		
Ordinary shares	2,836	2,920
Share premium	240,682	243,883
Capital reserve	10,337	11,343
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(199,558)	(210,544)
Total equity	52,881	46,186
Total liabilities and equity	60,965	52,213

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2018	2017	2018
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,062)	(4,484)	(7,652)	(9,554)
SALES AND MARKETING EXPENSES	(288)	(360)	(969)	(844)
GENERAL AND ADMINISTRATIVE EXPENSES	(844)	(883)	(1,874)	(1,958)
OPERATING LOSS	(5,194)	(5,727)	(10,495)	(12,356)
NON-OPERATING INCOME (EXPENSES), NET	(4)	663	(9)	1,125
FINANCIAL INCOME	304	287	761	462
FINANCIAL EXPENSES	(3)	(11)	(9)	(217)
NET LOSS AND COMPREHENSIVE LOSS	(4,897)	(4,788)	(9,752)	(10,986)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.05)	(0.05)	(0.13)	(0.10)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	94,487,470	106,630,704	76,571,351	106,524,332

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

	Ordinary shares	Share premium	Other Comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2017	1,513	199,567	(1,416)	10,569	(175,206)	35,027
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2017:						
Issuance of share capital, net	1,056	30,241	-	-	-	31,297
Employee stock options exercised	1	320	-	(321)	-	-
Employee stock options forfeited and expired	-	1,240	-	(1,240)	-	-
Share-based compensation	-	-	-	858	-	858
Comprehensive loss for the period	-	-	-	-	(9,752)	(9,752)
BALANCE AT JUNE 30, 2017	2,570	231,368	(1,416)	9,866	(184,958)	57,430
	in USD thousands					
	Ordinary shares	Share premium	Other Comprehensive loss	Capital reserve	Accumulated deficit	Total
BALANCE AT JANUARY 1, 2018	2,836	240,682	(1,416)	10,337	(199,558)	52,881
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2018:						
Issuance of share capital, net	83	2,764	-	-	-	2,847
Employee stock options exercised	-	399	-	(399)	-	-
Employee stock options forfeited and expired	1	38	-	(39)	-	-
Share-based compensation	-	-	-	1,444	-	1,444
Comprehensive loss for the period	-	-	-	-	(10,986)	(10,986)
BALANCE AT JUNE 30, 2018	2,920	243,883	(1,416)	11,343	(210,544)	46,186

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

	Six months ended June 30,	
	2017	2018
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(9,752)	(10,986)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,746	(2,054)
Net cash used in operating activities	(8,006)	(13,040)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(36,422)	(15,000)
Maturities of short-term deposits	24,233	24,385
Proceeds from realization of long-term investment	-	1,500
Purchase of property and equipment	(90)	(76)
Purchase of intangible assets	(3,721)	(37)
Net cash provided by (used in) investing activities	(16,000)	10,772
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	28,312	2,847
Repayments of bank loan	(47)	(47)
Net cash provided by financing activities	28,265	2,800
INCREASE IN CASH AND CASH EQUIVALENTS	4,259	532
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	218	147
CASH AND CASH EQUIVALENTS - END OF PERIOD	6,946	5,789

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

		Six months ended June 30,	
		2017	2018
		in USD thousands	
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization		250	288
Long-term prepaid expenses		(1)	(2)
Exchange differences on cash and cash equivalents		(218)	(147)
Gain on adjustment of warrants to fair value		-	(625)
Gain on realization of long-term investment		-	(500)
Share-based compensation		858	1,444
Interest and exchange rate differences on short-term deposits		(273)	(351)
Interest and linkage differences on bank loan		-	(1)
		616	106
Changes in operating asset and liability items:			
Increase in prepaid expenses and other receivables		(623)	(776)
Increase (decrease) in accounts payable and accruals		1,753	(1,384)
		1,130	(2,160)
		1,746	(2,054)
Supplementary information on interest received in cash		258	377
Supplementary non-cash investment		2,985	-

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2018

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2018

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2017	June 30, 2018
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CURRENT ASSETS		
Cash and cash equivalents	5,110	5,789
Short-term bank deposits	44,373	35,339
Prepaid expenses	307	1,231
Other receivables	586	438
Total current assets	50,376	42,797
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Long-term prepaid expenses	61	63
Long-term investment	1,000	-
Property and equipment, net	2,505	2,318
Intangible assets, net	7,023	7,035
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Liabilities and equity		
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COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	6,027
EQUITY		
Ordinary shares	2,836	2,920
Share premium	240,682	243,883
Capital reserve	10,337	11,343
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(199,558)	(210,544)
Total equity	52,881	46,186
Total liabilities and equity	60,965	52,213

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

BioLineRx Ltd.

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(UNAUDITED)

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

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CASH FLOWS - OPERATING ACTIVITIES		
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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Six months ended June 30,	
	2017	2018
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	250	288
Long-term prepaid expenses	(1)	(2)
Exchange differences on cash and cash equivalents	(218)	(147)
Gain on adjustment of warrants to fair value	-	(625)
Gain on realization of long-term investment	-	(500)
Share-based compensation	858	1,444
Interest and exchange rate differences on short-term deposits	(273)	(351)
Interest and linkage differences on bank loan	-	(1)
	616	106
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(623)	(776)
Increase (decrease) in accounts payable and accruals	1,753	(1,384)
	1,130	(2,160)
	1,746	(2,054)
Supplementary information on interest received in cash	258	377
Supplementary non-cash investment	2,985	-

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

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 also 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, with a focus on the field of immuno-oncology.

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 June 30, 2018, and for the three and six months then ended, were approved by the Board of Directors on August 7, 2018, 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 June 30, 2018 and for the three and six 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 International Financial Reporting Standards (“IFRS”). The condensed consolidated interim financial statements should be read in conjunction with the Company’s annual financial statements as of December 31, 2017 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS. The results of operations for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of these interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2017 and for the year then ended, except as follows: (i) IFRS No. 9, “Financial Instruments,” which was effective from January 1, 2018, did not have a material effect on the Company’s financial statements; (ii) IFRS No. 15, “Revenue from Contracts with Customers,” also effective from January 1, 2018, is not relevant to the Company’s financial statements because the Company does not have any revenues; (iii) IFRS No. 16, “Leases,” which is not yet in effect and which the Company has not adopted early, was disclosed in the 2017 annual financial statements. The Company is currently evaluating the potential effect of this new guidance on its consolidated financial statements.

NOTE 4 – ISSUANCES OF SHARE CAPITAL AND WARRANTS

a. At-the-market (“ATM”) sales agreement with BTIG

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 \$30.0 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. From the effective date of the agreement through June 30, 2018, 3,880,210 ADSs were sold under the program for total net proceeds of approximately \$3.9 million, leaving an available balance under the facility of approximately \$26.0 million as of June 30, 2018.

b. 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 June 30, 2018 was based on the then current price of an ADS, a risk-free interest rate of 2.63% and an average standard deviation of 53.8%.

NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)**NOTE 5 – SHAREHOLDERS' EQUITY**

As of December 31, 2017 and June 30, 2018, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2017	June 30, 2018
Authorized share capital	250,000,000	250,000,000
Issued and paid-up share capital	105,063,437	108,029,516
	In USD and NIS	
	December 31, 2017	June 30, 2018
Authorized share capital (in NIS)	25,000,000	25,000,000
Issued and paid-up share capital (in NIS)	10,506,344	10,802,952
Issued and paid-up share capital (in USD)	2,836,139	2,919,910

NOTE 6 – REALIZATION OF INVESTMENT IN JOINT VENTURE (iPharma)

In 2016, the Company established a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China, with each party contributing initial seed capital to the venture of \$1.0 million. The joint venture, named iPharma, focused on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. In April 2018, the Company sold its holdings in the joint venture to I-Bridge Capital for cash consideration of \$1.5 million. The gain of \$0.5 million is included in non-operating income in the statement of comprehensive loss.

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 6, 2018 (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 two clinical-stage therapeutic candidates – BL-8040 and AGI-134 – and one commercialized product – BL-5010. In addition, we have one other therapeutic candidate in pre-clinical development. We have generated 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.

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 (a tradename of Merck & Co., Inc., Kenilworth, New Jersey) in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT/KEYNOTE-202 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 from the monotherapy portion of this study show that BL-8040 increases infiltration of T cells into the tumor, induces an increase in the number of total immune cells in the peripheral blood, and decreases the frequency of peripheral blood regulatory T cells (Tregs). We have expanded the COMBAT/KEYNOTE-202 study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. Regulatory submissions required to conduct the additional arm of the study have been made and its initiation is planned for the fourth quarter of 2018. Top-line results from the initial dual combination arm of trial are expected in the second half of 2018, while results from the new triple combination arm of the study are expected in the second half of 2019.
- 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. Top-line results from this study are anticipated in the first half of 2019.
- Ø In September 2016, we entered into a collaboration with Genentech, Inc., or Genentech (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 TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in various solid tumors and hematologic malignancies. The clinical study collaboration between us and Genentech is part of MORPHEUS, Roche's novel cancer immunotherapy development platform. 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. A third Phase 1b/2 study is planned in lung cancer; however, the timing for initiation of this study is currently unclear. 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, or 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 the Society of Hematologic Oncology and ASH in September and December 2016, respectively, we presented detailed, positive safety and response rate data for subjects treated with a combination of BL-8040 and high dose cytarabine, or HiDAC. At the annual meeting of the European Hematology Association (EHA) in June 2018, we presented positive overall survival data from the long-term follow-up part of this study. We continue to monitor long-term survival data for patients in the study and, in parallel, are planning our next clinical development steps in this indication.
- 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 conducting 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 continue to discuss with our collaboration partners the potential conduct of an interim analysis on this study based on various factors, including the occurrence of a minimum number of reported relapse events and/or exposure to provide a reasonable statistical powering for the analysis. Our current best estimate for the timing of such potential interim analysis is mid-2019, with top-line results from the trial expected in 2021.
- Ø In September 2017, we initiated a Phase 1b/2 trial in AML, known as the BATTLE trial, under the collaboration with Genentech referred to above in “— Solid tumors.” The trial will focus on the maintenance treatment of patients with intermediate- and high-risk AML who have achieved a complete response following induction and consolidation therapy. Up to 60 patients are planned to be enrolled in this single arm, open-label study, planned to take place at approximately 22 sites in the U.S., Europe and Israel. Top-line results from this study are 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 in allogeneic stem-cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology, or WUSM. In May 2018, we announced positive top-line results of this study showing, among other things, 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.

- Ø In December 2017, we commenced a randomized, controlled Phase 3 registrational trial for BL-8040, known as the GENESIS trial, for the mobilization of HSCs for autologous transplantation in patients with multiple myeloma. The trial commenced with an initial dose-confirmation, lead-in part, designed to include 10-30 patients, after which, following approval from the study's Data Monitoring Committee, the trial is to progress to the randomized, placebo-controlled main part, designed to include 177 patients in more than 25 centers. Following review of the positive results from treatment of the first 11 patients, the Data Monitoring Committee recommended that the lead-in part of the study should be stopped and that the Company should move immediately to the second part. Top-line results of this randomized, placebo-controlled main part of the study are expected in 2020.

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 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 regression of established primary tumors after injection with AGI-134 and 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. In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors. Additional objectives are to perform a wide array of biomarker studies, to demonstrate the mechanism of AGI-134 and to assess its efficacy by clinical and pharmacodynamic parameters.
 - 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/verrucae) 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. We are currently developing one pre-clinical project, BL-1230, in the framework of this collaboration, with the ongoing scientific support of Novartis. The companies are continuing to evaluate late pre-clinical and early clinical projects, with the goal of potentially bringing additional projects into our pipeline.

In December 2014, we entered into an exclusive out-licensing arrangement with 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. 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 2016, we established a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China, with each party contributing initial seed capital to the venture of \$1.0 million. The joint venture, named iPharma, focused on the development of innovative clinical and pre-clinical therapeutic candidates to serve the Chinese and global healthcare markets. As the joint venture’s activities were not part of our current strategic focus, we decided that participation in the joint venture would no longer be advantageous for the Company. Accordingly, in April 2018, we sold our holdings in the joint venture to I-Bridge Capital for cash consideration of \$1.5 million. The gain of \$0.5 million is recorded in our June 30, 2018 financial statements.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Bellerophon Therapeutics, Inc., or 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. In August 2018, Bellerophon exercised its contractual right to terminate the licensing arrangement based on its determination that the results of the clinical trial it had carried out did not warrant further development of BL-1040. As a result of Bellerophon’s decision, we terminated our in-license agreement with B.G. Negev Technologies and Applications Ltd. See “Recent Company Developments — Termination of Therapeutic Candidate.”

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 June 30, 2018, we held \$41.1 million of cash, cash equivalents and short-term bank deposits.

Recent Company Developments

Pre-Clinical and Clinical Development

BL-8040

Clinical Trials

In July 2018, we announced expansion of the COMBAT/KEYNOTE-202 trial to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. The triple combination arm will focus on second-line pancreatic cancer patients and will test the potentially synergistic effects of chemotherapy with the combination of BL-8040 and KEYTRUDA.

In August 2018, we announced positive results from the lead-period of the GENESIS trial. Results of the first 11 patients show that BL-8040 in combination with standard G-CSF treatment is safe and tolerable. In addition, the data show that nine of the 11 patients (82%) reached the primary endpoint threshold of $\geq 6 \times 10^6$ CD34 cells/kg with only one dose of BL-8040 and in up to 2 apheresis sessions. Furthermore, seven of the 11 patients (64%) reached the threshold of $\geq 6 \times 10^6$ CD34 cells/kg in a single apheresis session only. These data demonstrate the potential of BL-8040 treatment to reduce the number of administrations and apheresis sessions, as well as hospitalization costs, related to the preparation of multiple myeloma patients for autologous HSC transplantation. Based on these data, the Data Monitoring Committee recommended that the lead-in part of the study should be stopped and that the Company should move immediately to the randomized, placebo-controlled part of the study.

In June 2018, at the 23rd Congress of the EHA in Stockholm, Sweden, we reported long-term survival data that showed significantly enhanced overall survival of r/r AML patients treated with a combination of BL-8040 and HiDAC in the Phase 2a proof-of-concept trial carried out in the U.S. and Israel. The response rate for all dosing levels was 29% and median overall survival was 9.1 months, compared with historical data on overall survival of 6.1 months for HiDAC alone. In addition, a new finding showed a statistically significant correlation between patient response and the mobilization of AML blasts. Responding patients demonstrated a clear and significant increase in the number of AML blasts in the peripheral blood following BL-8040 treatment, whereas non-responding patients were largely unaffected. In patients receiving the 1.5 mg/kg dose selected for expansion (n=23), the response rate was 39% and median overall survival was 10.7 months with 1-year, 2-year and 3-year survival rates of 38.1%, 23.8% and 23.8%, respectively. Furthermore, median overall survival for responding patients at the 1.5 mg/kg dose (n=9) was 21.8 months, with 1-year, 2-year and 3-year survival rates of 66.7%, 44.4% and 44.4%, respectively. Responding patients also demonstrated a statistically significant mean 6.3-fold increase (p=0.003) in the number of AML blasts in the peripheral blood following BL-8040 monotherapy treatment, whereas in non-responding patients the mean-fold increase was minor and non-significant (1.66-fold; p=0.21).

At the EHA Congress, we also presented positive top-line results from the Phase 2 clinical trial being carried out at WUSM to assess BL-8040 as a single agent for hematopoietic stem cell mobilization in an allogeneic transplantation setting. Mobilization of hematopoietic stem and progenitor cells, or HSPCs, for the purpose of donor (allogeneic) transplantation after high-dose chemotherapy is currently performed using a 4-5 day treatment cycle with G-CSF and a 1-2 day apheresis procedure. Single-agent treatment with BL-8040 showed similar efficacy in only one administration. In addition, BL-8040 showed non-inferiority in recipient engraftment, with all transplanted recipients successfully engrafting with BL-8040-mobilized grafts.

Intellectual Property

In May 2018, the European Patent Office (EPO) issued a Decision to Grant a patent claiming the use of BL-8040 with cytarabine for the treatment of AML. This patent will be valid through March 2034, with the option of up to five years' patent term extension, thus providing significant additional intellectual property protection for the use of BL-8040 for AML. Member patents were also granted in Japan and Hong Kong. Additional corresponding patent applications are pending in China (a Notice of Acceptance was received), Israel (a Notice of Acceptance was received), the United States, India, Korea, Mexico, Brazil, Canada and Australia.

Clinical Trials

In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that will be a multicenter, open-label study that will take place in the UK and Israel, with possible expansion to the US and additional countries in Europe in 2019. The study is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors. Additional objectives are to perform a wide array of biomarker studies and to demonstrate the mechanism of AGI-134. Furthermore, efficacy will be assessed by clinical and pharmacodynamic parameters. The study will be comprised of two parts: (i) an accelerated dose-escalation part to assess the safety and tolerability of intratumorally injected AGI-134 as a monotherapy, as well as to determine the maximum tolerated dose and the recommended dose for part 2 of the study; and (ii) a dose expansion part at the recommended dose, comprised of three cohorts and designed to assess the safety, tolerability and anti-tumor activity of AGI-134 as a monotherapy in a basket cohort of multiple solid tumor types, as well as in two additional cohorts in combination with an immune checkpoint inhibitor – in metastatic colorectal cancer and head and neck squamous cell carcinoma.

Capital Resources

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 \$26.0 million.

Corporate matters

On April 23, 2018, we received written notice (the “Notification Letter”) from The Nasdaq Stock Market (“Nasdaq”) stating that we were not in compliance with the minimum bid price requirement set forth in Nasdaq’s rules for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) (the “Rule”) requires listed securities to maintain a minimum bid price of \$1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our ADSs for the 30 consecutive business days beginning March 8, 2018, we no longer met the minimum bid price requirement as of the date of the Notification Letter. We were provided with 180 days, or until October 22, 2018, to regain compliance with the Rule.

Innovative Pharmaceutical Concepts, or IPC, the licensor of BL-5010, has recently notified us claiming it believes we have not fulfilled certain aspects of the BL-5010 license agreement, and has threatened to terminate the license agreement. We believe that IPC’s claims are groundless and disagree completely with its assertions. We intend to avail ourselves of all legal remedies available in order to protect our rights, and those of Perrigo, to the BL-5010 product. We believe this matter is not material to our business or financial condition, since BL-5010 is no longer within our strategic focus on oncology and immunology, and future cash flows from sales of the product are not expected to be material to our future operating results.

Termination of Therapeutic Candidate

As disclosed above, we formally terminated the BL-1040 project as a result of Bellerophon’s decision to terminate its license agreement with BioLine. The BL-1040 project had not been active in any significant way since late 2015.

Revenues

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

We expect our revenues, if any, for the next several years to be derived primarily from future payments under our current out-licensing agreement with Perrigo 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"> 1. Phase 2a study for relapsed or refractory AML completed 2. Phase 2b study in AML consolidation treatment line (BLAST) ongoing 3. Phase 2 study in allogeneic stem-cell mobilization completed 4. Phase 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; partial results presented at ASCO-GI in January 2018 5. Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, ongoing 6. Phase 1b/2 study in AML, in collaboration with Genentech (BATTLE), commenced 7. Phase 1b/2 studies in pancreatic and gastric cancer, under collaboration with Genentech (MORPHEUS) ongoing 8. Phase 3 registration study in autologous stem-cell mobilization commenced (GENESIS); partial results from initial dose-confirmation, lead-in part of study announced August 2018 	<ol style="list-style-type: none"> 1. Follow-up for overall survival is ongoing; evaluation and decision regarding next clinical development steps 2. Possible interim results in mid-2019; top-line results expected in 2021 3. Follow-up on acute and chronic GvHD by H2 2019 4. Top-line results from dual combination arm expected in H2 2018; top-line results from triple combination arm expected in H2 2019 5. Top-line results anticipated in H1 2019 6. Top-line results expected in 2020 7. Partial results in pancreatic cancer expected by end of 2018 8. Top-line results from randomized, placebo-controlled main part of study expected in 2020
AGI-134	Phase 1/2a study commenced in July 2018	Initial results from monotherapy arm of study expected by end of 2020
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 one additional project in the pre-clinical stage of development (BL-1230) that is 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, 2015, 2016 and 2017; for the six months ended June 30, 2018; and on an aggregate basis since project inception.

	Year Ended December 31,			Six Months Ended	Total Costs Since
	2015	2016	2017	June 30, 2018	Project Inception
	<i>(in thousands of U.S. dollars)</i>				
BL-8040	7,045	8,281	12,369	5,088	42,114
AGI-134	-	-	3,730	2,039	5,769
BL-5010	400	75	32	37	4,213
Other projects	3,573	2,647	2,628	1,549	118,308
Total gross direct project costs	11,018	11,003	18,759	8,713	170,404

From our inception through June 30, 2018, we have incurred research and development expenses of approximately \$206.1 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 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, as well as the capital gain from realization of our investment in iPharma.

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, 2017.

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 six-month periods ended June 30, 2018 and 2017.

Cost of revenues

We did not record any cost of revenues during each of the three- or six-month periods ended June 30, 2018 and 2017.

Research and development expenses

At December 31, 2014, our drug development pipeline 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. During 2017, we terminated two therapeutic candidates in our pipeline, and added one therapeutic candidate to the pipeline, so that our drug development pipeline as of December 31, 2017 consisted of seven therapeutic candidates. Subsequent to December 31, 2017, we terminated three therapeutic candidates in our pipeline, so that our drug development pipeline as of the date of this report consists of four 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 June 30,			Six months ended June 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Research and development expenses, net	4,062	4,484	422	7,652	9,554	1,902

Comparison of three-month periods ending June 30, 2018 and 2017

Research and development expenses for the three months ended June 30, 2018 were \$4.5 million, an increase of \$0.4 million, or 10.4%, compared to \$4.1 million for the three months ended June 30, 2017. The increase resulted primarily from higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230.

Comparison of six-month periods ending June 30, 2018 and 2017

Research and development expenses for the six months ended June 30, 2018 were \$9.6 million, an increase of \$1.9 million, or 24.9%, compared to \$7.7 million for the six months ended June 30, 2017. The increase resulted primarily from higher expenses associated with new BL-8040 clinical studies commenced during 2017, as well as higher expenses associated with AGI-134, including final preparations for initiation of the Phase 1/2a study, and expenses associated with BL-1230.

Sales and marketing expenses

	Three months ended June 30,			Six months ended June 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Sales and marketing expenses	288	360	72	969	844	(125)

Comparison of three-month periods ending June 30, 2018 and 2017

Sales and marketing expenses for the three months ended June 30, 2018 were \$0.4 million, an increase of \$0.1 million, or 25%, compared to \$0.3 million for the three months ended June 30, 2017. The increase resulted primarily from one-time consulting fees related to market research in the 2018 period.

Comparison of six-month periods ending June 30, 2018 and 2017

Sales and marketing expenses for the six months ended June 30, 2018 were \$0.9 million, a decrease of \$0.1 million, or 12.9%, compared to \$1.0 million for the six months ended June 30, 2017. The decrease resulted primarily from one-time legal fees related to AGI-134 paid in the 2017 period.

General and administrative expenses

	Three months ended June 30,			Six months ended June 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
General and administrative expenses	844	883	39	1,874	1,958	84

Comparison of three-month periods ending June 30, 2018 and 2017

General and administrative expenses for the three months ended June 30, 2018 were \$0.9 million, similar to the comparable period in 2017.

Comparison of six-month periods ending June 30, 2018 and 2017

General and administrative expenses for the six months ended June 30, 2018 were \$1.9 million, similar to the comparable period in 2017.

Non-operating income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Non-operating income (expenses), net	(4)	663	667	(9)	1,125	1,134

Comparison of three-month and six-month periods ending June 30, 2018 and 2017

Non-operating income (expenses) for the three and six months ended June 30, 2018 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet and the capital gain from realization of our investment in iPharma. Non-operating income (expenses) for the three and six months ended June 30, 2017 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments were highly influenced by our share price at each period end (revaluation date).

Financial income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Financial income	304	287	(17)	761	462	(299)
Financial expenses	(3)	(11)	(8)	(9)	(217)	(208)
Net financial income (expense)	301	276	(25)	752	245	(507)

Comparison of three-month periods ending June 30, 2018 and 2017

We recognized net financial income of \$0.3 million for the three months ended June 30, 2018, similar to the comparable period in 2017. Net financial income for both periods relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on our bank deposits.

Comparison of six-month periods ending June 30, 2018 and 2017

We recognized net financial income of \$0.3 million for the six months ended June 30, 2018 compared to net financial income of \$0.8 million for the six months ended June 30, 2017. Net financial income for the 2018 period primarily relates to investment income earned on our bank deposits, offset by losses recorded on foreign currency hedging transactions. Net financial income for the 2017 period relates primarily to gains recorded on foreign currency hedging transactions and investment income earned on our 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 June 30, 2018, we held \$41.1 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 our ATM Program with BTIG, we may sell, from time to time, and at our discretion, up to \$30 million of our ADSs during the term of the program. During the six months ended June 30, 2018, we sold 2,935,244 ADSs under the program, resulting in net proceeds to BioLine of approximately \$2.9 million (net of \$90,000 commissions paid to BTIG). As of the date of this report, we have an available balance under the program of approximately \$26.0 million.

Net cash used in operating activities was \$13.0 million for the six months ended June 30, 2018, compared with net cash used in operating activities of \$8.0 million for the six months ended June 30, 2017. The \$5.0 million increase in net cash used in operating activities during the six-month period in 2018, compared to the six-month period in 2017, was the result of increased research and development expenses in the 2018 period, as well as a decrease in accounts payable.

Net cash provided by investing activities was \$10.8 million for the six months ended June 30, 2018, compared to net cash used in investing activities of \$16.0 million for the six months ended June 30, 2017. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits, as well as the investment in Agalimmune in 2017 and the realization of our investment in iPharma in 2018.

Net cash provided by financing activities was \$2.8 million for the six months ended June 30, 2018, compared to net cash provided by financing activities of \$28.3 million for the six months ended June 30, 2017. The decrease in cash flows from financing activities reflects the public offering completed in April 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 into 2020, 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.