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 2021

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 May 26, 2021, the Registrant issued a press release announcing its financial results for the three months ended March 31, 2021. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of March 31, 2021 and for the three months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated May 26, 2021;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of March 31, 2021 and for the three months then ended; and

Exhibit 3: Registrant's operating and financial review as of March 31, 2021 and for the three months then ended.

This Form 6-K, the text under the heading "Financial Results for the Quarter Ended March 31, 2021" 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: May 26, 2021

Exhibit 1

For Immediate Release

BioLineRx Reports First Quarter 2021 Financial Results and Provides Corporate Update

- Phase 3 GENESIS study in stem-cell mobilization (SCM) demonstrated highly statistically significant positive results across all primary and secondary endpoints -

- ~90% of patients in treatment arm underwent transplantation following only one dose of Motixafortide and only one apheresis session; potentially positions Motixafortide + G-CSF to become new standard of care in this indication -

- Company proceeding with activities in support of NDA submission targeted for H1 2022 -

- Management to hold conference call today, May 26, at 10:00 am EST -

Tel Aviv, Israel, May 26, 2021 -- 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, 2021 and provides a corporate update.

Significant events and achievements during the first quarter 2021 and subsequent period:

- Announced positive topline results from GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization (SCM). The data demonstrate that the study successfully met all primary and secondary endpoints with an exceptionally high level of statistical significance ($p<0.0001$).

- 88.3% of patients receiving Motixafortide + G-CSF underwent transplantation after only ONE administration of Motixafortide and in only ONE apheresis session, compared to 10.8% for G-CSF alone; potentially supports Motixafortide on top of G-CSF as new standard-of-care mobilization agent in autologous bone-marrow transplantation.

- The Company is proceeding with activities in support of an NDA submission in this indication anticipated in the first half of 2022, including a pre-NDA meeting with the FDA planned for the second half of this year.

- Presented data at the 2021 American Association for Cancer Research (AACR) Annual Meeting analyzing results by liver metastasis status from the Company's Phase 2a COMBAT/KEYNOTE-202 triple combination study testing Motixafortide in metastatic pancreatic cancer. The analysis further strengthened the results reported from the study in December 2020, since not only were substantially all patients initially diagnosed with stage 4 disease, but the vast majority (~80%) of the patients had liver metastases, emphasizing the extremely difficult patient population in this study.

- Strengthened balance sheet with underwritten public offering resulting in gross proceeds of $34.5 million.

"Subsequent to the end of the first quarter, we were extremely excited to announce positive topline results from our GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization for autologous bone marrow transplantation in multiple myeloma patients," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The results demonstrated, with a high degree of statistical significance, a meaningful clinical benefit from adding Motixafortide to the current standard of care, G-CSF, for the mobilization of the targeted number of stem cells required for transplantation. While this was not a head-to-head study, our results compare very favorably to the registrational study of plerixafor.

"Importantly, almost 90% of patients in the treatment cohort underwent transplantation after only one administration of Motixafortide and in only one apheresis session, compared to 10.8% for G-CSF alone. We believe this positions Motixafortide to become the new standard of care in this indication, with a clear clinical benefit of 'one dose, one apheresis, 90% mobilization success rate.' We are working diligently to submit a New Drug Application to the FDA in the first half of next year. If approved, this would be transformative for BioLineRx, and a huge milestone in the Company's history.

"Regarding our PDAC program, the compelling liver metastases data that we recently presented at AACR further strengthen an already robust case for continued development in this very challenging indication. We continue to engage in discussions with potential partners regarding future development.

"To support these and other initiatives, including continued advancement of our second clinical candidate, the anti-cancer vaccine AGI-134, we raised $34.5 million in January that we believe will finance the Company through multiple potentially value-creating milestones," concluded Mr. Serlin.

Upcoming Significant Expected Milestones:

- Initial results from Part 2 of the Phase 1/2a trial of AGI-134 in solid tumors in the second half of 2021;

- Pre-NDA meeting with the FDA for SCM in the second half of 2021;

- NDA submission for SCM in the first half of 2022.

Financial Results for the Quarter Ended March 31, 2021

Research and development expenses for the quarter ended March 31, 2021 were $4.3 million, a decrease of $1.1 million, or 21.1%, compared to $5.4 million for the quarter ended March 31, 2020. The decrease resulted primarily from lower expenses associated with the Motixafortide COMBAT clinical trial, as well as lower expenses associated with the AGI-134 study.

Sales and marketing expenses for the quarter ended March 31, 2021 were $0.2 million, similar to sales and marketing expenses for the quarter ended March 31, 2020.

General and administrative expenses for the quarter ended March 31, 2021 were $1.0 million, a decrease of $0.2 million, or 18.2% compared to $1.2 million for the quarter ended March 31, 2020. The decrease resulted primarily from a decrease in share-based compensation.

The Company's operating loss for the quarter ended March 31, 2021 amounted to $5.5 million, compared to an operating loss of $6.8 million for the quarter ended March 31, 2020.

Non-operating expenses amounted to $4.6 million for the quarter ended March 31, 2021, compared to non-operating income of $0.5 million for the quarter ended March 31, 2020. Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of warrant liabilities on the Company’s balance sheet.

Net financial expenses amounted to $0.2 million for the quarter ended March 31, 2021, compared to net financial expenses of $0.3 million for the quarter ended March 31, 2020. 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, 2021 amounted to $10.2 million, compared with a net loss of $6.6 million for the quarter ended March 31, 2020.

The Company held $58.1 million in cash, cash equivalents and short-term bank deposits as of March 31, 2021.

Net cash used in operating activities was $6.2 million for the quarter ended March 31, 2021, compared with net cash used in operating activities of $6.7 million for the quarter ended March 31, 2020. The $0.5 million decrease in net cash used in operating activities between the two periods was primarily the result of a decrease in research and development expenses.

Net cash used in investing activities was $36.3 million for the quarter ended March 31, 2021, compared to net cash provided by investing activities of $6.2 million for the quarter ended March 31, 2020. 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 $41.9 million for the quarter ended March 31, 2021, compared to net cash provided by financing activities of $0.4 million for the quarter ended March 31, 2020. The cash flows in 2021 primarily reflect the underwritten public offering of the Company's ADSs in January 2021, warrant exercises and net proceeds from an ATM facility, offset by repayments of a loan from Kreos Capital. The cash flows in 2020 primarily reflect the net proceeds from an ATM facility, offset by repayments of a loan from Kreos Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Wednesday, May 26, 2021 at 10:00 a.m. EDT. To access the conference call, please dial +1-866-744-5399 from the US or +972-3-918-0610 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 28, 2021; please dial +1-888-295-2634 from the US or +972-3-925-5904 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 that was successfully evaluated in a Phase 3 study in stem-cell mobilization for autologous bone-marrow transplantation. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also 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.

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 COVID-19 pandemic; 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 February 23, 2021. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	December 31, 2020	March 31, 2021
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	16,831	16,047
Short-term bank deposits	5,756	42,036
Prepaid expenses	152	1,079
Other receivables	141	190
Total current assets	22,880	59,352
NON-CURRENT ASSETS		
Property and equipment, net	1,341	1,243
Right-of-use assets, net	1,355	1,297
Intangible assets, net	21,714	21,707
Total non-current assets	24,410	24,247
Total assets	47,290	83,599
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	3,092	3,220
Accounts payable and accruals:		
Trade	5,918	5,756
Other	1,440	1,100
Lease liabilities	191	140
Total current liabilities	10,641	10,216
NON-CURRENT LIABILITIES		
Warrants	10,218	5,247
Long-term loans, net of current maturities	2,740	1,891
Lease liabilities	1,661	1,598
Total non-current liabilities	14,619	8,736
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,260	18,952
EQUITY		
Ordinary shares	9,870	18,731
Share premium	279,241	321,920
Warrants	-	975
Capital reserve	12,322	12,616
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(277,987)	(288,179)
Total equity	22,030	64,647
Total liabilities and equity	47,290	83,599

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31,	
	2020	2021
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,422)	(4,278)
SALES AND MARKETING EXPENSES	(175)	(154)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,243)	(1,017)
OPERATING LOSS	(6,840)	(5,449)
NON-OPERATING INCOME (EXPENSES), NET	469	(4,561)
FINANCIAL INCOME	140	117
FINANCIAL EXPENSES	(414)	(299)
NET LOSS AND COMPREHENSIVE LOSS	(6,645)	(10,192)
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.04)	(0.02)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	176,454,423	559,537,952

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

	Ordinary shares	Share premium	Warrants	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 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	4,907	267,140	-	12,488	(1,416)	(254,611)	28,508

	Ordinary shares	Share premium	Warrants	Capital Reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2021	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2021:							
Issuance of share capital and warrants, net	6,805	24,979	975	-	-	-	32,759
Warrants exercised	2,051	17,523	-	-	-	-	19,574
Employee stock options exercised	5	38	-	(38)	-	-	5
Employee stock options forfeited and expired	-	139	-	(139)	-	-	-
Share-based compensation	-	-	-	471	-	-	471
Comprehensive loss for the period	-	-	-	-	-	(10,192)	(10,192)
BALANCE AT MARCH 31, 2021	18,731	321,920	975	12,616	(1,416)	(288,179)	64,647

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2020	2021
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,645)	(10,192)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(93)	3,963
Net cash used in operating activities	(6,738)	(6,229)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(6,000)	(42,000)
Maturities of short-term deposits	12,191	5,758
Purchase of property and equipment	-	(19)
Net cash provided by (used in) investing activities	6,191	(36,261)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,103	42,765
Employee stock options exercised	7	5
Repayments of loans	(682)	(814)
Repayments of lease liabilities	(41)	(49)
Net cash provided by financing activities	387	41,907
DECREASE IN CASH AND CASH EQUIVALENTS	(160)	(583)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(65)	(201)
CASH AND CASH EQUIVALENTS - END OF PERIOD	5,072	16,047

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2020	2021
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	321	182
Exchange differences on cash and cash equivalents	65	201
Fair value adjustments of warrants	(476)	4,597
Share-based compensation	663	471
Interest and exchange differences on short-term deposits	(108)	(38)
Interest on loans	44	93
Exchange differences on lease liability	(82)	(65)
	427	5,441
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(238)	(976)
Decrease in accounts payable and accruals	(282)	(502)
	(520)	(1,478)
	(93)	3,963
Supplemental information on interest received in cash	184	22
Supplemental information on interest paid in cash	275	200
Supplemental information on non-cash portion of transaction related to exercised warrants	-	9,568

Exhibit 2

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF MARCH 31, 2021

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF MARCH 31, 2021

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Other receivables	141	190
Total current assets	22,880	59,352
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Property and equipment, net	1,341	1,243
Right-of-use assets, net	1,355	1,297
Intangible assets, net	21,714	21,707
Total non-current assets	24,410	24,247
Total assets	47,290	83,599
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	3,092	3,220
Accounts payable and accruals:		
Trade	5,918	5,756
Other	1,440	1,100
Lease liabilities	191	140
Total current liabilities	10,641	10,216
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Long-term loans, net of current maturities	2,740	1,891
Lease liabilities	1,661	1,598
Total non-current liabilities	14,619	8,736
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,260	18,952
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Ordinary shares	9,870	18,731
Share premium	279,241	321,920
Warrants	-	975
Capital reserve	12,322	12,616
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(277,987)	(288,179)
Total equity	22,030	64,647
Total liabilities and equity	47,290	83,599

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 March 31,	
	2020	2021
	in USD thousands	
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NET LOSS AND COMPREHENSIVE LOSS	(6,645)	(10,192)
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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	4,907	267,140	-	12,488	(1,416)	(254,611)	28,508

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Comprehensive loss for the period	-	-	-	-	-	(10,192)	(10,192)
BALANCE AT MARCH 31, 2021	18,731	321,920	975	12,616	(1,416)	(288,179)	64,647

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

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CASH AND CASH EQUIVALENTS - END OF PERIOD	5,072	16,047

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BioLineRx Ltd.

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Supplemental information on interest paid in cash	275	200
Supplemental information on non-cash portion of transaction related to exercised warrants	-	9,568

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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 the Company has succeeded in generating significant revenues from a number of out-licensing transactions in the past, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into the first half of 2024. 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.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of March 31, 2021, and for the three months then ended, were approved by the Board of Directors on May 20, 2021, 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, 2021 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, 2020 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, 2021 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

The preparation of financial statements in conformity with IFRS requires management to make 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, in the process of applying the Company's accounting policies. 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 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, 2020 and for the year then ended.

NOTE 4 – AT-THE-MARKET ("ATM") SALES AGREEMENT WITH HCW

In September 2020, the Company entered into an 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.

During the three months period ended March 31, 2021, the Company issued a total of 482,983 ADSs for total gross proceeds of $1.4 million. Subsequent to March 31, 2021 and through the date of this report, the Company issued a total of 2,504,633 ADSs for total gross proceeds of $12.0 million. From the effective date of the agreement through the date of this report, 5,623,349 ADSs were sold under the program for total gross proceeds of approximately $19.4 million, leaving an available balance under the facility of approximately $5.6 million as of the date of this report.

NOTE 5 – UNDERWRITTEN PUBLIC OFFERING

In January 2021, the Company completed an underwritten public offering of 14,375,000 of its ADSs at a public offering price of $2.40 per ADS. The offering raised total gross proceeds of $34.5 million, with net proceeds of $31.4 million after deducting fees and expenses. In addition, warrants to purchase 718,750 ADSs were granted to the underwriters. These warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $3.00 per ADS.

The fair value of the warrants on the issuance date was approximately $1.0 million, which was recorded as issuance costs, and computed using the Black and Scholes option pricing model, based upon the then current price of an ADS, a risk-free interest rate of approximately 0.45% and an average standard deviation of approximately 73.8%.

NOTE 6 – SHAREHOLDERS' EQUITY

As of December 31, 2020 and March 31, 2021, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2020	March 31, 2021
Authorized share capital	1,500,000,000	1,500,000,000
Issued and paid-up share capital	349,169,545	639,164,912

	In USD and NIS	
	December 31, 2020	March 31, 2021
Authorized share capital (in NIS)	150,000,000	150,000,000
Issued and paid-up share capital (in NIS)	34,916,955	63,916,491
Issued and paid-up share capital (in USD)	9,869,795	18,731,177

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 February 23, 2021 (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;
- the impact of the COVID-19 pandemic 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

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, 2020.

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 stem-cell mobilization, solid tumors and AML, 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 stem-cell mobilization, solid tumors and acute myeloid leukemia, or AML.

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 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 Data Monitoring Committee, or 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. In May 2021, we announced positive top-line results from the Phase 3 trial. Based on an analysis of data on all 122 enrolled patients (the intent to treat population) we found highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in addition to G-CSF, as compared to placebo plus G-CSF ($p<0.0001$). The addition of motixafortide to G-CSF also allowed 88.3% of patients to undergo transplantation after only one apheresis session, compared to 10.8% in the G-CSF arm – an 8.2-fold increase. The combination was also found to be safe and well tolerated. In parallel, we are proceeding with all activities in support of a New Drug Application, or NDA, submission in this indication anticipated in the first half of 2022, including a pre-NDA meeting with the FDA planned for the second half of 2021.

Solid tumors

- In January 2016, we entered into a clinical 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 and in December 2020, we announced the final results of the study. The results of the study showed substantial improvement as compared to comparable historical results of other pancreatic cancer studies across all study endpoints. Of the 38 evaluable patients, median overall survival was 6.5 months, median progression free survival was 4.0 months, confirmed overall response rate was 13.2%, overall response rate was 21.2% and disease control rate was 63.2%. The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event and severe adverse event profiles were as expected with chemotherapy-based treatment regimens. We are currently planning next development steps for this program, including discussions with potential collaboration partners and development of a protocol for a randomized controlled study.

- 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 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

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. In March 2021, we completed the monitoring of long-term survival data for patients in the study and are evaluating our next clinical development steps in this indication.

- In August 2015, we initiated 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. During 2020, 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 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.

COVID-19

- During the first half of 2020, we initiated the evaluation of motixafortide as a potential therapy for COVID-19-induced inflammatory lung disorders, including acute respiratory distress syndrome, or 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. As the incidence of COVID-19 in Israel has declined dramatically since the beginning of 2021 as a result of a highly successful vaccination campaign, results of the preliminary analysis, which were expected in the second half of 2021, are now expected in 2022 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

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, Israel, Spain and the United States. 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, in April 2020, enrollment to the clinical trial was temporarily suspended. In August 2020, we renewed study enrollment. Initial proof-of-mechanism of action efficacy results from the second part of the study are 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), payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding received from the Israel Innovation Authority, or IIA. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future upfront, milestone, royalty or other payments that we may receive from our existing out-licensing agreements, potential future upfront or milestone payments that we may receive from out-licensing transactions for our other therapeutic candidates, interest earned on our investments and additional capital to be raised through public or private equity offerings or debt financings. As of March 31, 2021, we held $58.1 million of cash, cash equivalents and short-term bank deposits.

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) completed; top-line results announced May 2021 showed highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in addition to G-CSF ($p<0.0001$). In addition, the combination was found to be safe and well tolerated. 2. Phase 2a study in pancreatic cancer (COMBAT/KEYNOTE-202) completed; full results showing improvement in all endpoints announced December 2020. 3. Phase 2a study for relapsed or refractory AML completed. 4. Phase 2 investigator-initiated study in first-line PDAC patients. 5. Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections.	1. a. Pre-NDA meeting with FDA in second half of 2021. b. NDA submission in first half of 2022. 2. Evaluation and planning of next clinical development steps, including discussions towards potential collaborations. 3. Evaluation and decision regarding next clinical development steps. 4. Data from the study is anticipated in mid-2022* 5. Results of the preliminary analysis are expected in 2022*
AGI-134	Phase 1/2a study, ongoing	Initial proof-of-mechanism efficacy results of part 2 of study expected in second half of 2021

*These studies are investigator-initiated studies; therefore, the timelines are ultimately controlled by the independent investigators and are subject to change.

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 product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

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

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

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

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

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of derivative liabilities on account of the warrants issued in equity financings we carried out in July 2017, February 2019, May 2020 and June 2020. 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 sales agreement between the Company and H.C. Wainwright & Co., LLC, or Wainwright, entered into in September 2020, pursuant to which the Company is entitled, to offer and sell ADSs having an aggregate offering price of up to $25.0 million, or the ATM Facility, and the pro-rata share of issuance expenses from the placements related to the warrants. 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 consist of interest earned on our cash, cash equivalents and short-term bank deposits; interest expense related to our loan from Kreos Capital; 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.

Critical 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, 2020. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates using 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, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which impact the carrying value of our assets and liabilities that are not readily apparent from other sources. Actual results will differ from these estimates and such differences may be significant.

Results of Operations

Revenues

We did not record any revenues during each of the three-month periods ended March 31, 2021 and 2020.

Cost of revenues

We did not record any cost of revenues during each of the three-month periods ended March 31, 2021 and 2020.

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,		
	2020	2021	Increase (decrease)
	(in thousands of U.S. dollars)		
Research and development expenses	5,422	4,278	(1,144)

Research and development expenses for the three months ended March 31, 2021 were $4.3 million, a decrease of $1.1 million, or 21.1%, compared to $5.4 million for the three months ended March 31, 2020. The decrease resulted primarily from lower expenses associated with the motixafortide COMBAT clinical trial and lower expenses associated with the AGI-134 study.

Sales and marketing expenses

	Three months ended March 31,		
	2020	2021	Increase (decrease)
	(in thousands of U.S. dollars)		
Sales and marketing expenses	175	154	(21)

Sales and marketing expenses for the three months ended March 31, 2021 were $0.2 million, similar to the comparable period in 2020.

General and administrative expenses

	Three months ended March 31,		
	2020	2021	Increase (decrease)
	(in thousands of U.S. dollars)		
General and administrative expenses	1,243	1,017	(226)

General and administrative expenses for the three months ended March 31, 2021 were $1.0 million, a decrease of $0.2 million, or 18.2%, compared to $1.2 million for the three months ended March 31, 2020. The decrease resulted primarily from a decrease in share-based compensation.

Non-operating income (expenses), net

	Three months ended March 31,		
	2020	2021	Increase (decrease)
	(in thousands of U.S. dollars)		
Non-operating income (expenses), net	469	(4,561)	(5,030)

We recognized net non-operating expenses of $4.6 million for the three months ended March 31, 2021, compared to net non-operating income of $0.5 million for the three months ended March 31, 2020. Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of warrant liabilities on our balance sheet.

Financial income (expenses), net

	Three months ended March 31,		
	2020	2021	Increase (decrease)
	(in thousands of U.S. dollars)		
Financial income	140	117	(23)
Financial expenses	(414)	(299)	115
Net financial income (expenses)	(274)	(182)	92

We recognized net financial expenses of $0.2 million for the three months ended March 31, 2021 compared to net financial expenses of $0.3 million for the three months ended March 31, 2020. 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 our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding from the IIA. As of March 31, 2021, we held $58.1 million of cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

In January 2021, we sold 14,375,000 ADSs in a public offering at $2.40 per ADS, resulting in gross proceeds of $34.5 million. In connection with the offering, we paid an aggregate of $3.1 million in placement agent fees and expenses, and issued placement agent warrants to purchase 718,750 ADS. The placement agent warrants are immediately exercisable at a price of $3.00 per ADS, and expire five years from the date of offering.

Pursuant to our ATM Facility, during the three months ended March 31, 2021, we sold 482,983 ADSs, resulting in gross proceeds to us of $1.4 million. Subsequent to March 31, 2021 and through the date of this report, we issued a total of 2,504,633 ADSs under the facility for total gross proceeds of $12.0 million. As of the date of this report, there is an available balance under the facility of $5.6 million.

Net cash used in operating activities was $6.2 million for the three months ended March 31, 2021, compared with net cash used in operating activities of $6.7 million for the three months ended March 31, 2020. The $0.5 million decrease in net cash used in operating activities between the two periods was primarily the result of a decrease in research and development expenses.

Net cash used in investing activities was $36.3 million for the three months ended March 31, 2021, compared to net cash provided by investing activities of $6.2 million for the three months ended March 31, 2020. 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 $41.9 million for the three months ended March 31, 2021, compared to net cash provided by financing activities of $0.4 million for the three months ended March 31, 2020. The cash flows in 2021 primarily reflect the underwritten public offering of our ADSs in January 2021, warrant exercises and net proceeds from the ATM Facility, offset by repayments of the loan from Kreos Capital. The cash flows in 2020 primarily reflect the net proceeds from a previous ATM facility, offset by repayments of the loan from Kreos Capital.

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 current projected cash requirements into the first half of 2024, we will require 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 impact of the COVID-19 pandemic 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

Presented below, for the convenience of the reader, is share and per-share information in ADSs (each ADS represents 15 ordinary shares).

	Three months ended March 31,	
	2020	2021
	(in U.S. dollars)	
Loss per ADS – basic and diluted	0.56	0.27

	December 31, 2020	March 31, 2021
	(in number of ADSs)	
Authorized share capital	100,000,000	100,000,000
Issued and paid-up capital	23,277,970	42,610,995