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 2016

_____

BioLineRx Ltd.

(Translation of Registrant's name into English)

_____

2 HaMa'ayan Street
Modi'in 7177871, Israel
(Address of Principal Executive Offices)

_____

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

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

Yes ☐ No ☒

On November 22, 2016, the Registrant will issue a press release announcing its financial results for the three and nine months ended September 30, 2016. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2016 and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 22, 2016;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2016 and for the three and nine months then ended; and

Exhibit 3 - Registrant's operating and financial review as of September 30, 2016 and for the three and nine 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: November 22, 2016

Exhibit 1

BioLineRx Reports Third Quarter 2016 Financial Results

Tel Aviv, Israel, November 22, 2016 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, today reports its financial results for the third quarter ended September 30, 2016.

Highlights and achievements during third quarter of 2016 and to date:

- Signing of significant immuno-oncology collaboration with Genentech, a member of the Roche Group, for several Phase 1b studies for BL-8040 in combination with Genentech's Atezolizumab, in multiple solid tumor indications and AML
- Steady progress in existing immuno-oncology collaboration with MSD (known as Merck in the US and Canada), with initiation of a Phase 2a study in pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA®
- Signing of immuno-oncology collaboration with MD Anderson Cancer Center for additional Phase 2a combination study in pancreatic cancer, as part of strategic clinical research immunotherapy collaboration between MSD and MD Anderson Cancer Center
- In-licensing of three new projects under strategic collaboration with Novartis, including two novel liver fibrosis/failure projects, and a novel anti-inflammatory treatment for dry eye syndrome
- Presentation of growing body of clinical evidence surrounding BL-8040 at leading medical and scientific conferences, including an oral presentation at the upcoming ASH 2016
- Expanded geographic reach with new joint venture in China for development of novel drug candidates

Expected upcoming significant milestones for 2017:

- Partial results from Phase 2 study for BL-8040 in stem-cell mobilization for allogeneic transplantation expected by Q1 2017
- Partial results in immuno-oncology Phase 2a study for pancreatic cancer for BL-8040 in combination with Merck's KEYTRUDA® expected by H2 2017
- Phase 1b immuno-oncology studies for BL-8040 in combination with Genentech's Atezolizumab, in multiple solid tumor indications and AML, expected to commence during 2017

Philip A. Serlin, Chief Executive Officer of BioLineRx, remarked, "The third quarter of 2016 demonstrated our continued ability to leverage our leading BL-8040 oncology platform, as well as our access to cutting edge technologies. In particular, our immunotherapy collaboration efforts continued to bear fruit, with the signing of a significant agreement with Genentech to carry out multiple clinical trials in a variety of oncology indications, as well as a collaboration agreement with MD Anderson Cancer Center. Meanwhile, our immunotherapy collaboration with Merck, announced earlier in the year, steadily progressed, with our Phase 2a clinical trial in pancreatic cancer now in active enrollment. Further, following extensive due diligence, we are now pleased to roll out three programs under our Novartis collaboration, including two in the exciting field of liver fibrosis. We expect a number of additional novel assets to enter our pipeline in 2017, including several within the framework of the Novartis collaboration. Finally, we continue to highlight growing clinical evidence supporting our lead oncology program, BL-8040, which is regularly featured at leading medical and scientific conferences."

"We are excited about our prospects ahead and are focused on achieving our expected milestones for 2017 and beyond. With $39 million of cash on hand, we remain well positioned to carry out our operational plans for the next few years," Mr. Serlin concluded.

Financial Results for the Third Quarter Ended September 30, 2016

Research and development expenses for the three months ended September 30, 2016 were $3.0 million, an increase of $0.4 million, or 14.7%, compared to $2.6 million for the comparable period in 2015. The increase resulted primarily from spending on new projects and from increased spending on BL-8040 in the 2016 period. Research and development expenses for the nine months ended September 30, 2016 were $8.2 million, a decrease of $0.4 million, or 5.1%, compared to $8.7 million for the comparable period in 2015. The decrease resulted primarily from lower expenditures for BL-7010 during the 2016 period and conclusion of one of the clinical trials for BL-8040 in 2015, partially offset by increased spending on a new project.

Sales and marketing expenses for the three months ended September 30, 2016 were $0.41 million, an increase of $0.14 million, or 54.3%, compared to $0.27 million for the comparable period in 2015. The increase resulted primarily from consultancy and legal expenses related to increased business development activity in the 2016 period. Sales and marketing expenses for the nine months ended September 30, 2016 were $0.9 million, an increase of $0.1 million, or 12.6%, compared to $0.8 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

General and administrative expenses for the three months ended September 30, 2016 were $1.1 million, an increase of $0.4 million, or 47.6%, compared to $0.8 million for the comparable period in 2015. The increase resulted primarily from an increase in non-cash share-based compensation. General and administrative expenses for the nine months ended September 30, 2016 were $3.0 million, an increase of $0.4 million, or 14.4%, compared to $2.6 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

The Company's operating loss for the three months ended September 30, 2016 amounted to $4.5 million, compared with an operating loss of $3.6 million for the corresponding 2015 period. The Company's operating loss for the nine months ended September 30, 2016 amounted to $12.1 million, similar to the comparable period in 2015.

Non-operating income (expenses) for the three and nine months ended September 30, 2016 and 2015 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet. These fair-value adjustments, which were material in the 2015 periods, but not material in the 2016 periods, are highly influenced by the Company's share price at each period end (revaluation date).

Net financial income (expenses) for the three and nine months ended September 30, 2016 and 2015 primarily relate to investment income earned on bank deposits, as well as banking fees.

The Company's net loss for the three months ended September 30, 2016 amounted to $4.3 million, compared with a net loss of $1.6 million for the corresponding 2015 period. The Company's net loss for the nine months ended September 30, 2016 amounted to $11.6 million, compared with a net loss of $10.7 million for the corresponding 2015 period.

The Company held $38.9 million in cash, cash equivalents and short-term bank deposits as of September 30, 2016.

Net cash used in operating activities was $10.4 million for the nine months ended September 30, 2016, compared with net cash used in operating activities of $11.0 million for the comparable period in 2015. The $0.6 million decrease in net cash used was primarily the result of an increase in other receivables.

Net cash provided by investing activities for the nine months ended September 30, 2016 was $7.3 million, compared to net cash used in investing activities of $18.7 million for the comparable period in 2015. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the nine months ended September 30, 2016 was $1.5 million, compared to net cash provided by financing activities of $29.3 million for the comparable period in 2015. The decrease in cash flows from financing activities reflects the underwritten public offering which was completed in March 2015.

Conference Call and Webcast Information

BioLineRx will hold a conference call to discuss its third quarter end September 30, 2016 results today, November 22, 2016, at 10:00 a.m. EST. To access the conference call, please dial 1-866-744-5399 from the US, or +972-3-918-0692 internationally. The call will also be available via live webcast through BioLineRx's website, www.biolinerx.com. A replay of the conference call will be available approximately two hours after completion of the live conference call. To access the replay, please dial 1-866-276-1485 from the US or +972-3-925-5944 internationally. The replay will be available through November 25, 2016.

(Tables follow)

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

BioLineRx's 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 recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 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) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and has recently signed 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 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 10, 2016. 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, 2015	September 30, 2016
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,544	4,014
Short-term bank deposits	42,119	34,894
Prepaid expenses	229	203
Other receivables	291	303
Total current assets	48,183	39,414
NON-CURRENT ASSETS		
Long-term prepaid expenses	58	54
Property and equipment, net	2,909	2,654
Intangible assets, net	152	155
Total non-current assets	3,119	2,863
Total assets	51,302	42,277
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term bank loan	93	93
Accounts payable and accruals:		
Trade	1,910	2,274
Other	1,137	1,000
Total current liabilities	3,140	3,367
NON-CURRENT LIABILITIES		
Long-term bank loan, net of current maturities	344	272
Warrants	208	29
Total non-current liabilities	552	301
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	3,692	3,668
EQUITY		
Ordinary shares	1,455	1,460
Share premium	196,201	198,380
Other comprehensive loss	(1,416)	(1,416)
Capital reserve	10,735	11,106
Accumulated deficit	(159,365)	(170,921)
Total equity	47,610	38,609
Total liabilities and equity	51,302	42,277

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2016	2015	2016
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES, NET	(2,576)	(2,954)	(8,678)	(8,233)
SALES AND MARKETING EXPENSES	(265)	(409)	(824)	(928)
GENERAL AND ADMINISTRATIVE EXPENSES	(762)	(1,125)	(2,594)	(2,968)
OPERATING LOSS	(3,603)	(4,488)	(12,096)	(12,129)
NON-OPERATING INCOME (EXPENSES), NET	1,983	(14)	1,096	182
FINANCIAL INCOME	85	172	363	403
FINANCIAL EXPENSES	(91)	(4)	(111)	(12)
NET LOSS AND COMPREHENSIVE LOSS	(1,626)	(4,334)	(10,748)	(11,556)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.03)	(0.08)	(0.21)	(0.21)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	54,632,788	56,426,202	50,306,892	55,912,486

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, 2015	1,055	167,331	(1,416)	9,800	(144,965)	31,805
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2015:						
Issuance of share capital, net	395	28,449	-	-	-	28,844
Employee stock options forfeited and expired		170		(170)		-
Share-based compensation	-	-	-	770	-	770
Comprehensive loss for the period	-	-	-	-	(10,748)	(10,748)
BALANCE AT SEPTEMBER 30, 2015	1,450	195,950	(1,416)	10,400	(155,713)	50,671

	Ordinary shares	Share premium	Other comprehensive loss	Capital reserve	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2016	1,455	196,201	(1,416)	10,735	(159,365)	47,610
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2016:						
Issuance of share capital, net	4	1,591	-	-	-	1,595
Employee stock options exercised	1	128	-	(128)	-	1
Employee stock options forfeited and expired	-	460	-	(460)	-	-
Share-based compensation	-	-	-	959	-	959
Comprehensive loss for the period	-	-	-	-	(11,556)	(11,556)
BALANCE AT SEPTEMBER 30, 2016	1,460	198,380	(1,416)	11,106	(170,921)	38,609

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

	Nine months ended September 30,	
	2015	2016
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(10,748)	(11,556)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(232)	1,128
Net cash used in operating activities	(10,980)	(10,428)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(51,262)	(28,978)
Maturities of short-term deposits	34,878	36,480
Maturities of restricted deposits	166	-
Purchase of property and equipment	(2,466)	(164)
Purchase of intangible assets	(22)	(24)
Net cash provided by (used in) investing activities	(18,706)	7,314
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital, net	28,844	1,595
Proceeds of bank loan	467	-
Repayments of bank loan	(8)	(72)
Proceeds from exercise of employee stock options	-	1
Net cash provided by financing activities	29,303	1,524
DECREASE IN CASH AND CASH EQUIVALENTS	(383)	(1,590)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,790	5,544
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(87)	60
CASH AND CASH EQUIVALENTS - END OF PERIOD	5,320	4,014

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

	Nine months ended September 30,	
	2015	2016
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	322	368
Long-term prepaid expenses	(7)	4
Interest and exchange rate differences on short-term deposits	(113)	(277)
Share-based compensation	770	959
Exchange differences on cash and cash equivalents	87	(60)
Gain on adjustment of warrants to fair value	(1,096)	(179)
	(37)	815
Changes in operating asset and liability items:		
Decrease (Increase) in prepaid expenses and other receivables	(700)	14
Increase in accounts payable and accruals	505	299
	(195)	313
	(232)	1,128
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	228	-
Supplementary information on interest received in cash	105	310

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2016

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2016

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Accumulated deficit	(159,365)	(170,921)
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The accompanying notes are an integral part of these condensed financial statements.

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

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	2015	2016	2015	2016
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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Nine months ended September 30,	
	2015	2016
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
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Net cash used in operating activities	(10,980)	(10,428)
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BioLineRx Ltd.
APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

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Increase in accounts payable and accruals	505	299
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	(232)	1,128
Supplementary information on investing activities not involving cash flows:		
Property and equipment acquired on supplier trade credit	228	-
Supplementary information on interest received in cash	105	310

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003. Since incorporation, BioLineRx and its consolidated entities (collectively, the "Company") have been engaged in the development of therapeutics, from pre-clinical development to advanced clinical trials, for a wide range of medical needs.

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.

The Company has been engaged in drug development since its incorporation. Although the Company has generated significant revenues from a number of out-licensing transactions, the Company cannot determine with reasonable certainty when and if it will have sustainable profits.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of September 30, 2016, and for the three and nine months then ended, were approved by the Board of Directors on November 22, 2016, 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, 2016 and for the three and nine months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair statement of financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2015 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2015 and for the year then ended.

NOTE 4 – ISSUANCES OF SHARE CAPITAL

a. Underwritten public offerings of American Depositary Shares

In March 2015, the Company completed an underwritten public offering of 14,375,000 ADSs at a public offering price of $2.00 per ADS. The offering raised a total of $28.8 million, with net proceeds of approximately $26.5 million, after deducting fees and expenses.

b. Share purchase agreement with Lincoln Park Capital

In May 2014, BioLineRx and Lincoln Park Capital Fund ("LPC"), entered into a $20 million, 36-month purchase agreement, whereby LPC agreed to purchase, from time to time, up to $20 million of BioLineRx's ADSs, subject to certain limitations, during the 36-month term of the purchase agreement.

During the nine months ended September 30, 2016, BioLineRx sold a total of 1,550,853 ADSs to LPC for aggregate gross proceeds of $1,627,000. In connection with these issuances, a total of 38,772 ADSs was issued to LPC as a commitment fee and a total of $33,000 was paid to Oberon Securities as a finder's fee. On a cumulative basis, from the effective date of the purchase agreement through the approval date of these financial statements, BioLineRx has sold a total of 2,843,454 ADSs to LPC for aggregate gross proceeds of $4,870,000. In connection with these issuances, a total of 85,642 ADSs was issued to LPC as a commitment fee and a total of $97,000 was paid to Oberon Securities as a finder's fee.

NOTE 5 – SHAREHOLDERS' EQUITY

As of December 31, 2015 and September 30, 2016, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2015	September 30, 2016
Authorized share capital	150,000,000	150,000,000
Issued and paid-up share capital	54,818,057	56,432,589

	In USD and NIS	
	December 31, 2015	September 30, 2016
Authorized share capital (in NIS)	15,000,000	15,000,000
Issued and paid-up share capital (in NIS)	5,481,806	5,643,259
Issued and paid-up share capital (in USD)	1,455,159	1,459,464

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 10, 2016 (the "Annual Report").

Forward Looking Statements

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

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

- the initiation, timing, progress and results of our preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model 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 dedicated to identifying, in-licensing and developing therapeutic candidates that have advantages over currently available therapies or address unmet medical needs. Our current development pipeline consists of three main clinical therapeutic candidates: BL-8040, BL-7010 and BL-5010. In addition, we have five other therapeutic candidates in clinical and pre-clinical development. We generate our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a relatively high probability of therapeutic and commercial success. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case by case basis, the commercialization of our therapeutic candidates independently. Our focus is principally on the therapeutic areas of oncology and immunology. However, we may also in-license therapeutic compounds outside of these areas in connection with our strategic collaboration with Novartis Pharma AG, or Novartis, as well as to a limited extent for our independent pipeline as the opportunities arise.

Clinical-Stage Pipeline

The following is a description of our three main clinical therapeutic candidates:

- BL-8040 is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we intend to develop for multiple cancer and hematological indications.

  - In the first quarter of 2016, we completed a Phase 2a trial for the treatment of relapsed or refractory acute myeloid leukemia (r/r AML) which was conducted at six world-leading cancer research centers in the U.S. and at five premier sites in Israel. In March 2016, we announced positive top-line results from this study and in September 2016 we presented detailed results of the study at the Society of Hematologic Oncology (SOHO) Annual Meeting in Houston, Texas. In December 2016, we will present additional positive correlative data from the study, as well as detailed mechanism-of-action data, at the 58th American Society of Hematology (ASH) Annual Meeting and Exhibition in San Diego, California.

  - BL-8040 is also being investigated 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. In this regard, we are currently running a significant Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group. The Phase 2b trial is a double-blind, placebo-controlled, randomized, multi-center study aimed at assessing the efficacy of BL-8040 in addition to standard consolidation therapy in AML patients. Up to 194 patients will be enrolled in the trial. The primary endpoint of the study is to compare the relapse-free survival (RFS) time in AML subjects in their first remission during a minimum follow-up time of 18 months after randomization. We are considering performing an interim analysis on this study in 2018, with top-line results expected in 2019.

  - 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 treatment for stem cell mobilization at Hadassah Medical Center in Jerusalem. In March 2016, we announced the initiation of a Phase 2 trial for BL-8040 for allogeneic stem-cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. Partial results from this study are expected in the first quarter of 2017, with topline results by the end of 2017.

  - In January 2016, we entered into a collaboration with MSD, known as Merck in the U.S. and Canada, in the field of cancer immunotherapy. In this regard, in September 2016 we initiated a Phase 2a study, known as the COMBAT study, focusing on evaluating the safety and efficacy of BL-8040 in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in up to 30 patients with metastatic pancreatic adenocarcinoma. The study is an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T cells into the tumor and their reactivity.

- In August 2016, we entered into an additional collaboration for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer – this time with MD Anderson Cancer Center. The study will be conducted as an investigator-sponsored study, as part of a strategic clinical research collaboration between Merck and MD Anderson Cancer Center aimed at evaluating KEYTRUDA in combination with various treatments and novel drugs, including BL-8040. The open-label, single center, single-arm Phase 2 study will focus on the mechanism of action by which both drugs might synergize. In addition to assessing clinical response, the study will include multiple assessments to evaluate the biological anti-tumor effects induced by the combination. BioLineRx will supply BL-8040 for the study, which is expected to commence by the end of 2016.

- In September, 2016, we entered into a collaboration with Genentech, Inc., a member of the Roche Group, to support several Phase 1b studies investigating BL-8040 in combination with Atezolizumab, Genentech's anti-PDL1 cancer immunotherapy, in multiple cancer indications. The Phase 1b studies, which are all expected to commence in 2017, will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters, in hematologic malignancies and solid tumors.

- 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.

- 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.

- BL-7010 is a novel, non-absorbable, orally available, high-molecular-weight co-polymer intended for the treatment of celiac disease and gluten sensitivity. In November 2014, we reported final results from a Phase 1/2 trial that was conducted at Tampere Hospital in Finland, a leading site for celiac research. This study was conducted based on an initial medical device submission, under a conditional approval received from the regulatory authorities. BL-7010 was found to be safe and well tolerated in both single- and repeated-dose administrations. In January 2016, we received confirmation regarding the classification of BL-7010 as a Class IIb medical device in the European Union.

  Over the last eighteen months, we have invested considerable efforts in examining alternative development and commercialization pathways for BL-7010, in addition to the celiac disease pathway, including as a food supplement, to potentially address the multi-billion-dollar market for gluten sensitivity. We believe the gluten sensitivity market has a significantly shorter time to market than drug or device pathways, especially in the U.S. market, where the device pathway is not available for BL-7010. We are currently conducting a number of activities towards the development of BL-7010 as a food supplement, including the development of a suitable product formulation, preparation of the documents necessary for a GRAS designation submission, and preparations for a relatively small clinical trial to support the marketing efforts we may conduct regarding gluten and/or gluten sensitivity. We expect to complete these activities by mid-2017, to support partnering discussions for the food supplement market in the U.S. and other relevant territories at that time. We will also continue to evaluate the pathway in Europe for celiac disease and will decide about the timing and scope of the next efficacy study for European registration by early next year.

- BL-5010 is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2010, we announced positive results from a Phase 1/2 clinical trial of BL-5010. We have received European confirmation of the regulatory pathway classification of BL-5010 as a Class IIa medical device. In December 2014, we entered into an exclusive out-licensing arrangement with Omega Pharma, a division of Perrigo Company plc, for the rights to BL-5010 for over-the-counter, or OTC, indications in the territory of Europe, Australia and additional selected countries. During 2015, Omega Pharma conducted a 30-patient, open-label clinical study to evaluate the advantages of BL-5010 in one of the intended OTC indications. Study results indicate that BL-5010 is safe and efficacious. In March 2016, Omega Pharma received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial product launch of this first OTC indication (warts/verrucas) commenced in the second quarter of 2016 and it is already being sold in a number of countries in the EU. The launch in additional EU countries will continue to be gradually carried out by Omega Pharma over the next year, and beyond that time frame for additional territories. To date, we have not recorded material revenues from our collaboration with Omega Pharma, but we expect revenues to gradually increase as the first product launch expands. Our current estimate for peak future royalty revenues from the first indication is in the $2-4 million per year range, and we estimate that it may take another few years to gradually ramp up to this level.

Principal Partnering and Collaboration Agreements

In December 2014, we entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. Under the agreement, we intend, in collaboration with Novartis, to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis. Through the date of this report, we have brought three pre-clinical projects into our pipeline under the Novartis collaboration, and Novartis has flagged several additional projects that we intend to bring into our pipeline during 2017.

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

In January 2016, we entered into the collaboration with MSD to investigate the combination of KEYTRUDA and BL-8040 in pancreatic cancer, as described in “Clinical-Stage Pipeline” above.

In July 2016, we entered into an additional collaboration agreement for the investigation of BL-8040 in combination with KEYTRUDA in pancreatic cancer – this time with MD Anderson Cancer Center – as described in “Clinical-Stage Pipeline” above.

In September 2016, we entered into a collaboration with Genentech, a member of the Roche Group, to support several Phase 1b studies investigating BL-8040 in combination with Atezolizumab, Genentech’s anti-PDL1 cancer immunotherapy, in multiple cancer indications. Under the agreement, Genentech will sponsor and conduct several Phase 1b trials in multiple solid cancer indications. In addition, we will sponsor and conduct a Phase 1b study in AML patients. The studies are planned as open-label, multicenter, single-arm trials designed to evaluate the safety and efficacy of the combination of BL-8040 and Atezolizumab. Upon completion of the studies, both parties will have the option to expand the collaboration to include a pivotal registration study.

Other Partnering and Collaboration Agreements

In August 2016, we announced the establishment of a joint venture with I-Bridge Capital, a Chinese venture capital fund focused on developing innovative therapies in China. The joint venture, named iPharma, will develop innovative clinical and pre-clinical therapeutic candidates originating primarily in Israel to serve the Chinese and global healthcare markets. Under the terms of the joint venture agreement, each partner will provide seed capital of one million dollars to the venture. We will screen and identify promising early-stage drug candidates originating primarily in Israel with emphasis on therapeutic indications that are of special interest for the Chinese population. These therapeutic candidates will then be in-licensed by iPharma for further development and commercialization in China and possibly in other countries as well. The project screening process has begun and several candidates have already been identified.

In 2009, we entered into an exclusive, worldwide, royalty-bearing licensing arrangement with Bellerophon. Under the agreement, we granted Bellerophon an exclusive, worldwide license to develop, manufacture and commercialize BL-1040 for use in the prevention, mitigation and treatment of injuries to the myocardial tissue of the heart. Under the arrangement, Bellerophon is obligated to use commercially reasonable efforts to complete clinical development of, and to commercialize, BL-1040 or products related thereto. We received an upfront payment of $7.0 million upon the execution of the license agreement. Upon successful completion of the Phase 1/2 clinical trial, Bellerophon paid us a milestone payment of $10.0 million in March 2010, and we are entitled to receive additional milestone and royalty payments upon the occurrence of certain events.

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

In May 2016, we entered into a collaboration with MaRS Innovation, the commercialization agent for fifteen of Toronto's top academic institutions. Under the terms of the agreement, BioLineRx intends to review innovative projects and assets of startup companies originating from MaRS Innovation's members, to identify in-licensing, co-development or other partnering opportunities.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding previously received from the Office of the Chief Scientist of the Israeli Ministry of Economy and Industry (OCS), payments received under out-licensing arrangements, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone and royalty payments that we may receive from our existing out-licensing agreements, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of September 30, 2016, we held $38.9 million of cash, cash equivalents and short-term bank deposits.

Recent Company Developments

Changes in Company Management

In August 2016, we announced that Philip A. Serlin would become Chief Executive Officer of the Company effective October 10, 2016. Mr. Serlin joined the Company in 2009 as its Chief Financial and Operating Officer. He succeeds Kinneret Savitsky, Ph.D., who joined the Company in 2004 and served as its Chief Executive Officer since 2010. Taking Mr. Serlin's place as Chief Financial Officer is Ms. Mali Zeevi, CPA, who joined the Company in 2009 and served as its Senior Director of Finance and Reporting since 2011.

In August 2016, we announced the departure of Arnon Aharon, M.D., our Chief Medical Officer, effective November 30, 2016. We are in the process of filling the positions of Vice President, Medical Affairs and Vice President, Development, which we expect to complete in the near future.

Pre-Clinical and Clinical Development

BL-8040

In September 2016, we announced the initiation of a Phase 2a trial for BL-8040 in combination with KEYTRUDA for the treatment of patients with pancreatic cancer. The study will be conducted in the US, Israel and additional countries. The Phase 2a study, named the COMBAT study, is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of the combination of BL-8040 and KEYTRUDA in up to 30 subjects with metastatic pancreatic adenocarcinoma.

In September 2016, we presented successful final results of BL-8040's Phase 2a clinical trial in r/r AML at the 4th Annual Meeting of SOHO in Houston, Texas. The Phase 2a study assessed the efficacy of BL-8040, as a single agent and in combination with Cytarabine (Ara-C), for the treatment of r/r AML. The reported data set includes 45 patients. The majority of patients in the study were heavily pretreated, with 45% of patients being refractory to one or two remission induction treatments, 19% of patients having relapsed after a short first remission of less than 12 months, and 17% of patients having undergone two or more relapses. In addition, the treated patient population included patients that had relapsed post allogeneic stem-cell transplantation (17%), as well as secondary AML patients (24%), both conditions which represent difficult-to-treat populations with poor prognoses. Results show that treatment with BL-8040 in combination with Ara-C was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg. Response to treatment was associated with efficient CXCR4 inhibition, resulting in high mobilization of blasts and induction of their differentiation. The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). In the 1.5 mg/kg dose selected for the expansion phase of the study (n=22), the composite complete remission rate was 41%. These response rates are superior to the historical response rate of approximately 20% reported for high-risk AML patients treated with Ara-C alone. Furthermore, the ongoing follow-up of patients participating in the study's expansion phase and responding to the combination treatment suggests long durability of the remissions achieved, with two-thirds of these patients still alive, based on a follow-up period to date of up to 12 months.

In November 2016, we disclosed positive Phase 2a correlative data, as well as detailed mechanism-of-action data, for BL-8040 that will be presented at the 58th American Society of Hematology (ASH) Annual Meeting and Exhibition in San Diego, California, taking place in December 2016. First, in a poster titled, "The Selective Anti Leukemic Effect of BL-8040, a Peptidic CXCR4 Antagonist, is Mediated by Induction of Leukemic Blast Mobilization, Differentiation and Apoptosis: Results of Correlative Studies from a Ph2a Trial in Acute Myeloid Leukemia", we report the final correlative results from our Phase 2a trial in r/r AML described above. In addition to the results of treatment with BL-8040 in combination with Ara-C, BL-8040 monotherapy was shown to have a substantial therapeutic effect. Treatment with BL-8040 as a single agent triggered robust mobilization of AML blasts from the bone marrow to the peripheral blood stream, and the extent of mobilization was correlated with a positive response to treatment. The preferential mobilization of AML blasts over normal cells (4.7-fold vs. 1.4-fold, respectively) was further confirmed by FISH analysis in a subset of patients. In addition, BL-8040 monotherapy resulted in a 40% increase in AML blast apoptosis.

Second, in an oral presentation at ASH, entitled "The High Affinity CXCR4 Inhibitor, BL-8040, Induces Apoptosis of AML Blasts and their Terminal Differentiation by Blocking AKT/ERK Survival Signals and Downregulating BCL-2, MCL-1 and Cyclin-D1 through Regulation of miR-15a/16-1 Expression", to be delivered by Prof. Amnon Peled from the Hadassah Medical Center and Biokine Therapeutics, we report detailed data on the mechanism-of-action by which BL-8040 directly induces apoptosis of AML cells. The data presented are from in vitro studies using human AML cell lines and human primary AML samples, as well as in vivo studies using human primary AML cells engrafted in NOD scid gamma (NSG) mice. The results of the pre-clinical studies show that BL-8040 treatment in vivo triggered mobilization of AML blasts from their protective bone marrow microenvironment and induced their terminal differentiation, further supporting the data we presented at the American Association for Cancer Research annual conference earlier this year. In addition, the studies illustrate how BL-8040 increases the expression and activity of a special class of microRNA precursors termed miR-15a/16-1. These microRNA molecules have been previously linked to cancer, and shown to suppress the activity of several tumor-related pro-survival proteins. Therefore, by increasing the expression of miR-15a/16-1 microRNA molecules, BL-8040 decreases the expression of tumor-survival proteins and promotes tumor cell death. Importantly, in both in vitro and in vivo experiments, BL-8040 was found to synergize with a selective Bcl-2 inhibitor (Venetoclax) and an FLT3 inhibitor (Quizartinib, also known as AC220) in inducing AML cell death, pointing at potential drug combination treatments.

New projects

In August 2016, we signed an exclusive, worldwide agreement with Hadasit, the Technology Transfer Company of Hadassah Medical Organization, or Hadasit, for the in-licensing of a drug candidate for the treatment of liver fibrosis, and in particular, non-alcoholic steatohepatitis (NASH). This drug candidate, to be called BL-1210, is the first project to be in-licensed under the framework of our strategic collaboration with Novartis for the screening and development of novel drug candidates. The pre-clinical project, developed by Prof. Rifaat Safadi, Head of the Liver Unit, Department of Medicine at Hadassah Medical Center, Jerusalem, Israel, offers a novel mechanism for controlling liver fibrosis through modulation of the immune system. BioLineRx will address the novel drug target that will modulate the immune system to ultimately reduce the liver fibrogenesis and therefore reduce liver scarring. Limiting the fibrosis process this way will potentially control the disease progression.

In September 2016, we signed an exclusive, worldwide agreement with BGN Technologies, the Technology Transfer Company of Ben-Gurion University of the Negev, or BGU, and Hadasit, for the in-licensing of a novel treatment for various liver failure conditions such as end-stage liver disease (ESLD) and for conditions potentially leading to liver failure such as NASH. This treatment, to be named BL-1220, is the second project in-licensed under the framework of our collaboration with Novartis. BL-1220 is an orally administered, novel composition of sodium alginate, developed by Professor Smadar Cohen from the Department of Biotechnology Engineering of BGU, and Professor Yaron Ilan, Head of Internal Medicine Department A, Hadassah Medical Center, Jerusalem. Pre-clinical results obtained in animal models of liver impairment suggest that BL-1220 has strong hepato-protective effects. Collectively, the data demonstrate that BL-1220 can restore liver function. This technology could be directed toward rapid regeneration of normal liver in both acute and chronic conditions of liver injury.

In November 2016, we signed an exclusive, worldwide agreement with Yissum Research Development Company, the technology transfer company of the Hebrew University of Jerusalem, for the in-licensing of a novel anti-inflammatory treatment for Dry Eye Syndrome (DES). This project, to be named BL-1230, is the third project in-licensed under the framework of our collaboration with Novartis. BL-1230 is a potent and selective cannabinoid receptor type 2 (CB2R) agonist developed by Professor Raphael Mechoulam from the Department of Medicinal Chemistry and Natural Products at the Faculty of Medicine of the Hebrew University. The involvement of CB2R in immune modulation is well established, and pre-clinical studies in three ocular inflammatory models have demonstrated that BL-1230 eye drops have significant anti-inflammatory activity, which attenuates the pathology and improves histological outcomes. In addition, we intend to explore the potential use of this compound in systemic inflammatory conditions.

Corporate matters

On July 20, 2016, 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 from June 3, 2016, 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 January 17, 2017, to regain compliance with the Rule.

On October 4, 2016, we received written notice from Nasdaq confirming that because our ADSs had closed with a bid price of at least $1.00 for at least 10 consecutive days, we had regained compliance with the Rule and the matter was therefore closed.

Revenues

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

We expect our revenues for the next several years to be derived primarily from payments under our current out-licensing agreement with Omega Pharma, our collaboration agreement with Novartis and other potential collaboration arrangements, including future royalties on product sales. To date, we have not recorded material revenues from our collaboration with Omega Pharma, but we expect revenues to gradually increase as the product launch expands.

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 rate is ongoing; positive correlative data to be presented in December 2016 at ASH Conference
	2. Phase 2b consolidation treatment for AML ongoing	2. Completion of enrollment and possible interim analysis results expected in 2018; top-line results expected in 2019
	3. Phase 2 study in stem cell mobilization ongoing	3. Partial results expected in Q1 2017; top-line results expected in 2017.
	4. Phase 2a study in pancreatic cancer, in collaboration with Merck, initiated	4. Partial results expected mid-2017; top-line results expected in H2 2018
	5. Phase 2a study in pancreatic cancer, in collaboration with MD Anderson Cancer Center	5. Commencement of study expected by end of 2016
	6. Phase 1b study in AML, in collaboration with Genentech	6. Commencement of study expected in H1 2017; top-line results expected in 2019
	7. Phase 1b studies in various solid tumors, in collaboration with Genentech	7. Commencement of studies expected in 2017; top-line results expected in 2019
BL-7010	Completed Phase 1/2 study; classified as Class IIb medical device in the EU	Submission of package for GRAS designation as food supplement in the U.S.; completion of formulation development as food supplement; initiation of clinical study for marketing purposes as food supplement; determination of appropriate timing for continued medical device development in Europe
BL-5010	Out-licensed to Omega Pharma; CE mark approval obtained; commercial launch of first OTC indication in Europe commenced	Gradual full roll-out of commercial launch over next year; 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 five additional projects in clinical and pre-clinical stages of development (BL-9020, BL-1210, BL-1220, BL-1230 and BL-1040) that are significantly less material to the Company's ongoing research and development expenditures.

Set forth below is a summary of the costs allocated to our main projects on an individual basis, as well as the costs allocated to our less significant projects on an aggregate basis, for the years ended December 31, 2013, 2014 and 2015; for the nine months ended September 30, 2016; and on an aggregate basis since project inception. Certain of such costs were covered by OCS funding, although OCS funds received have not been deducted from the direct project costs in the table.

	Year Ended December 31,			Nine Months Ended September 30,	Total Costs Since Project Inception
	2013	2014	2015	2016	
	(in thousands of U.S. dollars)				
BL-8040	3,910	4,698	7,045	6,083	22,459
BL-7010	1,905	3,756	1,657	756	8,908
BL-5010	251	1,282	400	61	4,130
Other projects	5,097	1,537	1,916	1,242	104,574
Total gross direct project costs	11,163	11,273	11,018	8,142	140,071

From our inception through September 30, 2016, we have incurred research and development expense of approximately $174.2 million. We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development projects, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

While we are currently focused on advancing each of our product development projects, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future out-licensing arrangements, when such out-licensing arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain therapeutic candidates or projects in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate.

The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the number of patients that participate in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an out-patient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

We expect our research and development expenses to remain our most significant cost as we continue the advancement of our clinical trials and preclinical product development projects and place significant emphasis on in-licensing new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in business development and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, professional fees for outside market research and consulting, legal services related to partnering transactions and travel costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, investor relations, information technology and human resources. Other significant general and administration costs include facilities costs, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in the private and direct placements which we conducted in February 2012 and 2013. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes the pro-rata share of issuance expenses from the placements related to the warrants. In addition, non-operating expense and income includes the initial commitment and finder's fees, as well as other one-time expenses, associated with the initial set-up of a share purchase agreement with Lincoln Park Capital, or LPC.

Financial Expense and Income

Financial expense and income consists of interest earned on our cash, cash equivalents and short-term bank deposits; bank fees and other transactional costs.

Significant Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2015.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Functional and Presentation Currency

Our functional and reporting currency is the U.S. dollar, or dollar, which is the primary currency of the economic environment in which we operate.

Results of Operations – Overview

Revenues

We did not record any material revenues during each of the three- or nine-month periods ended September 30, 2016 and 2015.

Cost of revenues

We did not record any material cost of revenues during each of the three- or nine-month periods ended September 30, 2016 and 2015.

Research and development expenses, net

At December 31, 2013, our drug development pipeline consisted of 10 therapeutic candidates. During 2014, we added a new compound to our pipeline and discontinued the development of two compounds from the pipeline, so that our drug development pipeline as of December 31, 2014 consisted of nine therapeutic candidates. During 2015, we did not add any new compounds to our pipeline and we discontinued the development of one compound from the pipeline, so that our drug development pipeline as of December 31, 2015 consisted of eight therapeutic candidates. Subsequent to December 31, 2015, we added three new compounds to our pipeline and we discontinued the development of three therapeutic candidates in our pipeline, so that our drug development pipeline as of the date of this report consists of eight 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,		
	2015	2016	Increase (decrease)	2015	2016	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	2,576	2,954	378	8,678	8,233	(445)

Comparison of three-month periods ending September 30, 2016 and 2015

Research and development expenses for the three months ended September 30, 2016 were $3.0 million, an increase of $0.4 million, or 14.7%, compared to $2.6 million for the three months ended September 30, 2015. The increase resulted primarily from spending on new projects and from increased spending on BL-8040 in the 2016 period.

Comparison of nine-month periods ending September 30, 2016 and 2015

Research and development expenses for the nine months ended September 30, 2016 were $8.2 million, a decrease of $0.4 million, or 5.1%, compared to $8.7 million for the nine months ended September 30, 2015. The decrease resulted primarily from lower expenditures for BL-7010 during the 2016 period and conclusion of one of the clinical trials for BL-8040 in 2015, partially offset by increased spending on a new project.

Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2015	2016	Increase (decrease)	2015	2016	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	265	409	144	824	928	104

Comparison of three-month periods ending September 30, 2016 and 2015

Sales and marketing expenses for the three months ended September 30, 2016 were $0.41 million, an increase of $0.14 million, or 54.3%, compared to $0.27 million for the three months ended September 30, 2015. The increase resulted primarily from consultancy and legal expenses related to increased business development activities in the 2016 period.

Comparison of nine-month periods ending September 30, 2016 and 2015

Sales and marketing expenses for the nine months ended September 30, 2016 were $0.9 million, an increase of $0.1million, or 12.6%, compared to $0.8 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2015	2016	Increase (decrease)	2015	2016	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	762	1,125	363	2,594	2,968	374

Comparison of three-month periods ending September 30, 2016 and 2015

General and administrative expenses for the three months ended September 30, 2016 were $1.1 million, an increase of $0.4 million, or 47.6%, compared to $0.8 million for the three months ended September 30, 2015. The increase resulted primarily from an increase in non-cash share-based compensation.

Comparison of nine-month periods ending September 30, 2016 and 2015

General and administrative expenses for the nine months ended September 30, 2016 were $3.0 million, an increase of $0.4 million, or 14.4%, compared to $2.6 million for the nine months ended September 30, 2015. The reason for the increase is similar to the one discussed above in the three-month comparison.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2015	2016	Increase (decrease)	2015	2016	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	1,983	(14)	(1,997)	1,096	182	(914)

Comparison of three-month and nine-month periods ending September 30, 2016 and 2015

Non-operating income (expenses) for the three and nine months ended September 30, 2016 and 2015 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date).

Financial income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2015	2016	Increase (decrease)	2015	2016	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	85	172	87	363	403	40
Financial expenses	(91)	(4)	(87)	(111)	(12)	(99)
Net financial income (expense)	(6)	168	174	252	391	139

Comparison of three-month and nine-month periods ending September 30, 2016 and 2015

Financial income (expenses), net for the three and nine months ended September 30, 2016 and 2015 primarily relate to investment income earned on our bank deposits, as well as banking fees.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, funding from the OCS, and payments received under our strategic licensing arrangements. At September 30, 2016, we held $38.9 million in cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

Pursuant to the share purchase agreement signed with LPC in May 2014, we may sell, from time to time, and at our discretion, up to $20 million of our ADSs to LPC during the 36-month term of the purchase agreement. From the effective date of the purchase agreement through the date of this report, we have sold an aggregate of approximately $4.9 million of our ADSs to LPC, leaving an available balance under the facility of approximately $15.1 million.

Net cash used in operating activities was $10.4 million for the nine months ended September 30, 2016, compared with net cash used in operating activities of $11.0 million for the nine months ended September 30, 2015. The $0.6 million decrease in net cash used was primarily the result of an increase in other receivables.

Net cash provided by investing activities for the nine months ended September 30, 2016 was $7.3 million, compared to net cash used in investing activities of $18.7 million for the nine months ended September 30, 2015. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and other investments during the respective periods.

Net cash provided by financing activities for the nine months ended September 30, 2016 was $1.5 million, compared to net cash provided by financing activities of $29.3 million for the nine months ended September 30, 2015. The decrease in cash flows from financing activities reflects the underwritten public offering which we completed in March 2015.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our projected cash requirements into 2018, we will require significant additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates; and
- payments to the OCS.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

Off-Balance Sheet Arrangements

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.