
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 2019

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 11, 2019, the Registrant issued a press release announcing its financial results for the three and nine months ended September 30, 2019. The Registrant is hereby also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2019 and for the three and nine months then ended. Attached hereto are the following exhibits:

[Exhibit 1: Registrant's press release dated November 11, 2019;](#)

[Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2019 and for the three and nine months then ended; and](#)

[Exhibit 3 - Registrant's operating and financial review as of September 30, 2019 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 12, 2019



For Immediate Release

**BioLineRx Reports Third Quarter 2019 Financial Results
and Provides Corporate Update**

***- On track for Phase 2 triple-combination data read-outs
in pancreatic cancer by year-end 2019 -***

***- Management to hold conference call today,
November 11, at 10:00 am EST -***

TEL AVIV, Israel, November 11, 2019 -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended September 30, 2019 and provides a corporate update.

Highlights and achievements during the third quarter 2019 and subsequent period:

- Continued to advance its COMBAT/KEYNOTE-202 Phase 2a trial in collaboration with Merck, evaluating BL-8040 in combination with pembrolizumab and chemotherapy in metastatic pancreatic cancer;
 - Obtained initial safety data from Part 1 of Phase 1/2a trial of AGI-134 and initiated patient dosing in Part 2, the monotherapy basket arm;
 - Presented positive triple-combination preclinical data from the evaluation of BL-8040 in combination with an anti PD-1 and chemotherapy in pancreatic cancer, which support BL-8040's mechanism of action and provide a very strong rationale for the triple-combination clinical study, at the Society for Immunotherapy of Cancer Annual Meeting (SITC);
 - Presented encouraging results from an MD Anderson investigator-sponsored, dual-combination study of BL-8040 in combination with KEYTRUDA in metastatic pancreatic cancer patients at SITC;
 - Invited to deliver an oral presentation highlighting new clinical data from the triple-combination COMBAT/KEYNOTE-202 Phase 2a study at the European Society of Medical Oncology Immuno-Oncology Congress in December.
-

“We are quickly approaching a potentially transformational milestone for our Company with the anticipated release of results by the end of the year from the triple combination arm of our ongoing COMBAT/KEYNOTE-202 study of BL-8040, KEYTRUDA® and chemotherapy in metastatic pancreatic cancer,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “Recent preclinical results from the triple combination of BL-8040, an anti PD-1 and chemotherapy, together with clinical results from two separate dual combination studies of BL-8040 and KEYTRUDA®, give us a high degree of conviction in BL-8040’s ability to modify the tumor microenvironment, thereby inducing infiltration of T-cells into the core and periphery of metastatic lesions. Based on our data to date, we believe we can potentially introduce a promising new treatment option not only for metastatic pancreatic cancer, but other difficult-to-treat solid tumor indications as well, where current standards of care are inadequate. At the same time, our trials of BL-8040 in AML and stem cell mobilization are progressing, with key data readouts expected next year.”

“Regarding our second clinical candidate, the universal anti-cancer vaccine AGI-134, we successfully completed Part 1 of the ongoing Phase 1/2a clinical trial in a range of solid tumor types, and quickly initiated dosing in Part 2. We look forward to initial results by year-end 2020,” Mr. Serlin concluded.

Upcoming Milestones

2019

- Response results from the Phase 2a triple combination COMBAT/KEYNOTE-202 pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under the collaboration with Merck;
- Oral presentation with additional data from the Phase 2a triple combination COMBAT/KEYNOTE-202 pancreatic cancer trial at the European Society of Medical Oncology Immuno-Oncology Congress in December

2020

- Progression-free survival and overall survival data from the COMBAT/KEYNOTE-202 Phase 2a triple combination study in mid-2020;
- Interim results from the Phase 2b AML consolidation study during the first half of 2020;
- Top-line results from Phase 3 GENESIS registrational study in stem cell mobilization in the second half of 2020;
- Initial results from Part 2 of Phase 1/2a trial of AGI-134 by year-end 2020.

Financial Results for the Third Quarter Ended September 30, 2019

Research and development expenses for the three months ended September 30, 2019 were \$5.6 million, an increase of \$0.6 million, or 11%, compared to \$5.0 million for the three months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT/KEYNOTE-202 clinical trials. Research and development expenses for the nine months ended September 30, 2019 were \$15.3 million, an increase of \$0.7 million, or 5%, compared to \$14.6 million for the nine months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT/KEYNOTE-202 clinical trials, offset by a decrease in expenses related to BL-1230, a project which was terminated.

Sales and marketing expenses for the three months ended September 30, 2019 were \$0.2 million, a decrease of \$0.1 million, or 31%, compared to \$0.3 million for the three months ended September 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses. Sales and marketing expenses for the nine months ended September 30, 2019 were \$0.7 million, a decrease of \$0.4 million, or 40%, compared to \$1.1 million for the nine months ended September 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses, including a one-time compensation payment in the 2018 period.

General and administrative expenses for the three months ended September 30, 2019 were \$0.9 million, similar to the comparable period in 2018. General and administrative expenses for the nine months ended September 30, 2019 were \$2.8 million, similar to the comparable period in 2018.

The Company's operating loss for the three months ended September 30, 2019 was \$6.6 million, compared to \$6.2 million for the three months ended September 30, 2018. The Company's operating loss for the nine months ended September 30, 2019 was \$18.7 million, compared to \$18.6 million for the comparable period in 2018.

Non-operating income for the three and nine months ended September 30, 2019 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses. Non-operating income (expense) 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, as well as a capital gain from realization of the investment in iPharma.

Net financial expenses amounted to \$0.4 million for the three months ended September 30, 2019 compared to net financial income of \$0.1 million for the three months ended September 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial income for the 2018 period primarily relates to investment income earned on bank deposits. Net financial expenses amounted to \$0.9 million for the nine months ended September 30, 2019 compared to net financial income of \$0.4 million for the nine months ended September 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on bank deposits. 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.

The Company's net loss for the three months ended September 30, 2019 amounted to \$3.9 million, compared with a net loss of \$6.3 million for the comparable period in 2018. The Company's net loss for the nine months ended September 30, 2019 amounted to \$15.6 million, compared with a net loss of \$17.3 million for the comparable period in 2018.

The Company held \$30.1 million in cash, cash equivalents and short-term bank deposits as of September 30, 2019.

Net cash used in operating activities was \$17.2 million for the nine months ended September 30, 2019, compared with net cash used in operating activities of \$19.0 million for the nine months ended September 30, 2018. The \$1.8 million decrease in net cash used in operating activities during the nine-month period in 2019, compared to the nine-month period in 2018, was primarily the result of changes in operating asset and liability items in the two periods, i.e., a decrease in prepaid expenses and other receivables in 2019 versus an increase in 2018, as well as an increase in accounts payable and accruals in 2019 versus a decrease in 2018.

Net cash provided by investing activities was \$2.1 million for the nine months ended September 30, 2019, compared to net cash provided by investing activities of \$16.0 million for the nine months ended September 30, 2018. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and the realization of the investment in iPharma in 2018.

Net cash provided by financing activities was \$16.6 million for the nine months ended September 30, 2019, compared to net cash provided by financing activities of \$2.8 million for the nine months ended September 30, 2018. The increase in cash flows from financing activities reflects the underwritten public offering completed in February 2019.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 11, 2019 at 10:00 a.m. EST. To access the conference call, please dial +1-888-407-2553 from the U.S. or +972-3-918-0644 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 13, 2019; please dial +1-888-782-4291 from the U.S. or +972-3-925-5904 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on multiple oncology indications. The Company's lead program, BL-8040, is a cancer therapy platform currently being evaluated in a Phase 2a study in pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. BL-8040 is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation. In addition, the Company has an ongoing collaboration agreement with Genentech, a member of the Roche Group, evaluating BL-8040 in combination with Genentech's atezolizumab in two Phase 1b/2 solid tumor studies.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being evaluated in a Phase 1/2a study.

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 28, 2019. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2019</u>
	<u>in USD thousands</u>	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	3,404	4,885
Short-term bank deposits	26,747	25,255
Prepaid expenses	488	277
Other receivables	1,339	1,285
Total current assets	<u>31,978</u>	<u>31,702</u>
NON-CURRENT ASSETS		
Long-term prepaid expenses	56	59
Property and equipment, net	2,227	1,923
Right-of-use assets	-	1,635
Intangible assets, net	21,972	21,906
Total non-current assets	<u>24,255</u>	<u>25,523</u>
Total assets	<u>56,233</u>	<u>57,225</u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	895	3,164
Accounts payable and accruals:		
Trade	4,493	5,303
Other	1,363	973
Lease liabilities	-	651
Total current liabilities	<u>6,751</u>	<u>10,091</u>
NON-CURRENT LIABILITIES		
Warrants	323	863
Long-term loans, net of current maturities	7,838	6,011
Lease liabilities	-	1,062
Total non-current liabilities	<u>8,161</u>	<u>7,936</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>14,912</u>	<u>18,027</u>
EQUITY		
Ordinary shares	3,110	4,129
Share premium	250,192	262,430
Capital reserve	11,955	12,153
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(222,520)	(238,098)
Total equity	<u>41,321</u>	<u>39,198</u>
Total liabilities and equity	<u>56,233</u>	<u>57,225</u>

BioLineRx Ltd.

**CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)**

	Three months ended September 30,		Nine months ended September 30,	
	2018	2019	2018	2019
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,027)	(5,558)	(14,581)	(15,252)
SALES AND MARKETING EXPENSES	(293)	(201)	(1,137)	(683)
GENERAL AND ADMINISTRATIVE EXPENSES	(892)	(884)	(2,850)	(2,763)
OPERATING LOSS	(6,212)	(6,643)	(18,568)	(18,698)
NON-OPERATING INCOME (EXPENSES), NET	(255)	3,055	870	3,976
FINANCIAL INCOME	154	247	534	628
FINANCIAL EXPENSES	(11)	(597)	(146)	(1,484)
NET LOSS AND COMPREHENSIVE LOSS	<u>(6,324)</u>	<u>(3,938)</u>	<u>(17,310)</u>	<u>(15,578)</u>
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.06)</u>	<u>(0.03)</u>	<u>(0.16)</u>	<u>(0.11)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>107,110,585</u>	<u>148,920,707</u>	<u>107,040,191</u>	<u>142,527,942</u>

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(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	<u>2,922</u>	<u>244,058</u>	<u>11,889</u>	<u>(1,416)</u>	<u>(216,868)</u>	<u>40,585</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	1,018	11,266	-	-	-	12,284
Employee stock options exercised	1	53	(53)	-	-	1
Employee stock options forfeited and expired	-	919	(919)	-	-	-
Share-based compensation	-	-	1,170	-	-	1,170
Comprehensive loss for the period	-	-	-	-	(15,578)	(15,578)
BALANCE AT SEPTEMBER 30, 2019	<u>4,129</u>	<u>262,430</u>	<u>12,153</u>	<u>(1,416)</u>	<u>(238,098)</u>	<u>39,198</u>

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JULY 1, 2018	2,920	243,883	11,343	(1,416)	(210,544)	46,186
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	2	39	-	-	-	41
Employee stock options exercised	-	8	(8)	-	-	-
Employee stock options forfeited and expired	-	128	(128)	-	-	-
Share-based compensation	-	-	682	-	-	682
Comprehensive loss for the period	-	-	-	-	(6,324)	(6,324)
BALANCE AT SEPTEMBER 30, 2018	<u>2,922</u>	<u>244,058</u>	<u>11,889</u>	<u>(1,416)</u>	<u>(216,868)</u>	<u>40,585</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JULY 1, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	128	829	-	-	-	957
Employee stock options exercised	-	26	(26)	-	-	-
Employee stock options forfeited and expired	-	53	(53)	-	-	-
Share-based compensation	-	-	397	-	-	397
Comprehensive loss for the period	-	-	-	-	(3,938)	(3,938)
BALANCE AT SEPTEMBER 30, 2019	<u>4,129</u>	<u>262,430</u>	<u>12,153</u>	<u>(1,416)</u>	<u>(238,098)</u>	<u>39,198</u>

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

	Nine months ended	
	September 30,	
	2018	2019
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(17,310)	(15,578)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,741)	(1,658)
Net cash used in operating activities	<u>(19,051)</u>	<u>(17,236)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(22,000)	(34,517)
Maturities of short-term deposits	36,613	36,637
Proceeds from realization of long-term investment	1,500	-
Purchase of property and equipment	(76)	(54)
Purchase of intangible assets	(40)	-
Net cash provided by investing activities	<u>15,997</u>	<u>2,066</u>
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital and warrants, net of issuance cost	2,888	16,836
Employee stock options exercised	-	1
Repayments of loans	(70)	(70)
Repayments of lease liabilities	-	(165)
Net cash provided by financing activities	<u>2,818</u>	<u>16,602</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(236)	1,432
CASH AND CASH EQUIVALENTS - BEGINNING		
OF PERIOD	5,110	3,404
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	<u>(171)</u>	<u>49</u>
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u><u>4,703</u></u>	<u><u>4,885</u></u>

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

	Nine months ended September 30,	
	2018	2019
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	414	667
Long-term prepaid expenses	(5)	(3)
Exchange differences on cash and cash equivalents	171	(49)
Gain on adjustment of warrants to fair value	(401)	(4,429)
Gain on realization of long-term investment	(500)	-
Share-based compensation	2,126	1,170
Warrant issuance costs	-	417
Interest and exchange rate differences on short-term deposits	(540)	(628)
Interest on loans	(1)	512
	<u>1,264</u>	<u>(2,343)</u>
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses and other receivables	(1,208)	265
Increase (decrease) in accounts payable and accruals	(1,797)	420
	<u>(3,005)</u>	<u>685</u>
	<u>(1,741)</u>	<u>(1,658)</u>
Supplemental information on interest received in cash	<u>598</u>	<u>628</u>
Supplemental information on interest paid in cash	<u>-</u>	<u>782</u>
Supplemental information on non-cash transaction -		
Initial establishment of right-of-use assets against lease liabilities	<u>-</u>	<u>1,878</u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2019

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2019

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

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2019</u>
	<u>in USD thousands</u>	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	3,404	4,885
Short-term bank deposits	26,747	25,255
Prepaid expenses	488	277
Other receivables	1,339	1,285
Total current assets	<u>31,978</u>	<u>31,702</u>
NON-CURRENT ASSETS		
Long-term prepaid expenses	56	59
Property and equipment, net	2,227	1,923
Right-of-use assets	-	1,635
Intangible assets, net	21,972	21,906
Total non-current assets	<u>24,255</u>	<u>25,523</u>
Total assets	<u><u>56,233</u></u>	<u><u>57,225</u></u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	895	3,164
Accounts payable and accruals:		
Trade	4,493	5,303
Other	1,363	973
Lease liabilities	-	651
Total current liabilities	<u>6,751</u>	<u>10,091</u>
NON-CURRENT LIABILITIES		
Warrants	323	863
Long-term loans, net of current maturities	7,838	6,011
Lease liabilities	-	1,062
Total non-current liabilities	<u>8,161</u>	<u>7,936</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>14,912</u>	<u>18,027</u>
EQUITY		
Ordinary shares	3,110	4,129
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Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(222,520)	(238,098)
Total equity	<u>41,321</u>	<u>39,198</u>
Total liabilities and equity	<u><u>56,233</u></u>	<u><u>57,225</u></u>

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

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2018	2019	2018	2019
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,027)	(5,558)	(14,581)	(15,252)
SALES AND MARKETING EXPENSES	(293)	(201)	(1,137)	(683)
GENERAL AND ADMINISTRATIVE EXPENSES	(892)	(884)	(2,850)	(2,763)
OPERATING LOSS	(6,212)	(6,643)	(18,568)	(18,698)
NON-OPERATING INCOME (EXPENSES), NET	(255)	3,055	870	3,976
FINANCIAL INCOME	154	247	534	628
FINANCIAL EXPENSES	(11)	(597)	(146)	(1,484)
NET LOSS AND COMPREHENSIVE LOSS	<u>(6,324)</u>	<u>(3,938)</u>	<u>(17,310)</u>	<u>(15,578)</u>
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.06)</u>	<u>(0.03)</u>	<u>(0.16)</u>	<u>(0.11)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>107,110,585</u>	<u>148,920,707</u>	<u>107,040,191</u>	<u>142,527,942</u>

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

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

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(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	<u>2,922</u>	<u>244,058</u>	<u>11,889</u>	<u>(1,416)</u>	<u>(216,868)</u>	<u>40,585</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	in USD thousands					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	1,018	11,266	-	-	-	12,284
Employee stock options exercised	1	53	(53)	-	-	1
Employee stock options forfeited and expired	-	919	(919)	-	-	-
Share-based compensation	-	-	1,170	-	-	1,170
Comprehensive loss for the period	-	-	-	-	(15,578)	(15,578)
BALANCE AT SEPTEMBER 30, 2019	<u>4,129</u>	<u>262,430</u>	<u>12,153</u>	<u>(1,416)</u>	<u>(238,098)</u>	<u>39,198</u>

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

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

	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JULY 1, 2018	2,920	243,883	11,343	(1,416)	(210,544)	46,186
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2018:						
Issuance of share capital, net	2	39	-	-	-	41
Employee stock options exercised	-	8	(8)	-	-	-
Employee stock options forfeited and expired	-	128	(128)	-	-	-
Share-based compensation	-	-	682	-	-	682
Comprehensive loss for the period	-	-	-	-	(6,324)	(6,324)
BALANCE AT SEPTEMBER 30, 2018	<u>2,922</u>	<u>244,058</u>	<u>11,889</u>	<u>(1,416)</u>	<u>(216,868)</u>	<u>40,585</u>
	<u>Ordinary shares</u>	<u>Share premium</u>	<u>Capital reserve</u>	<u>Other Comprehensive loss</u>	<u>Accumulated deficit</u>	<u>Total</u>
	<u>in USD thousands</u>					
BALANCE AT JULY 1, 2019	4,001	261,522	11,835	(1,416)	(234,160)	41,782
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2019:						
Issuance of share capital, net	128	829	-	-	-	957
Employee stock options exercised	-	26	(26)	-	-	-
Employee stock options forfeited and expired	-	53	(53)	-	-	-
Share-based compensation	-	-	397	-	-	397
Comprehensive loss for the period	-	-	-	-	(3,938)	(3,938)
BALANCE AT SEPTEMBER 30, 2019	<u>4,129</u>	<u>262,430</u>	<u>12,153</u>	<u>(1,416)</u>	<u>(238,098)</u>	<u>39,198</u>

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

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

	Nine months ended	
	September 30,	
	2018	2019
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(17,310)	(15,578)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,741)	(1,658)
Net cash used in operating activities	<u>(19,051)</u>	<u>(17,236)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(22,000)	(34,517)
Maturities of short-term deposits	36,613	36,637
Proceeds from realization of long-term investment	1,500	-
Purchase of property and equipment	(76)	(54)
Purchase of intangible assets	(40)	-
Net cash provided by investing activities	<u>15,997</u>	<u>2,066</u>
CASH FLOWS - FINANCING ACTIVITIES		
Issuances of share capital and warrants, net of issuance cost	2,888	16,836
Employee stock options exercised	-	1
Repayments of loans	(70)	(70)
Repayments of lease liabilities	-	(165)
Net cash provided by financing activities	<u>2,818</u>	<u>16,602</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(236)	1,432
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,110	3,404
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(171)	49
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>4,703</u>	<u>4,885</u>

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

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

	Nine months ended September 30,	
	2018	2019
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	414	667
Long-term prepaid expenses	(5)	(3)
Exchange differences on cash and cash equivalents	171	(49)
Gain on adjustment of warrants to fair value	(401)	(4,429)
Gain on realization of long-term investment	(500)	-
Share-based compensation	2,126	1,170
Warrant issuance costs	-	417
Interest and exchange rate differences on short-term deposits	(540)	(628)
Interest on loans	(1)	512
	<u>1,264</u>	<u>(2,343)</u>
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses and other receivables	(1,208)	265
Increase (decrease) in accounts payable and accruals	(1,797)	420
	<u>(3,005)</u>	<u>685</u>
	<u>(1,741)</u>	<u>(1,658)</u>
Supplemental information on interest received in cash	<u>598</u>	<u>628</u>
Supplemental information on interest paid in cash	<u>-</u>	<u>782</u>
Supplemental information on non-cash transaction -		
Initial establishment of right-of-use assets against lease liabilities	<u>-</u>	<u>1,878</u>

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

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

NOTE 1 – GENERAL INFORMATION

a. General

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

BioLineRx and its subsidiaries (collectively, the “Company”) are engaged in the development of therapeutics, primarily in clinical-stages, with a focus on the field of oncology.

In February 2007, BioLineRx listed its ordinary shares on the Tel Aviv Stock Exchange (“TASE”) and they have been traded on the TASE since that time. Since July 2011, BioLineRx’s American Depositary Shares (“ADSs”) have also been traded on the NASDAQ Capital Market.

In March 2017, the Company acquired Agalimmune Ltd. (“Agalimmune”), a privately-held company incorporated in the United Kingdom, with a focus on the field of immuno-oncology.

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, 2019, and for the three and nine months then ended, were approved by the Board of Directors on November 7, 2019, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

c. Change in ratio of ADSs

On July 15, 2019, the Company implemented a change in the ratio of its ADSs to ordinary shares, from one ADS representing one ordinary share to a new ratio of one ADS representing 15 ordinary shares. All ADSs and per ADSs amounts in these financial statements have been retroactively adjusted as if the change in ratio had been effected at the earliest date of these financial statements.

NOTE 2 – BASIS OF PREPARATION

The Company’s condensed consolidated interim financial statements as of September 30, 2019 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 as issued by the International Accounting Standards Board (“IFRS”). The condensed consolidated interim financial statements should be read in conjunction with the Company’s annual financial statements as of December 31, 2018 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, 2019 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, 2018 and for the year then ended, except for the adoption of IFRS No. 16, “Leases”.

a. Adjustments recognized on adoption of IFRS 16

The Company has adopted IFRS 16 retrospectively from January 1, 2019 but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. On adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as “operating leases” under the principles of IAS 17, “Leases.” These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee’s incremental borrowing rate as of January 1, 2019. The remeasurements to the lease liabilities were recognized as adjustments to the related right-of-use assets immediately after the date of initial application. The associated right-of-use assets for property leases were measured on a retrospective basis as if the new rules had always been applied. Other right-of use assets were measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognized in the balance sheet as of December 31, 2018. The lessee’s weighted average incremental borrowing rate applied to the lease liabilities on January 1, 2019 was 15.1%.

	January 1, 2019	September 30, 2019
	in USD thousands	
Composition of right-of-use assets by type:		
Property	1,552	1,451
Motor vehicles	326	184
Total right-of-use asset	1,878	1,635
Composition of lease liabilities recognized as of January 1, 2019:		
Current lease liabilities		713
Non-current lease liabilities		1,165
		1,878

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

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES (cont.)

b. Practical expedients applied on adoption of IFRS 16

In applying IFRS 16 for the first time, the Company has used the following practical expedients permitted by the standard:

- Use of a single discount rate to a portfolio of leases with reasonably similar characteristics;
- Reliance on previous assessments on whether leases are onerous;
- Accounting for operating leases with a remaining lease term of less than 12 months as of January 1, 2019, as short-term leases;
- Exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application;
- Use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Company has also elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4, “Determining whether an Arrangement contains a Lease.”

c. Other information relating to IFRS 16

As of September 30, 2019, the weighted average remaining lease term on the Company’s existing leases was 10.8 years for its property lease and 1.0 years for motor vehicle leases. Lease expense (substantially all of which is non-cash) for the nine months ended September 30, 2019 amounted to \$0.3 million. Cash paid for amounts included in the measurement of the operating lease liabilities for the nine months ended September 30, 2019 was \$0.1 million.

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, 2019, 942,910 ADSs were sold under the program for total net proceeds of approximately \$7.7 million, leaving an available balance under the facility of approximately \$22.3 million as of September 30, 2019.

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

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

b. Underwritten public offering

In February 2019, the Company completed an underwritten public offering of 1,866,667 of its ADSs and warrants to purchase 1,866,667 ADSs, at a public offering price of \$8.25 per ADS and accompanying warrant. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of \$11.25 per ADS. The offering raised a total of \$15.4 million, with net proceeds of \$14.1 million, after deducting fees and expenses. The amount of the offering consideration initially allocated to the warrants was \$5.0 million. Total issuance costs initially allocated to the warrants were \$0.4 million.

The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the date the contract was entered into and is 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 2.50% and an average standard deviation of 62.8%. The fair value of the warrants as of September 30, 2019 was based on the then current price of an ADS, a risk-free interest rate of 1.55% and an average standard deviation of 62.4%. The change in fair value from the date of issuance through September 30, 2019 amounted to \$4.1 million.

NOTE 5 – SHAREHOLDERS' EQUITY

As of December 31, 2018 and September 30, 2019, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2018	September 30, 2019
Authorized share capital	250,000,000	500,000,000
Issued and paid-up share capital	114,933,144	151,696,080
	In USD and NIS	
	December 31, 2018	September 30, 2019
Authorized share capital (in NIS)	25,000,000	50,000,000
Issued and paid-up share capital (in NIS)	11,493,314	15,169,608
Issued and paid-up share capital (in USD)	3,109,746	4,128,779

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 28, 2019 (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;
 - risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
 - competitive companies, technologies and our industry; and
 - statements as to the impact of the political and security situation in Israel on our business.
-

Overview

General

We are a clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – BL-8040, a novel peptide for the treatment of solid tumors, hematological malignancies and stem cell mobilization, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a 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.

Solid tumors

- > 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 was 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. Top-line results showed that the dual combination demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported BL-8040's ability to induce infiltration of tumor-reactive T-cells into the tumor, while reducing the number of immunosuppressive cells. In July 2018, we announced the expansion of the COMBAT/KEYNOTE-202 study under this collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. We initiated this arm of the trial in December 2018. We will be presenting response data from the triple combination arm of the study in an oral presentation at the Immuno-Oncology Congress 2019 of the European Society for Medical Oncology (ESMO I-O) to take place during December in Geneva, Switzerland. Overall survival results are expected in 2020.
- > In August 2016, in the framework of an agreement with MD Anderson Cancer Center, or MD Anderson, 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 supplied BL-8040 for this Phase 2b study, which commenced in January 2017. In November 2019, we announced encouraging top-line results of this dual-combination study.
- > In September 2016, we entered into a collaboration with Genentech, Inc., or Genentech (a member of the Roche Group), in the framework of which Genentech is currently carrying out two Phase 1b/2 studies investigating BL-8040 in combination with TECENTRIQ® (atezolizumab), Genentech's anti-PDL1 cancer immunotherapy, in solid tumors. 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. These studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters. As we are not the sponsor of these studies, we have had limited information about Genentech's data publication plan for these BL-8040-related arms within the MORPHEUS platform. Recently, however, we have been informed that the studies are being completed and that Genentech expects to report on the results during the first half of 2020.

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 United States and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. Results from the trial showed positive safety and response rate data for subjects treated with a combination of BL-8040 and high-dose cytarabine (Ara-C), or HiDAC. At the annual meeting of the European Hematology Association, or EHA, in June 2018, we presented positive overall survival data from the long-term follow-up part of this study. We continue to monitor long-term survival data for patients in the study and, in parallel, are planning our next clinical development steps in this indication.
- > 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 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. 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 events and/or exposure to provide a reasonable statistical powering for the analysis. We currently estimate the timing of such interim analysis for the first half of 2020. Top-line results from the trial are not expected before 2022.

Stem cell mobilization

- > In March 2015, we reported successful top-line 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. 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 CD34+ 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.
- > In December 2017, we commenced a randomized, placebo-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 then 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. Additional positive results from the lead-in period were reported at the annual meeting of the European Society for Blood and Marrow Transplantation held in March 2019, where it was announced that HSCs mobilized by BL-8040 in combination with G-CSF were successfully engrafted in all 11 patients. Top-line results of this randomized, placebo-controlled main part of the study are expected in the second half of 2020.

Other matters

- 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. The results of studies such as these are presented from time to time at relevant professional conferences.
- 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. In February 2019, the FDA granted Orphan Drug Designation to BL-8040 as a therapeutic for the treatment of pancreatic cancer.
- AGI-134, a clinical therapeutic candidate in-licensed by 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. 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. The multi-center, open-label study is currently being carried out in the UK and Israel and, following recent approval by the FDA for our Investigational New Drug (IND) application, is expected to expand to the US by the first half of 2020. Initial safety results from the first part of the study were announced at the beginning of September 2019; at the end of the same month, the second part of the study was commenced. Initial proof-of-mechanism efficacy results of the monotherapy arm from the second part of the study are expected by the end of 2020.
- Our commercialized, legacy therapeutic product, 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 Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in 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/verruccas) commenced in Europe in the second quarter of 2016. Since then, Perrigo invested in improving the product and during 2019 launched an improved version of the product in several European countries.

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. The collaboration agreement with Novartis will expire at the end of 2019.

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. Perrigo fulfilled its obligation to launch a licensed product commercially in the Territory in 2016. In addition, Perrigo is obligated to use commercially reasonable best efforts to obtain regulatory approval in the Territory for at least one more OTC indication and to commercialize BL-5010 for that indication. Compensation by Perrigo for the exclusive license includes an agreed amount for each unit sold. 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, see “— *Main Therapeutic Candidates*” above.

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 agreement, potential future upfront, milestone or royalty 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, 2019, we held \$30.1 million of cash, cash equivalents and short-term bank deposits.

Recent Company Developments

BL-8040 – Clinical Development

In November 2019, we announced that our abstract titled, “A Multi-Center Phase 2a Trial to Assess the Safety and Efficacy of BL-8040 (a CXCR4 inhibitor) in Combination with Pembrolizumab and Chemotherapy in Patients with Metastatic Pancreatic Adenocarcinoma (PDAC)” (Abstract ID: 255) was accepted for an oral presentation at the ESMO Immuno-Oncology Congress 2019 to take place during December 2019 in Geneva, Switzerland.

In November 2019, we announced top-line results of the Phase 2b trial conducted under the clinical collaboration with MD Anderson. The data demonstrated clinical activity of the dual combination in heavily pretreated patients. The open-label study enrolled 20 metastatic pancreatic cancer patients who progressed after at least one prior line of chemotherapy. Patients were treated for two weeks with BL-8040 as a single agent (1.25 mg/kg) followed by 3-week cycles of BL-8040 in combination with pembrolizumab (at days 1, 4, 8 and 11 of each cycle). Biopsies for tumor biology were performed before treatment, after BL-8040 monotherapy (optional), and after the drug combination. Of the 20 patients enrolled, 15 were evaluable for the primary endpoint of radiologic response. Of these 15 evaluable patients, one patient showed a partial response, two patients had stable disease and 12 patients experienced disease progression, resulting in a disease control rate of 20.0%. The overall median time to progression was two months, while the median time to progression for patients showing disease control was seven months. Median overall survival was seven months, while median survival for the patients showing disease control was 12 months. The combination was generally well tolerated with injection site discomfort being the most commonly reported adverse event. Four patients experienced grade 3 toxicities and one patient had a grade 4 dyspnea. In addition to the improved survival, tumor biopsies showed greater infiltration of T cells, especially cytotoxic CD8+ T cells, into the tumor niche in the responding patients, compared with patients that experienced disease progression. MD Anderson will be presenting the results from the study in a poster at the Annual Meeting of the Society for Immunotherapy of Cancer, or SITC, to take place during November 2019 in Baltimore.

BL-8040 – Preclinical Development

In October 2019, we announced that we will be delivering a poster presentation at the SITC Annual Meeting entitled “Combination of BL-8040, anti PD-1 and chemotherapy significantly reduced pancreatic tumor growth and changed the balance between CD4+/FOXP3+ cells and CD8+ cells in the tumor.”

AGI-134 – Clinical Development

In September 2019, we successfully completed the dose-escalation part of the Phase 1/2a clinical study for AGI-134. The drug was found to be safe and well tolerated, with no serious drug-related adverse events or dose-limiting toxicities reported. The maximal tolerated dose was not reached and the recommended dose for part 2 of the study was determined. In the same month, we began the second part of the study with the dosing of the first patient.

Corporate matters

On December 3, 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 July 29, 2019, we received written notice from Nasdaq confirming that we had regained compliance with the \$1.00 minimum bid price requirement.

On July 15, 2019, we implemented a change in the ratio of the Company’s ADSs to ordinary shares, from one ADS representing one ordinary share to a new ratio of one ADS representing 15 ordinary shares. The change in exchange ratio for the ADSs had the same effect as a 1-for-15 reverse stock split of the ADSs. In light of this change, all ADS amounts in this Operating and Financial Review have been stated based on the new ratio (i.e., subsequent to the 1-for-15 ratio change). The Company’s ordinary shares, which are not affected by the change, continue to trade on the Tel Aviv Stock Exchange.

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:

<u>Project</u>	<u>Status</u>	<u>Expected Near Term Milestones</u>
BL-8040	<ol style="list-style-type: none"> 1. Phase 2a study for relapsed or refractory AML completed 2. Phase 2b study in AML consolidation treatment line (BLAST) ongoing 3. Phase 2 study in allogeneic stem-cell mobilization completed 4. Phase 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; top-line results from dual combination arm announced in October 2018 5. Top-line results from Phase 2b study in pancreatic cancer, in collaboration with MD Anderson Cancer Center, were reported in November 2019 6. Phase 3 registration study in autologous stem-cell mobilization (GENESIS), ongoing 	<ol style="list-style-type: none"> 1. Follow-up for overall survival is ongoing; evaluation and decision regarding next clinical development steps 2. Interim results in H1 2020; top-line results expected in 2022 3. Follow-up on chronic GvHD during 2020. 4. Response results from triple combination arm expected in H2 2019; overall survival results expected in 2020 5. Follow-up for overall survival is ongoing 6. Top-line results from randomized, placebo-controlled main part of study expected in H2 2020
AGI-134	Part 2 of Phase 1/2a study commenced in September 2019	Initial proof-of-mechanism 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 improved product for first OTC indication in Europe commenced	Expansion of launch of improved product; pursuit of potential out-licensing partner(s) for OTC and non-OTC rights still held by us

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 equity financings we carried out in July 2017 and February 2019, as well as from debt financing we received in October 2018. 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. Sales-based royalties and other revenue from the license agreement with Perrigo have also been included as part of non-operating income, as the out-licensed product is not an integral part of our strategy and the amounts are not material.

Financial Expense and Income

Financial expense and income consists of interest earned on our cash, cash equivalents and short-term bank deposits; interest on loans, 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, 2018.

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 as endorsed by the IASB. 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, 2019 and 2018.

Cost of revenues

We did not record any cost of revenues during each of the three- or nine-month periods ended September 30, 2019 and 2018.

Research and development expenses

At December 31, 2016, our drug development pipeline 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. During 2018, we terminated four therapeutic candidates in our pipeline, so that our drug development pipeline as of December 31, 2018 and 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,		
	2018	2019	Increase (decrease)	2018	2019	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Research and development expenses, net	5,027	5,558	531	14,581	15,252	671

Comparison of three-month periods ending September 30, 2019 and 2018

Research and development expenses for the three months ended September 30, 2019 were \$5.6 million, an increase of \$0.6 million, or 11%, compared to \$5.0 million for the three months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT clinical trials.

Comparison of nine-month periods ending September 30, 2019 and 2018

Research and development expenses for the nine months ended September 30, 2019 were \$15.3 million, an increase of \$0.7 million, or 5%, compared to \$14.6 million for the nine months ended September 30, 2018. The increase resulted primarily from higher expenses associated with the BL-8040 GENESIS and COMBAT clinical trials, offset by a decrease in expenses related to BL-1230, a project which was terminated.

Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2018	2019	Increase (decrease)	2018	2019	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Sales and marketing expenses	293	201	(92)	1,137	683	(454)

Comparison of three-month periods ending September 30, 2019 and 2018

Sales and marketing expenses for the three months ended September 30, 2019 were \$0.2 million, a decrease of \$0.1 million, or 31%, compared to \$0.3 million for the three months ended September 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses.

Comparison of nine-month periods ending September 30, 2019 and 2018

Sales and marketing expenses for the nine months ended September 30, 2019 were \$0.7 million, a decrease of \$0.4 million, or 40%, compared to \$1.1 million for the nine months ended September 30, 2018. The decrease resulted primarily from a decrease in payroll and related expenses, including a one-time compensation payment in the 2018 period.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2018	2019	Increase (decrease)	2018	2019	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
General and administrative expenses	892	884	(8)	2,850	2,763	(87)

Comparison of three-month periods ending September 30, 2019 and 2018

General and administrative expenses for the three months ended September 30, 2019 were \$0.9 million, similar to the comparable period in 2018.

Comparison of nine-month periods ending September 30, 2019 and 2018

General and administrative expenses for the nine months ended September 30, 2019 were \$2.8 million, similar to the comparable period in 2018.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2018	2019	Increase (decrease)	2018	2019	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Non-operating income (expenses), net	(255)	3,055	3,310	870	3,976	3,106

Comparison of three-month and nine-month periods ending September 30, 2019 and 2018

Non-operating income for the three and nine months ended September 30, 2019 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet, offset by warrant offering expenses. 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. 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,		
	2018	2019	Increase (decrease)	2018	2019	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>					
Financial income	154	247	93	534	628	94
Financial expenses	(11)	(597)	(586)	(146)	(1,484)	(1,338)
Net financial income (expense)	143	(350)	(493)	388	(856)	(1,244)

Comparison of three-month periods ending September 30, 2019 and 2018

We recognized net financial expenses of \$0.4 million for the three months ended September 30, 2019 compared to net financial income of \$0.1 million for the three months ended September 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on our bank deposits. Net financial income for the 2018 period primarily relates to investment income earned on our bank deposits.

Comparison of nine-month periods ending September 30, 2019 and 2018

We recognized net financial expenses of \$0.9 million for the nine months ended September 30, 2019 compared to net financial income of \$0.4 million for the nine months ended September 30, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on our bank deposits. 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.

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, 2019, we held \$30.1 million in cash, cash equivalents and short-term bank deposits. We have invested substantially all our available cash funds in short-term bank deposits.

Pursuant to our ATM Program with BTIG, LLC, or 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, 2019, we sold 580,297 ADSs under the program, resulting in net proceeds to BioLine of approximately \$2.8 million (net of \$85,000 in commissions paid to BTIG). As of the date of this report, we have an available balance under the program of approximately \$22.3 million.

Net cash used in operating activities was \$17.2 million for the nine months ended September 30, 2019, compared with net cash used in operating activities of \$19.0 million for the nine months ended September 30, 2018. The \$1.8 million decrease in net cash used in operating activities during the nine-month period in 2019, compared to the nine-month period in 2018, was primarily the result of changes in operating asset and liability items in the two periods, i.e., a decrease in prepaid expenses and other receivables in 2019 versus an increase in 2018, as well as an increase in accounts payable and accruals in 2019 versus a decrease in 2018.

Net cash provided by investing activities was \$2.1 million for the nine months ended September 30, 2019, compared to net cash provided by investing activities of \$16.0 million for the nine months ended September 30, 2018. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits and the realization of our investment in iPharma in 2018.

Net cash provided by financing activities was \$16.6 million for the nine months ended September 30, 2019, compared to net cash provided by financing activities of \$2.8 million for the nine months ended September 30, 2018. The increase in cash flows from financing activities reflects the underwritten public offering completed in February 2019.

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 2021, 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

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.

Share and per-share information in ADSs

On July 15, 2019, we implemented a change in the ratio of our ADSs to ordinary shares, from one ADS representing one ordinary share to a new ratio of one ADS representing 15 ordinary shares. Accordingly, presented below, for the convenience of the reader, is share and per-share information in ADSs, on the basis of the new ADS ratio.

	Three months ended September 30,		Nine months ended September 30,	
	2018	2019	2018	2019
	<i>(in U.S. dollars)</i>			
Loss per ADS – basic and diluted	0.89	0.40	2.43	1.64
	December 31, 2018		September 30, 2019	
	<i>(in number of ADSs)</i>			
Authorized share capital	16,666,667	33,333,333		
Issued and paid-up capital	7,662,210	10,113,072		