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 2020

Commission file number: 001-35223

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 if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):_____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):_____

On November 23, 2020, the Registrant issued a press release announcing its financial results for the three and nine months ended September 30, 2020. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2020 and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 23, 2020;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2020 and for the three and nine months then ended; and

Exhibit 3: Registrant's operating and financial review as of September 30, 2020 and for the three and nine months then ended.

This Form 6-K, the text under the heading "Financial Results for the Quarter Ended September 30, 2020" in Exhibit 1, and Exhibit 2 and Exhibit 3 are 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 23, 2020

Exhibit 1

For Immediate Release

BioLineRx Reports Third Quarter 2020 Financial Results and Provides Corporate Update

- Phase 3 GENESIS study in SCM showed statistically significant positive results for primary endpoint in interim analysis; enrollment halted early; topline data in H1 2021 –

- Interim analysis for Phase 2b BLAST study in consolidation AML did not demonstrate statistically significant effect in primary endpoint; study will not continue; Company exploring alternative development options in AML –

- Phase 2a COMBAT/KEYNOTE-202 study in PDAC on track to report full results, including progression free survival and overall survival data, by year end -

- Management to hold conference call today, November 23, at 10:00 am EST –

TEL AVIV, Israel, November 23, 2020 -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended September 30, 2020 and provides a corporate update.

Significant events and achievements during the third quarter 2020 and subsequent period:

- Reported positive results from a pre-planned interim analysis of GENESIS Phase 3 trial of motixafortide for stem cell mobilization (SCM) in multiple myeloma patients. The Data Monitoring Committee (DMC) found statistically significant evidence favoring treatment with motixafortide in the primary endpoint, and subsequently issued a recommendation to cease patient enrollment immediately. In accordance with the DMC's recommendation, study enrollment was completed at 122 patients (instead of 177 as originally planned). SCM is the Company's most efficient path to registration;

- Announced initiation of Phase 2 investigator-initiated study of motixafortide in combination with LIBTAYO® and chemotherapy in first-line PDAC. The study is being run by Columbia University;

- Announced initiation of investigator-initiated Phase 1b study, led by Wolfson Medical Center in Holon, Israel, to evaluate motixafortide in patients hospitalized with acute respiratory distress syndrome (ARDS) secondary to COVID-19 and other respiratory viral infections;

- Renewed study enrollment in Part 2 of Phase 1/2a trial for AGI-134, which had been temporarily suspended in the second quarter of 2020 due to clinical operating risks associated with the COVID-19 pandemic;

- Conducted interim analysis for Phase 2b BLAST study in consolidation AML; analysis did not demonstrate statistically significant effect in primary endpoint; DMC recommended not to continue the study.

“The past several months have been very exciting for BioLineRx, highlighted by the very positive result of the interim analysis of our Phase 3 GENESIS study in stem cell mobilization” stated Philip Serlin, Chief Executive Officer of BioLineRx. “A statistically significant benefit in the primary endpoint was observed by combining motixafortide with the standard of care, G-CSF, leading the DMC to recommend that we cease study enrollment at 122 patients, instead of the 177 originally planned. We look forward to publishing final results of the study in the first half of next year, as we continue to advance motixafortide toward registration.

“With regard to the Phase 2b BLAST study in consolidation AML, based on the results of the interim analysis, the DMC recommended not to continue the study. Although we are disappointed by this outcome, particularly following the positive results that we previously observed in our Phase 1/2a study of motixafortide with cytarabine in relapsed/refractory AML, we continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment. We will decide on next steps in AML once we’ve had a chance to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from this study. I would also like to express our gratitude to the University of Halle, as study sponsor, and Dr. Carsten Müller-Tidow, as principal study investigator, as well as the other investigators and the patients who made this important trial possible.

“Finally, in the coming weeks, we plan to announce full results, including progression free survival (PFS) and overall survival (OS) data, on all study patients from the triple combination arm of our Phase 2a COMBAT/KEYNOTE-202 study in second-line PDAC. We previously shared preliminary positive overall response rate and disease control rate data, on approximately half of the patients enrolled in this study arm, at last year’s ESMO IO conference, and we remain optimistic that the combination of motixafortide and KEYTRUDA®, together with chemotherapy, will prove beneficial to survival as well.

“The significant and growing body of data that we are compiling on motixafortide, including the strikingly positive results of the interim analysis in the GENESIS phase 3 study reported last month, reassure us about the unique characteristics of motixafortide as the best-in-class CXCR4 antagonist, and confirm our belief that this promising compound can potentially serve as the backbone of combination therapies to treat a broad range of solid tumor and hematological cancers,” Mr. Serlin concluded.

Upcoming Expected Milestones

- Overall final results, including PFS and OS data, from the COMBAT/KEYNOTE-202 Phase 2a triple combination study in second-line PDAC by the end of 2020;
- Final results from the Phase 3 GENESIS trial in SCM in the first half of 2021;
- Preliminary results of the Phase 1b study in ARDS in the first half of 2021;
- Initial results from Part 2 of the Phase 1/2a trial of AGI-134 in solid tumors in the second half of 2021;
- Data from the Columbia University-initiated study of motixafortide in combination with LIBTAYO® and chemotherapy in first-line PDAC in mid-2022;

Financial Results for the Quarter Ended September 30, 2020

Research and development expenses for the three months ended September 30, 2020 were $3.5 million, a decrease of $2.1 million compared to $5.6 million for the comparable period in 2019. The decrease resulted primarily from termination of the BATTLE clinical study for motixafortide in 2019 and from lower expenses associated with the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second and third quarters of 2020. Research and development expenses for the nine months ended September 30, 2020 were $13.5 million, a decrease of $1.7 million, compared to $15.2 million for the nine months ended September 30, 2019. The decrease resulted primarily from lower expenses associated with the motixafortide COMBAT clinical trial and the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic mentioned above.

Sales and marketing expenses for three months ended September 30, 2020 were $0.3 million, an increase of $0.1 million compared to $0.2 million for the comparable period in 2019. The increase resulted primarily from consultancy services and market research for motixafortide offset by a decrease in payroll and related expenses related to a reduction in headcount. Sales and marketing expenses for the nine months ended September 30, 2020 were $0.7 million, similar to the comparable period in 2019**.**

General and administrative expenses for the three months ended September 30, 2020 were $0.9, similar to the comparable period in 2019. General and administrative expenses for the nine months ended September 30, 2020 were $2.8 million, similar to the comparable period in 2019.

The Company's operating loss for the three months ended September 30, 2020 amounted to $4.6 million, compared to an operating loss of $6.6 million for the comparable period in 2019. The Company's operating loss for the nine months ended September 30, 2020 was $17.1 million, compared to $18.7 million for the comparable period in 2019.

Non-operating income (expenses) for the three- and nine-month periods ended September 30, 2020 and 2019 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses and issuance expenses of the Company's ATM program.

Net financial expenses for the three months ended September 30, 2020 amounted to $0.3 million compared to net financial expenses of $0.4 million for the comparable period in 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial expenses for the nine months ended September 30, 2020 amounted to $0.9 million, similar to the comparable period in 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on bank deposits.

The Company's net loss for the three months ended September 30, 2020 amounted to $4.6 million, compared with a net loss of $3.9 million for the comparable period in 2019. The Company's net loss for the nine months ended September 30, 2020 amounted to $18.0 million, compared with a net loss of $15.6 million for the comparable period in 2019.

The Company held $20.8 million in cash, cash equivalents and short-term bank deposits as of September 30, 2020.

Net cash used in operating activities was $17.8 million for the nine months ended September 30, 2020, compared with net cash used in operating activities of $17.2 million for the nine months ended September 30, 2019. The $0.6 million increase in net cash used in operating activities during the nine-month period in 2020 was primarily the result of the decrease in accounts payable and accruals in the 2020 period.

Net cash provided by investing activities was $8.1 million for the nine months ended September 30, 2020, compared to net cash provided by investing activities of $2.1 million for the nine months ended September 30, 2019. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was $10.9 million for the nine months ended September 30, 2020, compared to net cash provided by financing activities of $16.6 million for the nine months ended September 30, 2019. The cash flows in 2020 primarily reflect the May and June financings and the net proceeds from the Company's ATM program, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering of our ADSs in February 2019, as well as net proceeds from the ATM facility.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, November 23, 2020 at 10:00 a.m. EST. To access the conference call, please dial +1-866-744-5399 from the US or +972-3-918-0664 internationally. The call will also be available via webcast and can be accessed through the Investor Relations page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until November 25, 2020; please dial +1-877-456-0009 from the US or +972-3-925-5929 internationally.

(Tables follow)

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform currently being evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, and for which positive data in respect of the study's primary endpoint was recently announced from an interim analysis, resulting in early cessation of recruitment. Motixafortide is also being evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated 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. Factors that could cause BioLineRx's 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 BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the coronavirus outbreak; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 12, 2020. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

Contact:
Tim McCarthy
LifeSci Advisors, LLC

+1-212-915-2564
tim@lifesciadvisors.com

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

	December 31, 2019	September 30, 2020
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	6,552
Short-term bank deposits	22,192	14,275
Prepaid expenses	108	269
Other receivables	613	327
Total current assets	28,210	21,423
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,462
Right-of-use assets, net	1,650	1,423
Intangible assets, net	21,891	21,731
Total non-current assets	25,357	24,616
Total assets	53,567	46,039
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	2,969
Accounts payable and accruals:		
Trade	7,794	5,933
Other	1,280	1,374
Lease liabilities	202	200
Total current liabilities	11,968	10,476
NON-CURRENT LIABILITIES		
Warrants	658	5,600
Long-term loans, net of current maturities	5,799	3,554
Lease liabilities	1,762	1,601
Total non-current liabilities	8,219	10,755
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	20,187	21,231
EQUITY		
Ordinary shares	4,692	8,281
Share premium	265,938	271,107
Capital reserve	12,132	12,835
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(265,999)
Total equity	33,380	24,808
Total liabilities and equity	53,567	46,039

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2020	2019	2020
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,558)	(3,484)	(15,252)	(13,546)
SALES AND MARKETING EXPENSES	(201)	(309)	(683)	(666)
GENERAL AND ADMINISTRATIVE EXPENSES	(884)	(856)	(2,763)	(2,843)
OPERATING LOSS	(6,643)	(4,649)	(18,698)	(17,055)
NON-OPERATING INCOME (EXPENSES), NET	3,055	294	3,976	(80)
FINANCIAL INCOME	247	39	628	214
FINANCIAL EXPENSES	(597)	(302)	(1,484)	(1,112)
NET LOSS AND COMPREHENSIVE LOSS	(3,938)	(4,618)	(15,578)	(18,033)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.03)	(0.02)	(0.11)	(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	148,920,707	296,508,550	142,527,942	231,380,969

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

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	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	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2020	4,692	265,938	12,132	(1,416)	(247,966)	33,380
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2020:						
Issuance of share capital, net	3,581	4,754	-	-	-	8,335
Employee stock options exercised	8	224	(224)	-	-	8
Employee stock options forfeited and expired	-	191	(191)	-	-	-
Share-based compensation	-	-	1,118	-	-	1,118
Comprehensive loss for the period	-	-	-	-	(18,033)	(18,033)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	12,835	(1,416)	(265,999)	24,808

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

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
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	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	Capital Reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JULY 1, 2020	8,281	271,107	12,639	(1,416)	(261,381)	29,230
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2020:						
Issuance of share capital, net	-	-	-	-	-	-
Employee stock options exercised	-	-	-	-	-	-
Employee stock options forfeited and expired	-	-	-	-	-	-
Share-based compensation	-	-	196	-	-	196
Comprehensive loss for the period	-	-	-	-	(4,618)	(4,618)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	12,835	(1,416)	(265,999)	24,808

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

	Nine months ended September 30,	
	2019	2020
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(15,578)	(18,033)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,658)	259
Net cash used in operating activities	(17,236)	(17,774)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(34,517)	(28,500)
Maturities of short-term deposits	36,637	36,626
Purchase of property and equipment	(54)	(1)
Net cash provided by investing activities	2,066	8,125
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	16,836	13,411
Employee stock options exercised	1	8
Repayments of loans	(70)	(2,338)
Repayments of lease liabilities	(165)	(162)
Net cash provided by financing activities	16,602	10,919
INCREASE IN CASH AND CASH EQUIVALENTS	1,432	1,270
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	49	(15)
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,885	6,552

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

	Nine months ended September 30,	
	2019	2020
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	667	737
Long-term prepaid expenses	(3)	-
Exchange differences on cash and cash equivalents	(49)	15
Fair value adjustments of warrants	(4,429)	(727)
Share-based compensation	1,170	1,118
Warrant issuance costs	417	593
Interest and exchange differences on short-term deposits	(628)	(209)
Interest on loans	512	370
Exchange differences on lease liability	-	4
	(2,343)	1,901
Changes in operating asset and liability items:		
Decrease in prepaid expenses and other receivables	265	125
Increase (decrease) in accounts payable and accruals	420	(1,767)
	685	(1,642)
	(1,658)	259
Supplemental information on interest received in cash	628	342
Supplemental information on interest paid in cash	782	671

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2020

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF SEPTEMBER 30, 2020

TABLE OF CONTENTS

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

	December 31, 2019	September 30, 2020
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	6,552
Short-term bank deposits	22,192	14,275
Prepaid expenses	108	269
Other receivables	613	327
Total current assets	28,210	21,423
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,462
Right-of-use assets, net	1,650	1,423
Intangible assets, net	21,891	21,731
Total non-current assets	25,357	24,616
Total assets	53,567	46,039
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	2,969
Accounts payable and accruals:		
Trade	7,794	5,933
Other	1,280	1,374
Lease liabilities	202	200
Total current liabilities	11,968	10,476
NON-CURRENT LIABILITIES		
Warrants	658	5,600
Long-term loans, net of current maturities	5,799	3,554
Lease liabilities	1,762	1,601
Total non-current liabilities	8,219	10,755
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	20,187	21,231
EQUITY		
Ordinary shares	4,692	8,281
Share premium	265,938	271,107
Capital reserve	12,132	12,835
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(265,999)
Total equity	33,380	24,808
Total liabilities and equity	53,567	46,039

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 September 30,		Nine months ended September 30,	
	2019	2020	2019	2020
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,558)	(3,484)	(15,252)	(13,546)
SALES AND MARKETING EXPENSES	(201)	(309)	(683)	(666)
GENERAL AND ADMINISTRATIVE EXPENSES	(884)	(856)	(2,763)	(2,843)
OPERATING LOSS	(6,643)	(4,649)	(18,698)	(17,055)
NON-OPERATING INCOME (EXPENSES), NET	3,055	294	3,976	(80)
FINANCIAL INCOME	247	39	628	214
FINANCIAL EXPENSES	(597)	(302)	(1,484)	(1,112)
NET LOSS AND COMPREHENSIVE LOSS	(3,938)	(4,618)	(15,578)	(18,033)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.03)	(0.02)	(0.11)	(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	148,920,707	296,508,550	142,527,942	231,380,969

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

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

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive loss	Accumulated deficit	Total
	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	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JANUARY 1, 2020	4,692	265,938	12,132	(1,416)	(247,966)	33,380
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2020:						
Issuance of share capital, net	3,581	4,754	-	-	-	8,335
Employee stock options exercised	8	224	(224)	-	-	8
Employee stock options forfeited and expired	-	191	(191)	-	-	-
Share-based compensation	-	-	1,118	-	-	1,118
Comprehensive loss for the period	-	-	-	-	(18,033)	(18,033)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	12,835	(1,416)	(265,999)	24,808

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

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

	Ordinary Shares	Share premium	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
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	4,129	262,430	12,153	(1,416)	(238,098)	39,198

	Ordinary Shares	Share premium	Capital Reserve	Other Comprehensive Loss	Accumulated deficit	Total
	in USD thousands					
BALANCE AT JULY 1, 2020	8,281	271,107	12,639	(1,416)	(261,381)	29,230
CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2020:						
Issuance of share capital, net	-	-	-	-	-	-
Employee stock options exercised	-	-	-	-	-	-
Employee stock options forfeited and expired	-	-	-	-	-	-
Share-based compensation	-	-	196	-	-	196
Comprehensive loss for the period	-	-	-	-	(4,618)	(4,618)
BALANCE AT SEPTEMBER 30, 2020	8,281	271,107	12,835	(1,416)	(265,999)	24,808

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,	
	2019	2020
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(15,578)	(18,033)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,658)	259
Net cash used in operating activities	(17,236)	(17,774)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(34,517)	(28,500)
Maturities of short-term deposits	36,637	36,626
Purchase of property and equipment	(54)	(1)
Net cash provided by investing activities	2,066	8,125
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	16,836	13,411
Employee stock options exercised	1	8
Repayments of loans	(70)	(2,338)
Repayments of lease liabilities	(165)	(162)
Net cash provided by financing activities	16,602	10,919
INCREASE IN CASH AND CASH EQUIVALENTS	1,432	1,270
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	49	(15)
CASH AND CASH EQUIVALENTS - END OF PERIOD	4,885	6,552

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,	
	2019	2020
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	667	737
Long-term prepaid expenses	(3)	-
Exchange differences on cash and cash equivalents	(49)	15
Fair value adjustments of warrants	(4,429)	(727)
Share-based compensation	1,170	1,118
Warrant issuance costs	417	593
Interest and exchange differences on short-term deposits	(628)	(209)
Interest on loans	512	370
Exchange differences on lease liability	-	4
	(2,343)	1,901
Changes in operating asset and liability items:		
Decrease in prepaid expenses and other receivables	265	125
Increase (decrease) in accounts payable and accruals	420	(1,767)
	685	(1,642)
	(1,658)	259
Supplemental information on interest received in cash	628	342
Supplemental information on interest paid in cash	782	671

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003.

BioLineRx and its subsidiaries (collectively, the "Company") are engaged in the development of therapeutics, primarily in 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 it has generated revenues from out-licensing transactions in the past, the Company has incurred accumulated losses in the amount of $266 million through September 30, 2020, and cannot determine with reasonable certainty when and if it will have sustainable profits. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements through the end of 2021. However, in the event that the Company does not begin to generate sustainable cash flows from its operating activities in the future, the Company will need to carry out significant cost reductions or raise additional funding. Management regularly evaluates various financing alternatives, including funding its clinical development activities via out-licensing or collaborations, and fundraising in the public or private equity markets. However, there is no certainty about the Company's ability to obtain such funding.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of September 30, 2020, and for the nine months then ended, were approved by the Board of Directors on November 23, 2020, 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, 2020 and for the three and nine months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair statement of financial position, results of operations, and cash flows in conformity with International Financial Reporting Standards ("IFRS"). The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2019 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, 2020 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 2 – BASIS OF PREPARATION (cont.)

In the process of preparing the interim financial statements, management makes estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity and expenses, as well as the related disclosures of contingent assets and liabilities. These inputs also consider, among other things, the implications of the COVID-19 pandemic on the Company's activities, and the resultant effects on critical and significant accounting estimates, most significantly in relation to the value of intangible assets. The COVID-19 pandemic has spread to many countries throughout the world, including to the United States, Europe and Israel, where the Company currently manufactures its therapeutic candidates and conducts its clinical trials. The Company has previously experienced some recruitment delays from the deepening and extended impact of COVID-19 on its clinical trials; however, at present, the Company does not believe these delays will significantly impact its clinical development plans. Future developments related to COVID-19 are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as its overall economic impact, and more specifically its effects on the financial markets. All estimates made by the Company related to the impact of COVID-19 in its financial statements may change in future periods. Actual results could differ from those estimates.

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, 2019 and for the year then ended.

NOTE 4 – EQUITY

a. At-the-market ("ATM") sales agreements

In October 2017, the Company entered into an at-the-market ("ATM") sales agreement with BTIG, LLC ("BTIG"), pursuant to which the Company was entitled, at its sole discretion, to 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 remained in effect. The Company agreed to pay BTIG a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. During the nine-month period ended September 30, 2020, the Company issued a total of 676,750 ADSs for total net proceeds of $1.4 million under the ATM facility. From the effective date of the agreement through September 30, 2020, an aggregate of 2,923,552 ADSs were sold under the facility for total gross proceeds of approximately $13.0 million. In September 2020, the Company terminated the agreement with BTIG.

In September 2020, the Company entered into a new ATM sales agreement with H.C. Wainwright & Co., LLC ("HCW"), pursuant to which the Company is entitled, at its sole discretion, to offer and sell through HCW, acting as sales agent, ADSs having an aggregate offering price of up to $25.0 million throughout the period during which the ATM facility remains in effect. The Company agreed to pay HCW a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. Expenses associated with establishment of the ATM facility with HCW amounted to $0.2 million, which were recorded in non-operating expenses during the period. As of September 30, 2020, no ADSs had been sold under the facility. Subsequent to September 30, 2020, an aggregate of 868,952 ADSs were sold under the facility, resulting in net proceeds of $1.7 million.

NOTE 4 – EQUITY (cont.)

b. Financings

In May and June 2020, the Company sold in registered direct offerings an aggregate of 7,653,145 ADSs at a price of $1.75 per ADS. In concurrent private placements, the Company issued to investors in the offerings unregistered warrants to purchase 7,653,145 ADSs. The warrants are exercisable immediately, expire two and half years from the date of issuance and have an exercise price of $2.25 per ADS. In addition, the Company granted to the placement agent's designees, as part of the placement fees, warrants to purchase 382,657 ADSs. These warrants are exercisable immediately, expire two and half years from the date of issuance and have an exercise price of $2.1875 per ADS. The offerings raised a total of $13.4 million, with net proceeds of $12.0 million, after deducting fees and expenses.

The warrants issued have been classified as a non-current financial liability due to a net settlement provision. This liability 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 approximately 0.20% and an average standard deviation of approximately 80.2%.The fair value of the warrants as of September 30, 2020 was based on the then current price of an ADS, a risk-free interest rate of 0.13% and an average standard deviation of approximately 87.3%. The change in fair value from the date of issuance through September 30, 2020 amounted to $0.5 million.

c. Stock options

In September 2020, the Board of Directors approved the re-pricing of outstanding "underwater" employee stock options for the purchase of approximately 12,300,000 ordinary shares (equivalent to approximately 820,000 ADSs), out of total employee stock options for the purchase of approximately 15,100,000 ordinary shares (equivalent to approximately 1,000,000 ADSs) outstanding at that time. The weighted average exercise price of the options subject to re-pricing was NIS 2.64 per share (equivalent to $11.60 per ADS). Following the re-pricing, the new exercise price of the options is NIS 1.00 per share (equivalent to $4.37 per ADS). The total compensation cost associated with the re-pricing was approximately $130,000, and will be recorded as an expense over the remaining vesting period of the re-priced options (which was not material for the quarter ended September 30, 2020).

In November 2020, the Company's Board of Directors approved an increase of 22,400,000 ordinary shares (equivalent to approximately 1,500,000 ADSs) to the total pool of authorized ordinary shares reserved for purposes of the Company's share incentive plan.

NOTE 4 – EQUITY (cont.)

d. Share capital

As of December 31, 2019, and September 30, 2020, the Company's share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2019	September 30, 2020
Authorized share capital	500,000,000	1,500,000,000
Issued and paid-up share capital	171,269,528	296,508,550

	In USD and NIS	
	December 31, 2019	September 30, 2020
Authorized share capital (in NIS)	50,000,000	150,000,000
Issued and paid-up share capital (in NIS)	17,126,953	29,650,855
Issued and paid-up share capital (in USD)	4,691,734	8,280,633

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 12, 2020, or 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"), our Report on Form 6-K filed on May 20, 2020, or the First Quarter Report, our Report on Form 6-K filed on August 6, 2020, or the Second Quarter Report, and elsewhere in this Report on Form 6-K. 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;
- the impact of coronavirus on our operations;
- 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 and ability to access sufficient 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.

Risk Factors

Except as set forth below, there are no material changes to the risk factors previously disclosed in our Annual Report and our Second Quarter Report.

Our business is subject to risks arising from a widespread outbreak of an illness or any other communicable disease, or any other public health crisis, such as the COVID-19 pandemic, which has impacted and could continue to impact our business.

The novel coronavirus outbreak, or COVID-19, has affected segments of the global economy and may materially affect our operations, including potentially interrupting our supply chain, clinical trial and commercialization activities. COVID-19 originated in Wuhan, China, in December 2019 and was declared a pandemic by the World Health Organization in March 2020. The virus has since spread to multiple countries, including to the United States, Europe and Israel, where we currently have our therapeutic candidates manufactured and conduct our clinical trials. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. For example, due to clinical operating issues associated with the COVID-19 pandemic, we previously reported the expectation of a delay of approximately nine months in the phase 1/2a study we are currently conducting for AGI-134, our second lead compound. The uncertainty surrounding the severity and continued spread of the coronavirus may result in a period of prolonged business disruption. COVID-19 may continue to impact our future operations, including potential interruptions to supply chains, clinical trials, commercialization activities and regulatory reviews and approvals. COVID-19 may also affect our employees and employees and operations at suppliers that may result in delays or disruptions in supply. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our shares. Additionally, if the COVID-19 pandemic has a significant impact on our business and financial results for an extended period of time, our liquidity and cash resources could be negatively impacted. Capital and credit markets have been disrupted by the crisis and exchanges have experienced increased volatility. As a result, access to additional financing may be challenging and is largely dependent upon evolving market conditions and other factors. We have taken precautionary measures, including, for example, a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second and third quarters of 2020, and may take additional measures, intended to minimize the risk of COVID-19 to our employees and operations. The extent of the impact of COVID-19 on our operational and financial performance, including our ability to execute our business strategies in the expected time frame or at all, will depend on future developments, such as the duration and spread of the COVID-19 pandemic and related restrictions and implications, all of which are uncertain and cannot be predicted.

Overview

General

We are a late clinical-stage biopharmaceutical development company with a strategic focus on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates − motixafortide (BL-8040), a novel peptide for the treatment of solid tumors, acute myeloid leukemia, or AML, 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. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. 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:

- Motixafortide is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we are developing for the treatment of solid tumors, 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 motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic pancreatic adenocarcinoma, or PDAC. 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 motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor, while reducing the number of immune regulatory cells. In July 2018, we announced the expansion of the COMBAT/KEYNOTE-202 study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA and chemotherapy. We initiated this arm of the trial in December 2018. In December 2019, we announced that preliminary data from the study indicated that the triple combination therapy showed a high level of disease control, including seven partial responders and 10 patients with stable disease out of 22 evaluable patients. In February 2020, we completed recruiting a total of 43 patients for the study. Data from the study continues to mature, and overall results are expected by the end of 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 motixafortide in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, was 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 motixafortide for this Phase 2b study, which commenced in January 2017. Final results from this study (based on a cut-off in July 2019 from 20 enrolled patients out of which 15 were evaluable) showed that the dual combination demonstrated clinical activity and encouraging overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor.

  - In October 2020, we announced that motixafortide will be tested in combination with the anti-PD-1 cemiplimab (LIBTAYO®) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line PDAC. This investigator-initiated Phase 2 study, led by Columbia University, will initially enroll 10-12 PDAC patients, and will be expanded to a total of 40 patients following an evaluation of the initial 10-12 patients based on pre-defined criteria. The primary endpoint of the study is the overall response rate. Secondary endpoints include safety and tolerability, progression free survival, duration of clinical benefit and overall survival. Data from the study is anticipated in mid-2022.

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 motixafortide 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 evaluating our next clinical development steps in this indication.

- Since August 2015, we have been conducting a double-blind, placebo-controlled, randomized, multi-center, Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, to assess the efficacy of motixafortide in addition to standard consolidation therapy (cytarabine) in AML patients who have responded to standard induction treatment and are in complete remission. Earlier this year, we finalized plans with our collaboration partners to conduct an interim analysis on 2/3 (N=128) of the 194 patients originally planned in the study, all of which had already completed treatment. Based on the interim analysis, the investigational arm of motixafortide combined with cytarabine did not demonstrate a statistically significant effect in the study's primary endpoint, and therefore, the Data Monitoring Committee, or DMC, recommended not to continue the study. We continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment, and we intend to decide on next steps in AML once we have had an opportunity to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from the study.

Stem cell mobilization

- In March 2015, we reported successful top-line results from a Phase 1 safety and efficacy trial for the use of motixafortide 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 motixafortide 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 motixafortide 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 motixafortide, known as the GENESIS trial, for the mobilization of hematopoietic stem cells, or 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 was designed to include 177 patients in more than 25 centers. Following review of the positive results from treatment of the first 11 patients, the DMC recommended that the lead-in part of the study 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 motixafortide in combination with G-CSF were successfully engrafted in all 11 patients.

In August 2020, we announced a decision to perform an interim analysis on approximately 65% of the original study sample size, primarily based on a significantly lower-than-anticipated patient-dropout rate in the study. In October 2020, we announced positive results from the interim analysis. Based on the statistically significant evidence favoring treatment with motixafortide, the study's independent DMC issued a recommendation to us that patient enrollment may be ceased immediately, without the need to recruit all 177 patients originally planned for the study. In accordance with the DMC's recommendation, study enrollment was complete at 122 patients. Full results for the study, including secondary and exploratory efficacy endpoints, as well as extended safety data, will be announced after the last patient enrolled reaches 100 days of follow-up post-transplantation, which is expected to occur in the first half of 2021.

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 motixafortide. These studies serve to further elucidate the mechanism of action for motixafortide. The results of studies such as these are presented from time to time at relevant professional conferences.

- ➢ Motixafortide has been granted three Orphan Drug Designations by the FDA: for use to mobilize HSCs from the bone marrow to peripheral blood for collection in autologous or allogeneic transplantation (granted in July 2012); for the treatment of AML (granted in September 2013); and for the treatment of pancreatic cancer (granted in February 2019). In January 2020, the European Medicines Agency, or EMA, granted Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer.

- AGI-134, a clinical therapeutic candidate in-licensed by our subsidiary, Agalimmune Ltd., 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, US and Israel. 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. Due to clinical operating issues associated with the COVID-19 pandemic, approximately half a year ago the clinical trial was temporarily suspended, which we continue to expect will lead to an approximate nine-month delay. Recently we have restarted study recruitment. As a result, initial proof-of-mechanism of action and efficacy results from the second part of the study are now expected in the second half of 2021.

- 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 products for treatment of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and during 2019 launched an improved version of the product in several European countries. In March 2020, we agreed that Perrigo could relinquish its license rights for certain countries that had been included in its territory according to the original license agreement, and was also no longer obligated to develop, obtain regulatory approval for and commercialize products for a second OTC indication. In turn, in March 2020, we agreed with our licensor of the rights to BL-5010, Innovative Pharmaceutical Concepts (IPC) Inc., or IPC, to return to IPC those license rights no longer out-licensed to Perrigo as a result of the agreement described in the preceding sentence, in consideration of the payment to us of royalties or fees on sublicense receipts.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the 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, 2020, we held $20.8 million of cash, cash equivalents and short-term bank deposits.

Recent Company Developments

Motixafortide as therapy for COVID-19-induced inflammatory lung disorders, including acute respiratory distress syndrome (ARDS)

Over the last few months, we have been evaluating motixafortide as a potential therapy for COVID-19-induced inflammatory lung disorders, including ARDS. In this regard, substantial data is emerging regarding the involvement of neutrophils, neutrophil extracellular traps (NETs), monocytes and macrophages in the development of ARDS secondary to COVID-19 and other viral infections; as well as the key involvement of CXCR4 as a mediator of those cells in the inflamed pulmonary tissue. Based on the scientific data indicating the importance of blocking the CXCR4/CXCL12 axis during ARDS, we believe that motixafortide may be of potential benefit for patients with ARDS.

Following our initial evaluation, in November 2020, we announced initiation of a Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections. The study is an investigator-initiated study, led by Wolfson Medical Center, in Israel, to evaluate motixafortide in patients hospitalized with ARDS. The primary endpoint of the study is to assess the safety of motixafortide in these patients; respiratory parameters and inflammatory biomarkers will be assessed as exploratory endpoints. Up to 25 patients will be enrolled in the study, with a preliminary analysis planned after ten patients have completed the initial treatment period. Results of the preliminary analysis are expected in the first half of 2021.

Recent financings

In May 2020, we sold to certain institutional investors an aggregate of 5,142,859 ADSs in a registered direct offering at $1.75 per ADS, resulting in gross proceeds of approximately $9,000,000. In addition, we issued to the investors unregistered warrants to purchase up to an aggregate of 5,142,859 ADSs in a private placement. The warrants are immediately exercisable and will expire two and one-half years from issuance at an exercise price of $2.25 per ADS, subject to adjustment as set forth therein. We paid an aggregate of $630,000 in placement agent fees plus certain expenses and issued unregistered placement agent warrants to purchase up to an aggregate of 257,143 ADS on substantially the same terms as the warrants except they have an exercise price of $2.1875 per ADS.

In June 2020, we sold to certain institutional investors an aggregate of 2,510,286 ADSs in a registered direct offering at $1.75 per ADS, resulting in gross proceeds of approximately $4,400,000. In addition, we issued to the investors unregistered warrants to purchase up to an aggregate of 2,510,286 ADSs in a private placement. The warrants are immediately exercisable and will expire two and one-half years from issuance at an exercise price of $2.25 per ADS, subject to adjustment as set forth therein. We paid an aggregate of $308,000 in placement agent fees plus certain expenses and issued unregistered placement agent warrants to purchase up to an aggregate of 125,514 ADS on substantially the same terms as the warrants except they have an exercise price of $2.1875 per ADS.

In September 2020 we entered into an at-the-market offering agreement, or the Offering Agreement, with H.C. Wainwright & Co., LLC, as agent, or H.C. Wainwright, pursuant to which we may offer and sell, from time to time, at our option, up to $25.0 million of our ADSs through an "at-the-market" equity offering program under which H.C. Wainwright will act as sales agent. Pursuant to a prospectus supplement dated September 25, 2020, we sold ADSs having an aggregate offering price of approximately $1.75 million at various times during the months of October and November 2020. Under an amended prospectus supplement dated November 13, 2020, we may sell up to an additional $4.43 million of our ADSs under the Sales Agreement. See discussion under "Liquidity and Capital Resources" for further information.

Revenues

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

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

Research and Development

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

Project	**Status**	**Expected Near Term Milestones**
motixafortide	1. Phase 3 registration study in autologous stem cell mobilization (GENESIS) ongoing, positive results from interim analysis announced October 2020; as recommended by DMC, study enrollment was completed at 122 patients 2. Phase 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; preliminary results from triple combination arm announced in December 2019; recruitment completed in February 2020 3. Phase 2a study for relapsed or refractory AML completed	1. Full results for the study expected in the first half of 2021 2. Overall results, including progression-free survival and overall survival, expected by end of 2020 3. Follow-up for overall survival is ongoing; evaluation and decision regarding next clinical development steps
AGI-134	Phase 1/2a study, ongoing	Initial proof-of-mechanism efficacy results of part 2 of study expected in second half of 2021

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, 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 therapeutic candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each therapeutic 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 cost of drug substance/product manufacturing, storage and shipment;
- 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 therapeutic candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our therapeutic 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, February 2019, May 2020 and June 2020, 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 issuance expenses of the ATM and 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, 2019.

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. 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

Revenues

We did not record any revenues during each of the three-month and nine-month periods ended September 30, 2020 and 2019.

Cost of revenues

We did not record any cost of revenues during each of the three-month and nine-month periods ended September 30, 2020 and 2019.

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,		
	2019	2020	Increase (decrease)	2019	2020	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	5,558	3,484	(2,074)	15,252	13,546	(1,706)

Comparison of three-month periods ending September 30, 2020 and 2019

Research and development expenses for the three months ended September 30, 2020 were $3.5 million, a decrease of $2.1 million, or 37.3%, compared to $5.6 million for the three months ended September 30, 2019. The decrease resulted primarily from termination of the BATTLE clinical study for motixafortide in 2019 and from lower expenses associated with the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic carried out in the second and third quarters of 2020.

Comparison of nine-month periods ending September 30, 2020 and 2019

Research and development expenses for the nine months ended September 30, 2020 were $13.5 million, a decrease of $1.7 million, or 11.2%, compared to $15.2 million for the nine months ended September 30, 2019. The decrease resulted primarily from lower expenses associated with the motixafortide COMBAT clinical trial and the AGI-134 study, as well as a decrease in payroll and related expenses due to a Company-wide salary reduction related to the COVID-19 pandemic mentioned above.

Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2019	2020	Increase (decrease)	2019	2020	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	201	309	108	683	666	(17)

Comparison of three-month periods ending September 30, 2020 and 2019

Sales and marketing expenses for the three months ended September 30, 2020 were $0.3 million, an increase of $0.1 million, or 53.7%, compared to $0.2 million for the three months ended September 30, 2019. The increase resulted primarily from consultancy services and market research for motixafortide offset by a decrease in payroll and related expenses related to a reduction in headcount.

Comparison of nine-month periods ending September 30, 2020 and 2019

Sales and marketing expenses for the nine months ended September 30, 2020 were $0.7 million, similar to the comparable period in 2019.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2019	2020	Increase (decrease)	2019	2020	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	884	856	(28)	2,763	2,843	80

Comparison of three-month periods ending September 30, 2020 and 2019

General and administrative expenses for the three months ended September 30, 2020 were $0.9 million, similar to the comparable period in 2019.

Comparison of nine-month periods ending September 30, 2020 and 2019

General and administrative expenses for the nine months ended September 30, 2020 were $2.8 million, similar to the comparable period in 2019.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2019	2020	Increase (decrease)	2019	2020	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	3,055	294	(2,761)	3,976	(80)	(4,056)

Comparison of three-month and nine-month periods ending September 30, 2020 and 2019

Non-operating income (expenses) for the three and nine months ended September 30, 2020 and 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 and issuance expenses of the ATM.

Financial income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2019	2020	Increase (decrease)	2019	2020	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	247	39	(208)	628	214	(414)
Financial expenses	(597)	(302)	295	(1,484)	(1,112)	372
Net financial income (expenses)	(350)	(263)	87	(856)	(898)	(42)

Comparison of three-month periods ending September 30, 2020 and 2019

We recognized net financial expenses of $0.3 million for the three months ended September 30, 2020 compared to net financial expenses of $0.4 million for the three months ended September 30, 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

Comparison of nine-month periods ending September 30, 2020 and 2019

We recognized net financial expenses of $0.9 million for the nine months ended September 30, 2020, similar to the comparable period in 2019. Net financial expenses for both periods primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, funding from the IIA, and payments received under our strategic licensing arrangements. At September 30, 2020, we held $20.8 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 prior ATM facility with BTIG, LLC, or BTIG, during the nine months ended September 30, 2020, we sold an aggregate of 676,750 ADSs under the facility, resulting in net proceeds to us of approximately $1.4 million (net of $44,000 in commissions paid to the sales agent). In September 2020, we terminated our ATM facility with BTIG and in connection with the termination, entered into a new $25.0 million ATM facility with HCW. Under the new facility with HCW, subsequent to September 30, 2020, we sold an aggregate of 868,952 ADSs resulting in net proceeds to us of approximately $1.7 million (net of $53,000 in commissions paid to the sales agent). As of the date of this report, we may offer and sell under the new ATM facility ADSs having an aggregate offering price of approximately $4.4 million pursuant to a prospectus supplement dated November 13, 2020.

Net cash used in operating activities was $17.8 million for the nine months ended September 30, 2020, compared with net cash used in operating activities of $17.2 million for the nine months ended September 30, 2019. The $0.6 million increase in net cash used in operating activities during the nine-month period in 2020 was primarily the result of the decrease in accounts payable and accruals in 2020.

Net cash provided by investing activities was $8.1 million for the nine months ended September 30, 2020, compared to net cash provided by investing activities of $2.1 million for the nine months ended September 30, 2019. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was $10.9 million for the nine months ended September 30, 2020, compared to net cash provided by financing activities of $16.6 million for the nine months ended September 30, 2019. The cash flows in 2020 primarily reflect the May and June financings and the net proceeds from the ATM facilities, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering of our ADSs in February 2019, as well as net proceeds from the ATM facility.

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 until the end of 2021, we will require significant additional financing in the future to fund our operations. The extent and timing of 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 impact of COVID-19 on our operations;
- 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;
- interest and principal payments on the loan from Kreos Capital;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates;
- market conditions; and
- payments to the IIA.

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,	
	2019	2020	2019	2020
	(in U.S. dollars)			
Loss per ADS – basic and diluted	(0.40)	(0.23)	(1.64)	(1.17)

	December 31, 2019	September 30, 2020
	(in number of ADSs)	
Authorized share capital	33,333,333	100,000,000
Issued and paid-up capital	11,417,969	19,767,237