
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 May 2020

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 May 20, 2020, the Registrant will issue a press release announcing its financial results for the three months ended March 31, 2020. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of March 31, 2020 and for the three months then ended. Attached hereto are the following exhibits:

[Exhibit 1: Registrant's press release dated May 20, 2020;](#)

[Exhibit 2: Registrant's condensed consolidated interim financial statements as of March 31, 2020 and for the three months then ended; and](#)

[Exhibit 3 - Registrant's operating and financial review as of March 31, 2020 and for the three 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: May 20, 2020



For Immediate Release

**BioLineRx Reports First Quarter 2020 Financial Results
and Provides Corporate Update**

- On track to report progression free survival and overall survival data from triple combination arm of ongoing COMBAT/KEYNOTE-202 Phase 2a trial in mid-2020 -

- Key data readouts in AML and stem cell mobilization expected by year-end -

- Management to hold conference call today, May 20, at 10:00 am EDT -

TEL AVIV, Israel, May 20, 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 March 31, 2020 and provides a corporate update.

Highlights and achievements during the first quarter 2020 and subsequent period:

- Completed recruitment of the triple combination arm of the COMBAT/KEYNOTE-202 study;
- Continued to advance the COMBAT/KEYNOTE-202 study toward progression free survival (PFS) and overall survival (OS) data in mid-2020;
- Received Orphan Drug Designation for motixafortide (BL-8040) for the Treatment of Pancreatic Cancer in Europe;
- Announced Notice of Allowance from USPTO for a broad patent covering motixafortide in combination with anti-PD-1 for the treatment of any and all types of cancer.

“The ongoing COVID-19 pandemic has caused an unprecedented disruption in business activities and continues to impact drug development timelines around the world,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “During this crisis, we have remained in close contact with our principal investigators, and we remain on track to report important survival data from the triple combination arm of our ongoing Phase 2a COMBAT/KEYNOTE-202 study in advanced second-line pancreatic cancer mid-year, consistent with our prior guidance. The compelling and sustained preliminary response data on 22 evaluable patients that we reported in December give us hope that the combination of motixafortide, KEYTRUDA® and chemotherapy could represent a significant breakthrough in one of the most difficult to treat cancers.

“We also continue to expect results from our ongoing BLAST Phase 2b study of motixafortide in consolidation therapy for AML patients and our GENESIS Phase 3 trial in stem cell mobilization for autologous transplantation in multiple myeloma patients by the end of this year.

“Development of our second clinical candidate, AGI-134, has been impacted by COVID-19, as enrollment in the Phase 1/2a trial has been temporarily suspended. We now expect data from that study in the second half of next year.

“We have taken swift actions in response to the pandemic to conserve cash and ensure that we can successfully navigate through this unprecedented time. But we remain as enthusiastic as ever about the broad therapeutic potential of motixafortide to treat a broad range of cancers, and we look forward to three important data readouts this year,” Mr. Serlin concluded.

Upcoming 2020 and 2021 Milestones

- Progression-free survival and overall survival data from the triple combination arm of the COMBAT/KEYNOTE-202 Phase 2a study in mid-2020;
- Interim results from the BLAST Phase 2b AML consolidation study in the second half of 2020;
- Results from the GENESIS Phase 3 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, which were initially expected by year-end 2020, are now anticipated in the second half of 2021 due to a temporary suspension of recruitment caused by the COVID-19 pandemic.

Financial Results for the Quarter Ended March 31, 2020

Research and development expenses for the quarter ended March 31, 2020 were \$5.4 million, an increase of \$1.0 million, or 23.5%, compared to \$4.4 million for the comparable period in 2019. The increase resulted primarily from higher expenses associated with the motixafortide COMBAT clinical trial as well as an increase in share-based compensation.

Sales and marketing expenses for the quarter ended March 31, 2020 were \$0.2 million, a decrease of \$0.1 million, or 31.6%, compared to \$0.3 million for the comparable period in 2019. The decrease resulted primarily from a decrease in payroll and related expenses.

General and administrative expenses for the quarter ended March 31, 2020 were \$1.2 million, an increase of \$0.3 million, or 33.7%, compared to \$0.9 million for the comparable period in 2019. The increase resulted primarily from an increase in share-based compensation.

The Company's operating loss for the quarter ended March 31, 2020 amounted to \$6.8 million, compared to an operating loss of \$5.6 million for the comparable period in 2019.

Non-operating income amounted to \$0.5 million for the quarter ended March 31, 2020, compared to non-operating expense of \$0.3 million for the comparable period in 2019. Non-operating income for the three months ended March 31, 2020 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet. Non-operating expenses for the three months ended March 31, 2019 primarily relate to warrant offering expenses offset by fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial expenses amounted to \$0.3 million for the quarter ended March 31, 2020, compared to net financial expenses of \$0.2 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.

The Company's net loss for the quarter ended March 31, 2020 amounted to \$6.6 million, compared with a net loss of \$6.2 million for the comparable period in 2019.

The Company held \$21.2 million in cash, cash equivalents and short-term bank deposits as of March 31, 2020.

Net cash used in operating activities was \$6.7 million for the quarter ended March 31, 2020, compared with net cash used in operating activities of \$4.6 million for the comparable period in 2019. The \$2.1 million increase in net cash used in operating activities during the three-month period in 2020, compared to the three-month period in 2019, was primarily the result of changes in operating asset and liability items in the two periods, i.e., an increase in prepaid expenses and other receivables in 2020 versus a decrease in 2019, as well as higher decrease in accounts payable and accruals in 2020 versus 2019.

Net cash provided by investing activities was \$6.2 million for the quarter ended March 31, 2020, compared to net cash used in investing activities of \$9.3 million for the comparable period in 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 \$0.4 million for the quarter ended March 31, 2020, compared to net cash provided by financing activities of \$14.9 million for the comparable period in 2019. The decrease 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, May 20, 2020 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-668-9141 from the US or +972-3-918-0609 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 May 22, 2020; please dial +1-888-782-4291 from the US or +972-3-925-5928 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 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. Motixafortide 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.

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.bioglinerx.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 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.

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

	<u>December 31,</u> <u>2019</u>	<u>March 31,</u> <u>2020</u>
	<u>in USD thousands</u>	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	5,072
Short-term bank deposits	22,192	16,109
Prepaid expenses	108	277
Other receivables	613	682
Total current assets	<u>28,210</u>	<u>22,140</u>
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,698
Right-of-use assets, net	1,650	1,565
Intangible assets, net	21,891	21,768
Total non-current assets	<u>25,357</u>	<u>25,031</u>
Total assets	<u>53,567</u>	<u>47,171</u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	2,777
Accounts payable and accruals:		
Trade	7,794	7,489
Other	1,280	1,303
Lease liabilities	202	197
Total current liabilities	<u>11,968</u>	<u>11,766</u>
NON-CURRENT LIABILITIES		
Warrants	658	182
Long-term loans, net of current maturities	5,799	5,076
Lease liabilities	1,762	1,639
Total non-current liabilities	<u>8,219</u>	<u>6,897</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>20,187</u>	<u>18,663</u>
EQUITY		
Ordinary shares	4,692	4,907
Share premium	265,938	267,140
Capital reserve	12,132	12,488
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(254,611)
Total equity	<u>33,380</u>	<u>28,508</u>
Total liabilities and equity	<u>53,567</u>	<u>47,171</u>

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

	Three months ended March 31,	
	2019	2020
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,392)	(5,422)
SALES AND MARKETING EXPENSES	(256)	(175)
GENERAL AND ADMINISTRATIVE EXPENSES	(930)	(1,243)
OPERATING LOSS	(5,578)	(6,840)
NON-OPERATING INCOME (EXPENSES), NET	(340)	469
FINANCIAL INCOME	210	140
FINANCIAL EXPENSES	(447)	(414)
NET LOSS AND COMPREHENSIVE LOSS	<u>(6,155)</u>	<u>(6,645)</u>
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.05)</u>	<u>(0.04)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>132,979,984</u>	<u>176,454,423</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>
	in USD thousands					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2019:						
Issuance of share capital, net	817	9,620	-	-	-	10,437
Employee stock options exercised	1	18	(18)	-	-	1
Employee stock options forfeited and expired	-	30	(30)	-	-	-
Share-based compensation	-	-	284	-	-	284
Comprehensive loss for the period	-	-	-	-	(6,155)	(6,155)
BALANCE AT MARCH 31, 2019	<u>3,928</u>	<u>259,860</u>	<u>12,191</u>	<u>(1,416)</u>	<u>(228,675)</u>	<u>45,888</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, 2020	4,692	265,938	12,132	(1,416)	(247,966)	33,380
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2020:						
Issuance of share capital, net	208	895	-	-	-	1,103
Employee stock options exercised	7	204	(204)	-	-	7
Employee stock options forfeited and expired	-	103	(103)	-	-	-
Share-based compensation	-	-	663	-	-	663
Comprehensive loss for the period	-	-	-	-	(6,645)	(6,645)
BALANCE AT MARCH 31, 2020	<u>4,907</u>	<u>267,140</u>	<u>12,488</u>	<u>(1,416)</u>	<u>(254,611)</u>	<u>28,508</u>

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

	Three months ended	
	March 31,	
	2019	2020
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,155)	(6,645)
Adjustments required to reflect net cash used in operating activities (see appendix below)	1,533	(93)
Net cash used in operating activities	<u>(4,622)</u>	<u>(6,738)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(21,510)	(6,000)
Maturities of short-term deposits	12,228	12,191
Purchase of property and equipment	(31)	-
Net cash provided by (used in) investing activities	<u>(9,313)</u>	<u>6,191</u>
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	14,989	1,103
Employee stock options exercised	1	7
Repayments of loans	(23)	(682)
Repayments of lease liabilities	(50)	(41)
Net cash provided by financing activities	<u>14,917</u>	<u>387</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	982	(160)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(2)	(65)
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u><u>4,384</u></u>	<u><u>5,072</u></u>

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

	Three months ended	
	March 31,	
	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	213	321
Long-term prepaid expenses	1	-
Exchange differences on cash and cash equivalents	2	65
Fair value adjustments of warrants	(79)	(476)
Share-based compensation	284	663
Warrant issuance costs	417	-
Interest and exchange differences on short-term deposits	(195)	(108)
Interest on loans	154	44
Exchange differences on lease liability	-	(82)
	<u>797</u>	<u>427</u>
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses and other receivables	786	(238)
Decrease in accounts payable and accruals	(50)	(282)
	<u>736</u>	<u>(520)</u>
	<u>1,533</u>	<u>(93)</u>
Supplemental information on interest received in cash	<u>229</u>	<u>184</u>
Supplemental information on interest paid in cash	<u>238</u>	<u>275</u>

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF MARCH 31, 2020

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF MARCH 31, 2020

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

	<u>December 31,</u> <u>2019</u>	<u>March 31,</u> <u>2020</u>
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Total assets	<u><u>53,567</u></u>	<u><u>47,171</u></u>
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Accounts payable and accruals:		
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Total equity	<u>33,380</u>	<u>28,508</u>
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The accompanying notes are an integral part of these condensed consolidated interim financial statements.

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(UNAUDITED)

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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.

The Company’s American Depositary Shares (“ADSs”) are traded on the NASDAQ Capital Market, and its ordinary shares are traded on the Tel Aviv Stock Exchange (“TASE”).

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 \$255 million through March 31, 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 into the second quarter of 2021. Accordingly, absent additional funding or the generation of cash flows from its operations, the Company may be unable to carry out its current operating activities planned for the next 12 months from the date of approval of these financial statements.

Management is in the process of evaluating 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. These factors raise substantial doubt as to the Company’s ability to continue as a going concern.

The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not raise the requisite funds, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of March 31, 2020, and for the three months then ended, were approved by the Board of Directors on May 19, 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 March 31, 2020 and for the three 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, 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 months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

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 COVID-19 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. 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 – 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.

During the three months period ended March 31, 2020, the Company issued a total of 479,114 ADSs for total net proceeds of \$1.1 million. From the effective date of the agreement through March 31, 2020, 2,725,916 ADSs were sold under the program for total gross proceeds of approximately \$12.6 million, leaving an available balance under the facility of approximately \$17.4 million as of March 31, 2020.

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

NOTE 5 – SHAREHOLDERS’ EQUITY

As of December 31, 2019 and March 31, 2020, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2019	March 31, 2020
Authorized share capital	500,000,000	500,000,000
Issued and paid-up share capital	171,269,528	178,709,725
	In USD and NIS	
	December 31, 2019	March 31, 2020
Authorized share capital (in NIS)	50,000,000	50,000,000
Issued and paid-up share capital (in NIS)	17,126,953	17,870,972
Issued and paid-up share capital (in USD)	4,691,734	4,906,787

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 (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 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.
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Risk Factors

Except as set forth below, there are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2019.

The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, such as the COVID-19 pandemic, could adversely affect our business, results of operations and financial condition.

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. At present, we are not experiencing significant impacts or delays from COVID-19 on our clinical and development activities for our lead compound, motixafortide. However, we do expect a delay of between 6-12 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 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. Any COVID-19 related disruption could have a material adverse impact on our business and our results of operation and financial condition. 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, 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 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, 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.

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, 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 motixafortide 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 motixafortide'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 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 January 2020, we completed recruiting a total of 43 patients for the study, and overall results are expected in mid-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. Partial 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.

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.
- We are currently investigating motixafortide 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 motixafortide 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 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 to be in the second 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 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 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 motixafortide in combination with G-CSF were successfully engrafted in all 11 patients. 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 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.
- In September 2013, the FDA granted an Orphan Drug Designation to motixafortide as a therapeutic for the treatment of AML; and in January 2014, the FDA granted an Orphan Drug Designation to motixafortide as a treatment for stem cell mobilization. In January 2015, the FDA modified this Orphan Drug Designation for motixafortide for use either as a single agent or in combination with G-CSF. In February 2019, the FDA granted Orphan Drug Designation to motixafortide as a therapeutic for the treatment of pancreatic cancer. 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 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, 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, initial proof-of-mechanism of action and efficacy results from the second part of the study have been delayed and 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/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. 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 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 outlicensed to Perrigo as a result of the agreement described in the preceding sentence, in consideration of the payment to BioLineRx 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 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 March 31, 2020, we held \$21.2 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 and macrophages in the development of COVID-19 lung symptoms, including severe complications such as ARDS; as well as the key involvement of CXCR4 as the primary mediator of those cells in the inflamed alveolar tissue of the lung. We believe that motixafortide will succeed in modulating neutrophils and macrophages via CXCR4 inhibition, thus reducing their retention in the lungs, potentially resulting in improved morbidity and mortality. We are currently determining the optimal pathway to obtain initial clinical data in the shortest time possible.

In January 2020, we completed patient recruitment in the triple combination arm of our ongoing Phase 2a COMBAT/KEYNOTE-202 study. A total of 43 patients diagnosed with unresectable stage IV metastatic pancreatic adenocarcinoma (PDAC), who have progressed following first-line gemcitabine-based therapy, were enrolled as planned in the triple combination arm focusing on second-line pancreatic cancer patients. Patients receive motixafortide monotherapy priming treatment for five days, followed by combination cycles of chemotherapy (Onivyde[®]/5-fluorouracil/leucovorin), KEYTRUDA and motixafortide until progression. The primary endpoint of the study is the objective response rate (ORR). Secondary endpoints include overall survival, progression free survival, and disease control rate.

Regulatory matters

In January 2020, the EMA granted Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer. The EMA grants orphan medicinal product designation to investigational drugs intended to treat, prevent or diagnose a life-threatening or chronically debilitating disease affecting fewer than five in 10,000 people in the EU and for which no satisfactory treatment is available or, if such treatment exists, the medicine must be of significant benefit to those affected by the condition. Orphan medicinal product designation provides regulatory and financial incentives for companies to develop and market therapies, including ten years of market exclusivity, protocol assistance, fee reductions and EU-funded research.

Patent Protection

In February 2020, the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent application claiming the use of motixafortide combined with any PD-1 inhibitor for the treatment of any type of cancer. The PD-1 antagonist can be any agent that prevents and/or inhibits the biological function and/or expression of PD-1, such as KEYTRUDA. The targeted cancer can be solid, non-solid, and/or a cancer metastasis. This patent, when issued, will be valid until July 2036 with a possibility of up to five years patent term extension. Additional corresponding patent applications are pending in Europe, Japan, China, Canada, Australia, India, Korea, Mexico, Brazil and Israel.

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	<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 2a in pancreatic cancer under Merck collaboration (COMBAT/KEYNOTE-202) ongoing; preliminary results from triple combination arm announced in December 2019; recruitment completed in January 2020 4. Phase 3 registration study in autologous stem cell mobilization commenced (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 second half of 2020 3. Progression-free and overall survival results expected in mid-2020 4. Results from randomized, placebo-controlled main part of study expected in second half of 2020
AGI-134	Phase 1/2a study, ongoing	Initial proof-of-mechanism efficacy results of part 2 of study expected in second half of 2021
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

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 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 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, 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 periods ended March 31, 2020 and 2019.

Cost of revenues

We did not record any cost of revenues during each of the three-month periods ended March 31, 2020 and 2019.

Operating Results Comparison between Periods

Revenues and cost of revenues

See discussion under “Results of Operations.”

Research and development expenses

	Three months ended March 31,		
	2019	2020	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>		
Research and development expenses	4,392	5,422	1,030

Research and development expenses for the three months ended March 31, 2020 were \$5.4 million, an increase of \$1.0 million, or 23.5%, compared to \$4.4 million for the three months ended March 31, 2019. The increase resulted primarily from higher expenses associated with the motixafortide COMBAT clinical trial as well as an increase in share-based compensation.

Sales and marketing expenses

	Three months ended March 31,		
	2019	2020	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>		
Sales and marketing expenses	256	175	(81)

Sales and marketing expenses for the three months ended March 31, 2020 were \$0.2 million, a decrease of \$0.1 million, or 31.6%, compared to \$0.3 million for the three months ended March 31, 2019. The decrease resulted primarily from a decrease in payroll and related expenses.

General and administrative expenses

	Three months ended March 31,		
	2019	2020	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>		
General and administrative expenses	930	1,243	313

General and administrative expenses for the three months ended March 31, 2020 were \$1.2 million, an increase of \$0.3 million, or 33.7%, compared to \$0.9 million for the three months ended March 31, 2019. The increase resulted primarily from an increase in share-based compensation.

Non-operating income (expenses), net

	Three months ended March 31,		
	2019	2020	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>		
Non-operating income (expenses), net	(340)	469	809

We recognized net non-operating income of \$0.5 million for the three months ended March 31, 2020, compared to net non-operating expense of \$0.3 million for the three months ended March 31, 2019.

Non-operating income for the three months ended March 31, 2020 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. Non-operating expenses for the three months ended March 31, 2019 primarily relate to warrant offering expenses offset by fair-value adjustments of warrant liabilities on our balance sheet.

Financial income (expenses), net

	Three months ended March 31,		
	2019	2020	Increase (decrease)
	<i>(in thousands of U.S. dollars)</i>		
Financial income	210	140	(70)
Financial expenses	(447)	(414)	33
Net financial income (expenses)	<u>(237)</u>	<u>(274)</u>	<u>(37)</u>

We recognized net financial expenses of \$0.3 million for the three months ended March 31, 2020 compared to net financial expenses of \$0.2 million for the three months ended March 31, 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

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred losses and cash flow deficits from operations since inception, resulting in accumulated losses, as of March 31, 2020, of \$255 million. We believe that our existing cash and cash equivalents will only be sufficient to fund our projected cash needs into the second quarter of 2021. To meet future capital needs, we would need to raise additional capital through equity or debt financing or other strategic transactions. Management is in the process of evaluating various financing alternatives, including funding its clinical development activities through out-licensing or collaborations, and fundraising in the public or private equity markets.

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 March 31, 2020, we held \$21.2 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 three months ended March 31, 2020, we sold 479,114 ADSs under the program, resulting in net proceeds to BioLine of approximately \$1.1 million (net of \$34,200 in commissions paid to BTIG). As of the date of this report, we have an available balance under the program of approximately \$17.4 million.

Net cash used in operating activities was \$6.7 million for the three months ended March 31, 2020, compared with net cash used in operating activities of \$4.6 million for the three months ended March 31, 2019. The \$2.1 million increase in net cash used in operating activities during the three-month period in 2020, compared to the three-month period in 2019, was primarily the result of changes in operating asset and liability items in the two periods, i.e., an increase in prepaid expenses and other receivables in 2020 versus a decrease in 2019, as well as a larger decrease in accounts payable and accruals in 2020 versus 2019.

Net cash provided by investing activities was \$6.2 million for the three months ended March 31, 2020, compared to net cash used in investing activities of \$9.3 million for the three months ended March 31, 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 \$0.4 million for the three months ended March 31, 2020, compared to net cash provided by financing activities of \$14.9 million for the three months ended March 31, 2019. The decrease 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 the second quarter of 2021, we will require significant additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. 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;
- 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; 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 March 31,	
	2019	2020
	<i>(in U.S. dollars)</i>	
Loss per ADS – basic and diluted	<u>0.69</u>	<u>0.56</u>
	December 31, 2019	March 31, 2020
	<i>(in number of ADSs)</i>	
Authorized share capital	<u>33,333,333</u>	<u>33,333,333</u>
Issued and paid-up capital	<u>11,417,968</u>	<u>11,913,981</u>