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 2018

BioLineRx Ltd.

(Translation of Registrant's name into English)

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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 8, 2018, the Registrant will issue a press release announcing its financial results for the three and nine months ended September 30, 2018. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2018 and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 8, 2018;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2018 and for the three and nine months then ended; and

Exhibit 3 - Registrant's operating and financial review as of September 30, 2018 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 8, 2018

Exhibit 1

For Immediate Release

BioLineRx Reports Significant Progress Across Oncology Programs and Provides Third Quarter Financial Update

Management to hold conference call at 10:00 am EST

TEL AVIV, Israel, November 8, 2018 -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today reports its financial results for the third quarter ended September 30, 2018 and provided a corporate update.

Highlights and achievements during the third quarter 2018 and subsequent period:

- Reported positive results from lead-in period of Phase 3 GENESIS trial in stem-cell mobilization; data from first lead-in patient cohort prompted Data Monitoring Committee to recommend early continuation to randomized placebo-controlled part 2 of trial;

- Presented data from ongoing Phase 2a COMBAT/KEYNOTE-202 pancreatic cancer study in collaboration with Merck at the ESMO 2018 Congress demonstrating that BL-8040 in combination with KEYTRUDA® (pembrolizumab) showed encouraging disease control and overall survival in patients with metastatic pancreatic cancer; compelling pharmacodynamic data also demonstrated T-cell infiltration into tumors and a reduction of the tumor immuno-suppressive microenvironment;

- Based on COMBAT/KEYNOTE-202 results, announced expansion of immuno-oncology collaboration with Merck to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy;

- Entered into agreement with Biokine Therapeutics to increase the Company’s economic stake in BL-8040 to 80% from the previous level of 60%;

- Initiated Phase 1/2a multicenter, open-label clinical study in the UK and Israel for AGI-134, a novel immunotherapy evoking a direct anti-tumor response and vaccine effect for the treatment of solid tumors;

“We made significant progress during the third quarter and subsequent period advancing clinical development of both of our oncology programs – BL-8040 and AGI-134,” said Philip Serlin, Chief Executive Officer of BioLineRx. “The Phase 3 GENESIS study in stem-cell mobilization is now advancing in the randomized placebo-controlled part 2 of the trial. We are also rapidly moving forward in our expanded collaboration with Merck in pancreatic cancer, on the basis of the encouraging results recently presented at ESMO, with an additional cohort adding chemotherapy to the BL-8040/KEYTRUDA combination. Further, we are very pleased to have initiated the first-in-human clinical study for AGI-134, our unique immunotherapy cancer vaccine. These achievements follow BL-8040’s very promising results in relapsed/refractory AML that were presented at the recent EHA Congress during the second quarter, showing significantly improved overall survival compared to historical data.”

“BL-8040 is currently being evaluated in eight Phase 2 or Phase 3 clinical trials in multiple oncology indications, four of which are being run under collaborations with global pharma companies. In addition, based on the very promising data seen in relapsed/refractory AML, we intend to further pursue this indication and we continue to evaluate the optimal clinical development pathway going forward. The broad dataset from BL-8040’s robust clinical development program was the motivation behind our recent decision to significantly increase our economics in BL-8040, and sets the stage for a catalyst-rich 2019,” Mr. Serlin concluded.

Expected significant milestones through end of 2019:

- Initiation of Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under collaboration with Merck by the end of 2018;

- Potential interim results from Phase 2 AML consolidation study in mid-2019;

- Initial safety results from part 1 of Phase 1/2a trial for AGI-134 in second half of 2019;

- Top-line results from the Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under collaboration with Merck toward the end of 2019;

- Top-line results from one or more of the solid tumor trials under collaboration with Genentech during 2019.

Financial Results for the Third Quarter Ended September 30, 2018

Research and development expenses for the three months ended September 30, 2018 were $5.0 million, a decrease of $0.6 million, or 11.1 %, compared to $5.6 million for the three months ended September 30, 2017. The decrease resulted primarily from higher expenses associated with drug product development and manufacturing for AGI-134 in the 2017 period. Research and development expenses for the nine months ended September 30, 2018 were $14.6 million, an increase of $1.3 million, or 9.6 %, compared to $13.3 million for the nine months ended September 30, 2017. The increase in the 2018 period resulted primarily from higher expenses associated with BL-8040, including the GENESIS and COMBAT trials; preparations for initiation of the AGI-134 clinical trial; and BL-1230.

Sales and marketing expenses for the three months ended September 30, 2018 were $0.3 million, similar to the comparable period in 2017. Sales and marketing expenses for the nine months ended September 30, 2018 were $1.1 million, a decrease of $0.1 million, or 6.7%, compared to $1.2 million for the nine months ended September 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 September 30, 2018 were $0.9 million, a decrease of $0.3 million, or 22.7%, compared to $1.2 million for the three months ended September 30, 2017. The decrease resulted from a decrease in fees paid for consulting services. General and administrative expenses for the nine months ended September 30, 2018 were $2.9 million, a decrease of $0.2 million, or 5.9%, compared to $3.0 million for the nine months ended September 30, 2017. The decrease also resulted from a decrease in fees paid for consulting services.

The Company’s operating loss for the three months ended September 30, 2018 amounted to $6.2 million, compared with an operating loss of $7.1 million for the corresponding 2017 period. The Company’s operating loss for the nine months ended September 30, 2018 amounted to $18.6 million, compared with an operating loss of $17.6 million for the corresponding 2017 period.

Non-operating income (expenses) for the three and nine months ended September 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 nine months ended September 30, 2017 primarily relate to fair-value adjustments of warrant liabilities on the Company’s balance sheet.

Net financial income amounted to $0.1 million for the three months ended September 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 $0.4 million for the nine months ended September 30, 2018, compared to net financial income of $0.9 million for the nine months ended September 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 September 30, 2018 amounted to $6.3 million, compared with a net loss of $7.2 million for the corresponding period. The Company's net loss for the nine months ended September 30, 2018 amounted to $17.3 million, compared with a net loss of $17.0 million for the corresponding 2017 period.

The Company held $35.0 million in cash, cash equivalents and short-term bank deposits as of September 30, 2018.

Net cash used in operating activities was $19.1 million for the nine months ended September 30, 2018, compared with net cash used in operating activities of $14.2 million for the nine months ended September 30, 2017. The $4.9 million increase in net cash used in operating activities during the nine-month period in 2018, compared to the nine-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 increase in prepaid expenses and other receivables.

Net cash provided by investing activities was $16.0 million for the nine months ended September 30, 2018, compared to net cash used in investing activities of $19.5 million for the nine months ended September 30, 2017. The changes in cash flows from investing activities relate primarily 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 the investment in iPharma in 2018.

Net cash provided by financing activities was $2.8 million for the nine months ended September 30, 2018, compared to net cash provided by financing activities of $37.7 million for the nine months ended September 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, November 8, 2018 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 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 November 10, 2018; please dial +1-888-326-9310 from the U.S. or +972-3-925-5925 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, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), 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.

Forward Looking Statement

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, 2017	September 30, 2018
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,110	4,703
Short-term bank deposits	44,373	30,300
Prepaid expenses	307	1,266
Other receivables	586	835
Total current assets	50,376	37,104
NON-CURRENT ASSETS		
Long-term prepaid expenses	61	66
Long-term investment	1,000	-
Property and equipment, net	2,505	2,197
Intangible assets, net	7,023	7,033
Total non-current assets	10,589	9,296
Total assets	60,965	46,400
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	3,804
Other	1,113	1,028
Total current liabilities	6,722	4,925
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	86
Warrants	1,205	804
Total non-current liabilities	1,362	890
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	5,815
EQUITY		
Ordinary shares	2,836	2,922
Share premium	240,682	244,058
Other comprehensive loss	10,337	11,889
Capital reserve	(1,416)	(1,416)
Accumulated deficit	(199,558)	(216,868)
Total equity	52,881	40,585
Total liabilities and equity	60,965	46,400

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2018	2017	2018
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,654)	(5,027)	(13,306)	(14,581)
SALES AND MARKETING EXPENSES	(249)	(293)	(1,218)	(1,137)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,154)	(892)	(3,028)	(2,850)
OPERATING LOSS	(7,057)	(6,212)	(17,552)	(18,568)
NON-OPERATING INCOME (EXPENSES), NET	(333)	(255)	(342)	870
FINANCIAL INCOME	153	154	914	534
FINANCIAL EXPENSES	(6)	(11)	(15)	(146)
NET LOSS AND COMPREHENSIVE LOSS	(7,243)	(6,324)	(16,995)	(17,310)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.07)	(0.06)	(0.20)	(0.16)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	101,874,372	107,110,585	85,106,723	107,040,191

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					
BALANCE AT JANUARY 1, 2017	1,513	199,567	(1,416)	10,569	(175,206)	35,027
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2017:						
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)
BALANCE AT SEPTEMBER 30, 2017	2,809	239,606	(1,416)	10,227	(192,201)	59,025

	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	(1,416)	10,337	(199,558)	52,881
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	85	2,803	-	-	-	2,888
Employee stock options exercised	1	46	-	(47)	-	-
Employee stock options forfeited and expired	-	527	-	(527)	-	-
Share-based compensation	-	-	-	2,126	-	2,126
Comprehensive loss for the period	-	-	-	-	(17,310)	(17,310)
BALANCE AT SEPTEMBER 30, 2018	2,922	244,058	(1,416)	11,889	(216,868)	40,585

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

	Nine months ended September 30,	
	2017	2018
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(16,995)	(17,310)
Adjustments required to reflect net cash used in operating activities (see appendix below)	2,772	(1,741)
Net cash used in operating activities	(14,223)	(19,051)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(48,029)	(22,000)
Maturities of short-term deposits	33,327	36,613
Long-term investment	(1,000)	-
Proceeds from realization of long-term investment	-	1,500
Purchase of property and equipment	(109)	(76)
Purchase of intangible assets	(3,721)	(40)
Net cash provided by (used in) investing activities	(19,532)	15,997
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	37,761	2,888
Repayments of bank loan	(70)	(70)
Net cash provided by financing activities	37,691	2,818
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,936	(236)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	2,469	5,110
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	307	(171)
CASH AND CASH EQUIVALENTS - END OF PERIOD	6,712	4,703

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

	Nine months ended September 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	381	414
Long-term prepaid expenses	(8)	(5)
Interest and exchange rate differences on short-term deposits	(439)	(540)
Share-based compensation	1,309	2,126
Warrant issuance costs	17	-
Gain on realization of long-term investment	-	(500)
Interest and linkage differences on bank loan	-	(1)
Exchange differences on cash and cash equivalents	(307)	171
Loss (gain) on adjustment of warrants to fair value	316	(401)
	1,269	1,264
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(362)	(1,208)
Increase (decrease) in accounts payable and accruals	1,865	(1,797)
	1,503	(3,005)
	2,772	(1,741)
Supplementary information on interest received in cash	378	598
Supplementary non-cash investment	2,985	-

Exhibit 2

BioLineRx Ltd.

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

BioLineRx Ltd.

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

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CURRENT ASSETS		
Cash and cash equivalents	5,110	4,703
Short-term bank deposits	44,373	30,300
Prepaid expenses	307	1,266
Other receivables	586	835
Total current assets	50,376	37,104
NON-CURRENT ASSETS		
Long-term prepaid expenses	61	66
Long-term investment	1,000	-
Property and equipment, net	2,505	2,197
Intangible assets, net	7,023	7,033
Total non-current assets	10,589	9,296
Total assets	60,965	46,400
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	5,516	3,804
Other	1,113	1,028
Total current liabilities	6,722	4,925
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	157	86
Warrants	1,205	804
Total non-current liabilities	1,362	890
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	8,084	5,815
EQUITY		
Ordinary shares	2,836	2,922
Share premium	240,682	244,058
Other comprehensive loss	10,337	11,889
Capital reserve	(1,416)	(1,416)
Accumulated deficit	(199,558)	(216,868)
Total equity	52,881	40,585
Total liabilities and equity	60,965	46,400

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,	
	2017	2018	2017	2018
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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)
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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Nine months ended September 30,	
	2017	2018
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CASH FLOWS - OPERATING ACTIVITIES		
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Supplementary non-cash investment	2,985	-

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

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, 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.

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, 2018, and for the three and nine months then ended, were approved by the Board of Directors on November 8, 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 September 30, 2018 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 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 nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of 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 yet 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 September 30, 2018, 3,927,063 ADSs were sold under the program for total net proceeds of approximately $4.0 million, leaving an available balance under the facility of approximately $26.0 million as of September 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 September 30, 2018 was based on the then current price of an ADS, a risk-free interest rate of 2.91% and an average standard deviation of 54.1%.

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

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.

d. 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.

NOTE 5 – SHAREHOLDERS' EQUITY

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

	Number of ordinary shares	
	December 31, 2017	September 30, 2018
Authorized share capital	250,000,000	250,000,000
Issued and paid-up share capital	105,063,437	108,083,426

	In USD and NIS	
	December 31, 2017	September 30, 2018
Authorized share capital (in NIS)	25,000,000	25,000,000
Issued and paid-up share capital (in NIS)	10,506,344	10,808,343
Issued and paid-up share capital (in USD)	2,836,139	2,922,216

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.

NOTE 7 – EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

On October 2, 2018, the Company amended its license agreement with Biokine Therapeutics Ltd. (“Biokine”), originally dated September 2, 2012, relating to the in-licensing rights to BL-8040. The amendment reduces the payment owed by the Company to Biokine on sublicense receipts (as defined in the license agreement) from 40% to 20% of sublicense receipts in exchange for: (i) a cash payment from the Company to Biokine of $10 million; (ii) the issuance of ADSs with a value of $5 million and (iii) the payment of certain future milestone payments, up to an aggregate of $5 million in total, as specified in the amendment. Additionally, in certain limited instances, if the Company enters into a sublicense (as defined in the license agreement) within a defined period, the Company will pay Biokine an additional 10% of any upfront sublicense receipts received by the Company as a result of such sublicense.

The $10 million payment referred to above was financed in full via the receipt of a $10 million loan from Kreos Capital V (Expert Fund) L.P. (the “Lender”). As security for the loan, the Lender received a first-priority secured interest in all Company assets, including intellectual property. The loan has a 12-month interest-only period followed by a 36-month repayment period. Borrowings under the loan will bear interest at a fixed rate of 9.5% per annum (10.7%, including cash fees). In connection with providing the loan, the Lender received a warrant to purchase 957,549 ADSs at an exercise price of $0.94 per ADS. The warrant is exercisable for a period of ten years from the date of issuance.

Exhibit 3

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. 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 37 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 showed 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). Top-line results from the initial dual combination arm of the trial showed that the combination demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer. In addition, the results showed that BL-8040 significantly improves T-cell infiltration into the tumor and reduces immunosuppression in the tumor microenvironment, especially in combination with KEYTRUDA.

    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. 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.

- 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. As part of the collaboration, Genentech is also considering initiating a third Phase 1b/2 study in lung cancer. These studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters.

AML

- 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. Reports on the trial included 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 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.

- 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.

- 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 2021.

Stem-cell mobilization

- 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.

- 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 began with a lead-in period for dose confirmation, which was to include 10-30 patients and progress to the placebo-controlled main part, which is 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 we 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. The multicenter, open-label study will take place in the United Kingdom and Israel, with possible expansion to the United States and additional countries in Europe in 2019.

- 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/verrucas) 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

Since December 2014 we have been collaborating with Novartis for the co-development of selected Israeli-sourced novel drug candidates.

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 percentage of the gross revenue from the sale of licensed products, 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 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 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, or IIA), 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, 2018, we held $35.0 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 the 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 October 2018, we announced encouraging top-line results from the dual combination arm of the Phase 2a COMBAT/KEYNOTE-202 study at the European Society for Medical Oncology 2018 Congress. The data show that the treatment regimen was safe and well tolerated. The disease control rate (patients exhibiting a response or stable disease) was 34.5% for the evaluable population (N=29), including 1 patient (3.4%) with a partial response showing a 40% reduction in tumor burden, as well as 9 patients (31%) with stable disease, with a median treatment time of 72 days (37-267). Median overall survival (OS) in all patients (N=37) was 3.3 months with a 6-month survival rate of 34.4%. A significant observation was made in the subpopulation of patients receiving the study drugs as a second-line treatment (N=17), where the median overall survival was 7.5 months, with a 6-month survival rate of 51.5%. This compares favorably with historical median overall survival data of 6.1 months for the only currently approved second-line PDAC treatment (a chemotherapy combination of Onivyde®, 5-FU and leucovorin). Additional data from in-depth analyses of biopsies taken at screening and following monotherapy or combination treatment of BL-8040 and KEYTRUDA demonstrate that in 75% of the available biopsies, BL-8040 treatment promotes an increase in the number of infiltrating CD4+, CD8+ and CD8+Granzyme B+ cytotoxic T-cells. The greatest improvement in T-cell infiltration was observed following combination treatment of BL-8040 and KEYTRUDA and was correlated with stable disease for 8 cycles of treatment. Furthermore, increased infiltration of activated CD4 and CD8 T-cells was accompanied by a pronounced decrease in the number of tumor cells, as well as by a decrease in myeloid-derived suppressor cells, a cell type known to impede the anti-tumor immune response.

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 ≥ $6x10^6$ 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 ≥ $6x10^6$ 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.

AGI-134

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 approximately $26.0 million.

Corporate matters

In October 2018, we amended our license agreement with Biokine Therapeutics Ltd., or Biokine, relating to the in-licensing rights to BL-8040. The amendment reduces the payment owed by us to Biokine on Sublicense Receipts (as defined in the License Agreement) from 40% to 20% of Sublicense Receipts in exchange for (i) a cash payment by us to Biokine of $10 million, (ii) the issuance of restricted ADSs with a value of $5 million and (iii) the payment of certain future milestone payments, up to an aggregate of $5 million in total. The terms of the License Agreement otherwise remain unchanged and in full force and effect.

The $10 million payment to Biokine referred to above was financed in full by the receipt of $10 million in debt financing (the "Loan") from Kreos Capital V (Expert Fund) L.P., or Kreos Capital. The Loan has a 12-month interest-only period followed by a 36-month repayment period. The Loan will bear interest at a fixed rate of 9.5% per annum (10.7%, including cash fees). As security for the Loan, Kreos Capital has a first priority secured interest in all Company assets, including intellectual property. In connection with the Loan, Kreos received a warrant to purchase 957,549 ADSs (the "Warrant") at an exercise price of $0.9399, subject to typical adjustments. The Warrant is exercisable for a period of ten years from the date of issuance.

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 $1.00 minimum bid price requirement set forth in Nasdaq's rules for continued listing on The Nasdaq Capital Market. On October 10, 2018, we received written notice Nasdaq confirming that we had regained compliance with the $1.00 minimum bid price requirement.

Innovative Pharmaceutical Concepts, or IPC, the licensor of BL-5010, notified us earlier this year claiming it believes we have not fulfilled certain aspects of the BL-5010 license agreement, and threatened to terminate the license agreement. Since that time, IPC has taken no steps to terminate the license agreement. We believe that IPC's claims are groundless and we 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. Furthermore, 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 Candidates

As disclosed above, in August 2018 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.

During the third quarter of 2018 we terminated BL-1230 in light of scientific, regulatory and commercial considerations. BL-1230 was being investigated as a treatment for dry eye syndrome.

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	1. Phase 2a study for relapsed or refractory AML completed	1. Follow-up for overall survival is ongoing; evaluation and decision regarding next clinical development steps
	2. Phase 2b study in AML consolidation treatment line (BLAST) ongoing	2. Possible interim results in mid-2019; top-line results expected in 2021
	3. Phase 2 study in allogeneic stem-cell mobilization completed	3. Follow-up on acute and chronic GvHD by H2 2019
	4. Phase 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; top-line results from dual combination arm announced in October 2018	4. Top-line results from triple combination arm expected in H2 2019
	5. Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, ongoing	5. Top-line results anticipated in H1 2019
	6. Phase 1b/2 study in AML, in collaboration with Genentech (BATTLE), ongoing	6. Top-line results expected in 2021
	7. Phase 1b/2 studies in pancreatic and gastric cancer, under collaboration with Genentech (MORPHEUS) ongoing	7. Top-line results in 2019
	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	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 safety results from part 1 of study in mid-2019; initial efficacy results of monotherapy arm from part 2 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

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 nine months ended September 30, 2018; and on an aggregate basis since project inception.

	Year Ended December 31,			Nine Months Ended September 30,	Total Costs Since Project
	2015	2016	2017	2018	Inception
	(in thousands of U.S. dollars)				
BL-8040	7,045	8,281	12,369	8,516	45,542
AGI-134	-	-	3,730	2,875	6,605
BL-5010	400	75	32	52	4,228
Other projects	3,573	2,647	2,628	1,784	118,543
Total gross direct project costs	11,018	11,003	18,759	13,227	174,918

From our inception through September 30, 2018, we have incurred research and development expenses of approximately $211.1 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 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, a joint venture our holdings in which we sold in April 2018.

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 nine-month periods ended September 30, 2018 and 2017.

Cost of revenues

We did not record any cost of revenues during each of the three- or nine-month periods ended September 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 four therapeutic candidates in our pipeline, so that our drug development pipeline as of the date of this report consists of three 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,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	5,654	5,027	(627)	13,306	14,581	1,275

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

Research and development expenses for the three months ended September 30, 2018 were $5.0 million, a decrease of $0.6 million, or 11.1%, compared to $5.6 million for the three months ended September 30, 2017. The decrease resulted primarily from higher expenses associated with drug product development and manufacturing for AGI-134 in the 2017 period.

Comparison of nine-month periods ending September 30, 2018 and 2017

Research and development expenses for the nine months ended September 30, 2018 were $14.6 million, an increase of $1.3 million, or 9.6%, compared to $13.3 million for the nine months ended September 30, 2017. The increase in the 2018 period resulted primarily from higher expenses associated with BL-8040, including the GENESIS and COMBAT trials; preparations for initiation of the AGI-134 clinical trial; and BL-1230.

Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	249	293	44	1,218	1,137	(81)

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

Sales and marketing expenses for the three months ended September 30, 2018 were $0.3 million, similar to the comparable period in 2017.

Comparison of nine-month periods ending September 30, 2018 and 2017

Sales and marketing expenses for the nine months ended September 30, 2018 were $1.1 million, a decrease of $0.1 million, or 6.7%, compared to $1.2 million for the nine months ended September 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 September 30,			Nine months ended September 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	1,154	892	(262)	3,028	2,850	(178)

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

General and administrative expenses for the three months ended September 30, 2018 were $0.9 million, a decrease of $0.3 million, or 22.7%, compared to $1.2 million for the three months ended September 30, 2017. The decrease resulted from a decrease in fees paid for consulting services.

Comparison of nine-month periods ending September 30, 2018 and 2017

General and administrative expenses for the nine months ended September 30, 2017 were $2.9 million, a decrease of $0.2 million, or 5.9%, compared to $3.0 million for the nine months ended September 30, 2017. The decrease resulted from a decrease in fees paid for consulting services.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	(333)	(255)	78	(342)	870	1,212

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

Non-operating income (expenses) for the three and nine months ended September 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 nine months ended September 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 September 30,			Nine months ended September 30,		
	2017	2018	Increase (decrease)	2017	2018	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	153	154	1	914	534	(380)
Financial expenses	(6)	(11)	(5)	(15)	(146)	(131)
Net financial income (expense)	147	143	(4)	899	388	(511)

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

We recognized net financial income of $0.1 million for the three months ended September 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 nine-month periods ending September 30, 2018 and 2017

We recognized net financial income of $0.4 million for the nine months ended September 30, 2018 compared to net financial income of $0.9 million for the nine months ended September 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 IIA, and payments received under our strategic licensing arrangements. At September 30, 2018, we held $35.0 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 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 nine months ended September 30, 2018, we sold 2,982,097 ADSs under the program, resulting in net proceeds to BioLine of approximately $2.9 million (net of $91,000 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 $19.1 million for the nine months ended September 30, 2018, compared with net cash used in operating activities of $14.2 million for the nine months ended September 30, 2017. The $4.9 million increase in net cash used in operating activities during the nine-month period in 2018, compared to the nine-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 increase in prepaid expenses and other receivables.

Net cash provided by investing activities was $16.0 million for the nine months ended September 30, 2018, compared to net cash used in investing activities of $19.5 million for the nine months ended September 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 nine months ended September 30, 2018, compared to net cash provided by financing activities of $37.7 million for the nine months ended September 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.