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 August 2023

Commission file number: 001-35223

BioLineRx Ltd.

(Translation of registrant's name into English)

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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 ☐**

On August 30, 2023, the Registrant issued a press release announcing its financial results for the three and six months ended June 30, 2023. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of June 30, 2023 and for the three and six months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated August 30, 2023;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of June 30, 2023 and for the three and six months then ended; and

Exhibit 3: Registrant's operating and financial review as of June 30, 2023 and for the three and six months then ended.

This Form 6-K, the text under the heading "Second Quarter 2023 Financial Results" 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: August 30, 2023

Exhibit 1

FOR IMMEDIATE RELEASE

BioLineRx Reports Second Quarter 2023 Financial Results and Recent Corporate and Portfolio Updates

- On Track for September 9, 2023 PDUFA Target Action Date on NDA for Motixafortide in Stem Cell Mobilization (SCM) for Autologous Transplantation in Multiple Myeloma (MM) -

- Signed Exclusive License Agreement to Motixafortide in Asia Region with Concurrent Equity Investment -

- Announced Initiation of Investigator-Initiated Randomized Phase 2 Combination Trial with Motixafortide in First Line PDAC in Collaboration with Columbia University -

- Management to host conference call today, August 30, at 10:00 am EDT -

TEL AVIV, Israel, August 30, 2023 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases, today reported its unaudited financial results for the second quarter ended June 30, 2023, and provided corporate and portfolio updates.

“We had a very productive second quarter across all areas of the company, including our focused pre-launch preparation activities tied to the potential U.S. approval of motixafortide in the next few weeks, as well as the formation of a new strategic partnership, announced today, to develop and commercialize motixafortide in Asia,” said Philip Serlin, Chief Executive Officer of BioLineRx. “The partnership, which is subject to certain closing conditions, provides a pathway forward to pursue potential indications for motixafortide in stem cell mobilization and pancreatic cancer in Asia, as well as a source of substantial funding to the company.

Additionally, we advanced our second major development program for motixafortide in pancreatic cancer through the initiation of a randomized Phase 2 clinical trial with Columbia University in first line metastatic pancreatic cancer based on promising data from a single-arm pilot phase.

“Finally, our clinical trial collaboration with Washington University School of Medicine in St. Louis to evaluate motixafortide as monotherapy and in combination with natalizumab for stem cell mobilization for gene therapies in sickle cell disease continues to progress, and we anticipate clinical trial initiation this year. I am extremely pleased with our progress to date and look forward to a fruitful second half of the year, including our potential transition to a commercial stage company,” Mr. Serlin concluded.

Corporate Updates

- On track for September 9, 2023 PDUFA target action date on NDA for motixafortide in stem cell mobilization for autologous transplantation in multiple myeloma

- Signed exclusive license agreement to develop and commercialize motixafortide in Asia with concurrent equity investment; license agreement includes $15 million upfront payment, plus potential development, regulatory and sales milestones, and tiered double-digit royalties, as well as various development obligations for the licensee, including the planned initiation in China of a registrational study in stem-cell mobilization and a randomized Phase 2/3 study in first-line pancreatic cancer; straight common equity investment of $14.6 million in BioLineRx at $2.136 per ADS with no warrants; effectiveness and closing of transactions is contingent upon approval by Israeli Innovation Authority of license agreement within four months of execution, and other closing conditions

Clinical Portfolio Updates

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Announced publication in *Nature Medicine* of GENESIS Phase 3 clinical trial data evaluating motixafortide and G-CSF in stem cell mobilization for autologous transplantation in multiple myeloma

Pancreatic Ductal Adenocarcinoma

- Announced initiation of randomized, investigator-initiated Phase 2 clinical trial in collaboration with Columbia University, with joint funding of the study by Regeneron and BioLineRx, assessing motixafortide in combination with the PD-1 inhibitor cemiplimab and standard-of-care chemotherapy as first-line treatment in patients with mPDAC. Anticipate initial patient data in 2023. A poster of the amended clinical trial design was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June

Sickle Cell Disease & Gene Therapy

- Continued to advance plans for a clinical trial in collaboration with Washington University School of Medicine in St. Louis to evaluate motixafortide as monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell mobilization for gene therapies in sickle cell disease. Anticipate trial initiation later this year

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Evaluating next development pathways for AGI-134 program in consultation with scientific advisory board. Results from Phase 1/2a first-in-human, single-agent study announced in Q4 2022. Study met primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers

Second Quarter 2023 Financial Results

- Research and development expenses for the three months ended June 30, 2023 were $3.0 million, a decrease of $2.4 million, or 44.3%, compared to $5.4 million for the three months ended June 30, 2022. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide as well as lower expenses associated with the completed AGI-134 clinical trial
- Sales and marketing expenses for the three months ended June 30, 2023 were $5.6 million, an increase of $4.4 million, or 383.9% compared to $1.2 million for the three months ended June 30, 2022. The increase resulted primarily from the ramp-up of pre-launch activities related to motixafortide
- General and administrative expenses for the three months ended June 30, 2023 were $1.3 million, an increase of $0.3 million, or 24.4% compared to $1.0 million for the three months ended June 30, 2022. The increase resulted primarily from an increase in payroll and related expenses due to a small increase in headcount and share-based compensation, as well as small increases in a number of G&A expenses
- Net loss for the three months ended June 30, 2023 was $18.5 million, compared to $7.4 million for the three months ended June 30, 2022. The Company's net loss for the six months ended June 30, 2023 amounted to $30.7 million, compared to $12.4 million for the six months ended June 30, 2022. The increases in net loss for both the three and six months ended June 30, 2023 were due primarily to a non-operating expense of approximately $7.8 million and $10.8 million respectively, related to the revaluation of outstanding warrants resulting from an increase in the Company’s share price over the preceding three and six months
- As of June 30, 2023, the Company held cash, cash equivalents, and short-term bank deposits of $32.8 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024. This amount does not include $29.6 million in total funding from the exclusive license agreement and equity investment announced today, which the Company anticipates closing in Q3 subject to formal transaction approval by the Israeli Innovation Authority and other closing conditions

Conference Call and Webcast Information

To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. A live webcast and a replay of the call can be accessed through the event page on the Company'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. The call replay will be available approximately two hours after completion of the live conference call. A dial-in replay of the call will be available until September 1, 2023; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx
BioLineRx Ltd. is a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases. The company is advancing a pipeline of investigational medicines for patients with multiple myeloma, sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., BioLineRx is driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

Forward Looking Statement
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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, our planned and ongoing clinical trials, the plans and objectives of management for future operations, regulatory filings submitted to the FDA (including potential timing of the FDA's review of the NDA for motixafortide), commercial potential of motixafortide, expectations regarding the announced license agreement, statements relating to the private placement, including, as to the consummation of the private placement and license agreement, and our financial condition and results of operations. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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, including BioLineRx's ability to secure adequate and viable pricing and reimbursement coverage of any marketed product; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate and academic collaborations and licensees, including the collaboration contemplated in the license; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation or characterization 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 and ability to access sufficient additional financing; risks related to changes in healthcare laws, rules and regulations in the United States, Asia, or elsewhere; competitive companies, technologies and BioLineRx's industry, including generic entrants; risks related to unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 22, 2023. 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.

Contacts:

United States
John Lacey
BioLineRx
IR@biolinerx.com

Israel
Moran Meir
LifeSci Advisors, LLC
moran@lifesciadvisors.com

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

	December 31, 2022	June 30, 2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	10,104
Short-term bank deposits	40,495	22,711
Prepaid expenses	198	1,749
Other receivables	721	128
Total current assets	52,001	34,692
NON-CURRENT ASSETS		
Property and equipment, net	726	648
Right-of-use assets, net	1,772	1,583
Intangible assets, net	21,885	22,013
Total non-current assets	24,383	24,244
Total assets	76,384	58,936
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	1,542	3,078
Accounts payable and accruals:		
Trade	6,966	6,733
Other	1,744	2,260
Current maturities of lease liabilities	427	375
Total current liabilities	10,679	12,446
NON-CURRENT LIABILITIES		
Warrants	4,509	15,352
Long-term loan, net of current maturities	8,626	8,495
Lease liabilities	1,729	1,589
Total non-current liabilities	14,864	25,436
Total liabilities	25,543	37,882
EQUITY		
Ordinary shares	27,100	27,100
Share premium	338,976	339,045
Warrants	1,408	1,408
Capital reserve	14,765	15,616
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(360,699)
Total equity	50,841	21,054
Total liabilities and equity	76,384	58,936

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2023	2022	2023
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,395)	(3,006)	(9,830)	(6,690)
SALES AND MARKETING EXPENSES	(1,158)	(5,604)	(1,795)	(9,478)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,049)	(1,305)	(2,056)	(2,603)
OPERATING LOSS	(7,602)	(9,915)	(13,681)	(18,771)
NON-OPERATING INCOME (EXPENSES), NET	458	(7,733)	1,726	(10,649)
FINANCIAL INCOME	80	440	147	977
FINANCIAL EXPENSES	(379)	(1,337)	(565)	(2,264)
NET LOSS AND COMPREHENSIVE LOSS	(7,443)	(18,545)	(12,373)	(30,707)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.02)	(0.02)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	715,365,554	922,958,942	715,260,781	922,958,942

BioLineRx Ltd.
CONDENSED 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, 2022	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2022:							
Issuance of share capital, net	89	177	-	-	-	-	266
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	135	-	(135)	-	-	-
Share-based compensation	-	-	-	586	-	-	586
Comprehensive loss for the period	-	-	-	-	-	(12,373)	(12,373)
BALANCE AT JUNE 30, 2022	21,157	339,670	975	13,596	(1,416)	(317,414)	56,568

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2023	27,100	338,976	1,408	14,765	(1,416)	(329,992)	50,841
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2023:							
Employee stock options expired	-	69	-	(69)	-	-	-
Share-based compensation	-	-	-	920	-	-	920
Comprehensive loss for the period	-	-	-	-	-	(30,707)	(30,707)
BALANCE AT JUNE 30, 2023	27,100	339,045	1,408	15,616	(1,416)	(360,699)	21,054

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

	Six months ended June 30,	
	2022	2023
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(12,373)	(30,707)
Adjustments required to reflect net cash used in operating activities (see appendix below)	498	13,009
Net cash used in operating activities	(11,875)	(17,698)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(9,000)	(6,006)
Maturities of short-term deposits	24,141	24,000
Purchase of property and equipment	(62)	(99)
Purchase of intangible assets	-	(153)
Net cash provided by investing activities	15,079	17,742
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	266	-
Employee stock options exercised	2	-
Repayments of loan	(1,812)	-
Repayments of lease liabilities	(88)	(183)
Net cash used in financing activities	(1,632)	(183)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,572	(139)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(562)	(344)
CASH AND CASH EQUIVALENTS - END OF PERIOD	14,000	10,104

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

	Six months ended June 30,	
	2022	2023
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	314	457
Exchange differences on cash and cash equivalents	562	344
Fair value adjustments of warrants	(1,673)	10,843
Share-based compensation	586	920
Interest and exchange differences on short-term deposits	(142)	(210)
Interest on loan	68	1,405
Exchange differences on lease liability	(205)	(75)
	(490)	13,684
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(688)	(958)
Increase in accounts payable and accruals	1,676	283
	988	(675)
	498	13,009
Supplemental information on interest received in cash	146	761
Supplemental information on interest paid in cash	217	640
Supplemental information on non-cash transactions:		
Acquisition of right-of-use asset	-	66

Exhibit 2

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF JUNE 30, 2023

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF JUNE 30, 2023

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BioLineRx Ltd.
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Other receivables	721	128
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Accounts payable and accruals:		
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Capital reserve	14,765	15,616
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Accumulated deficit	(329,992)	(360,699)
Total equity	50,841	21,054
Total liabilities and equity	76,384	58,936

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

BioLineRx Ltd.
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	Three months ended June 30,		Six months ended June 30,	
	2022	2023	2022	2023
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		in USD		in USD
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WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	715,365,554	922,958,942	715,260,781	922,958,942

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Employee stock options expired	-	135	-	(135)	-	-	-
Share-based compensation	-	-	-	586	-	-	586
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BioLineRx Ltd.
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(UNAUDITED)

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BioLineRx Ltd.
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(UNAUDITED)

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Supplemental information on non-cash transactions:		
Acquisition of right-of-use asset	-	66

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003. BioLineRx and its subsidiaries (collectively, the "Company") are engaged in the development of therapeutics, primarily in pre-commercialization and 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"). Each ADS represents 15 ordinary shares.

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. In April 2022, the Company re-activated BioLineRx USA, Inc., a previously inactive subsidiary incorporated in the US, to engage in pre-commercialization and commercialization activities associated with the potential launch of motixafortide for stem-cell mobilization in the US. In this regard, the US Food and Drug Administration ("FDA") has accepted for review and filed the Company's New Drug Application ("NDA") for motixafortide in stem cell mobilization for autologous transplantation for multiple myeloma patients, and has assigned the NDA a Prescription Drug User Fee Act ("PDUFA") target action date of September 9, 2023.

b. Going concern

The Company has incurred accumulated losses in the amount of $361 million through June 30, 2023, and it expects to continue incurring losses and negative cash flows from operations until its product or products reach commercial profitability. Company management monitors rolling forecasts of the Company's liquidity reserves on the basis of anticipated cash flows and maintains liquidity balances at levels that are sufficient to meet its needs. 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.

The execution of an independent commercialization plan for motixafortide in the US implies an increased level of expenses prior to and following launch of the product. However, as is common with FDA approvals of innovative pharmaceutical products, there is significant uncertainty regarding the receipt of approval, as well as the timing and scope of any potential approval ultimately received in order to launch commercialization of the product. Therefore, the Company's cash flow projections are subject to various risks and uncertainties concerning their fulfilment, and these factors and the risk inherent in the Company's operations may cast significant doubt on the Company's ability to continue as a going concern. These consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

References in these IFRS financial statements to matters that may cast significant doubt about the Company's ability to continue as a going concern also raise substantial doubt as contemplated by the PCAOB standards.

NOTE 1 – GENERAL INFORMATION (cont.)

b. Going concern (cont.)

Management's plans include the independent commercialization of the Company's product and, if and when required, raising capital through the issuance of debt or equity securities, or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and/or raising capital, it may need to reduce activities, or curtail or cease operations.

c. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of June 30, 2023, and for the three and six months then ended, were approved by the Board of Directors on August 22, 2023, 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 June 30, 2023 and for the three and six 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 presentation of financial position, results of operations, and cash flows in conformity with International Financial Reporting Standards ("IFRS"). The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2022 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS. The results of operations for the three and six months ended June 30, 2023 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 pandemics and wars across the globe 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. In this regard, U.S. and global markets are currently experiencing volatility and disruption following the escalation of geopolitical tensions and the ongoing military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict are highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and the capital markets. As of the date of release of these financial statements, the Company estimates there are no material effects of this conflict on its financial position and results of operations.

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, 2022 and for the year then ended.

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

The Company maintains an ATM facility with H.C. Wainwright & Co., LLC ("HCW") pursuant to an ATM sales agreement entered into in September 2021. In accordance with the agreement, the Company is entitled, at its sole discretion, to offer and sell through HCW, acting as a 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 has agreed to pay HCW a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. During the six months ended June 30, 2023, no ADSs were issued by the Company. From the effective date of the agreement through the issuance date of this report, 608,651 ADSs have been sold under the program for total gross proceeds of approximately $1.4 million.

NOTE 5 – LONG-TERM LOAN

In September 2022, the Company entered into a $40 million loan agreement with Kreos Capital VII Aggregator SCSp ("Kreos Capital"). Pursuant to the agreement, the first tranche of $10 million was drawn down by the Company following execution of the definitive agreement, after completion of certain customary conditions to closing. The remaining $30 million will be made available in two additional tranches subject to the achievement of pre-specified milestones. The tranches are available for drawdown at the Company's discretion at various time points through October 1, 2024.

Each tranche carries a pre-defined interest-only payment period, followed by a loan principal amortization period of up to 36 months subsequent to the interest-only period. The interest-only periods are subject to possible extension based on certain pre-defined milestones. Borrowings under the financing will bear interest at a fixed annual rate of 9.5% (~11.0%, including associated cash fees). As security for the loan, Kreos Capital received a first-priority secured interest in all Company assets, including intellectual property, and the Company undertook to maintain a minimum cash balance. In addition, Kreos Capital will be entitled to mid-to-high single-digit royalties on motixafortide sales, up to a pre-defined cap.

The loan's current value includes the accrual of effective interest, including estimated future royalties.

NOTE 6 – WARRANTS FROM SEPTEMBER 2022 OFFERING

In September 2022, the Company completed a registered direct offering of 13,636,365 ADSs at a price of $1.10 per ADS. In concurrent private placements, the Company issued to investors in the offering unregistered warrants to purchase 13,636,365 ADSs. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $1.15 per ADS. In addition, the Company granted to the placement agent in the offering, as part of the placement fee, warrants to purchase 681,818 ADSs. These warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $1.375 per ADS. Gross proceeds from the offering totaled $15.0 million, with net proceeds of $13.5 million, after deducting fees and expenses. The offering consideration allocated to the placement agent warrants amounted to $0.4 million.

The warrants issued to the investors have been classified as a non-current financial liability due to a net settlement provision. This liability was initially recognized at its fair value on the issuance date and is subsequently accounted for at fair value at each balance sheet date. The fair value changes are charged to non-operating income and expense in the statement of comprehensive loss.

The fair value of the warrants is computed using the Black-Scholes option pricing model and is determined by using a level 3 valuation technique. The fair value of the warrants upon issuance was computed based on the then-current price of an ADS, a risk-free interest rate of 3.62%, and an average standard deviation of 82.5%. The gross consideration initially allocated to the investor warrants amounted to $9.1 million, with total issuance costs initially allocated to the warrants amounting to $0.8 million.

The fair value of the warrants amounted to $15,345,000 as of June 30, 2023, ($4,502,000 as of December 31, 2022) and was based on the then current price of an ADS, a risk-free interest rate of 4.3%, (4.1% as of December 31, 2022), an average standard deviation of 84.1%, (85.5% as of December 31, 2022), and on the remaining contractual life of the warrants.

The changes in fair value from December 31, 2022 through June 30, 2023 of $10,843,000 have been recorded as non-operating expenses in the statement of comprehensive loss.

As of June 30, 2023, none of these warrants had been exercised.

The placement agent warrants have been classified in shareholders' equity, with initial recognition at fair value on the date issued, using the same assumptions as the investor warrants.

NOTE 7 – SHAREHOLDERS' EQUITY

As of December 31, 2022 and June 30, 2023, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2022	June 30, 2023
Authorized share capital	2,500,000,000	2,500,000,000
Issued and paid-up share capital	922,958,942	922,958,942

	In USD and NIS	
	December 31, 2022	June 30, 2023
Authorized share capital (in NIS)	250,000,000	250,000,000
Issued and paid-up share capital (in NIS)	92,295,894	92,295,894
Issued and paid-up share capital (in USD)	27,100,201	27,100,201

NOTE 8 – SUBSEQUENT EVENTS

On August 27, 2023, the Company entered into a license agreement (the "License Agreement") with Hong Seng Technology Limited ("HST") and Guangzhou Gloria Biosciences Co., Ltd. ("Gloria" and together with HST, the "Purchaser Parties" or the "Licensee"), pursuant to which the Company granted HST an exclusive, royalty-bearing, sublicensable license to develop and commercialize motixafortide in Asia (other than Israel and certain other countries) (collectively, the "Territory") and to engage and authorize Gloria to perform services under the License Agreement in the Territory. In addition, the Company granted the Licensee a first offer right with respect to the grant of certain rights in motixafortide outside of the Territory. Effectiveness of the License Agreement is conditioned, among other things, upon obtaining the consent of the Israeli Innovation Authority (the "IIA") within four months from the execution of the License Agreement.

NOTE 8 – SUBSEQUENT EVENTS (cont.)

Pursuant to the terms of the License Agreement, the Licensee is required to deposit a $15 million upfront payment in escrow within seven days after execution of the License Agreement, which will be released from escrow and transferred to the Company on the date that consent of the License Agreement is provided by the IIA, so long as that consent is obtained within four months from the execution of the License Agreement. The Company is also entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. In addition, the Company is eligible to receive tiered double-digit royalties (ranging from 10-20%), on a country-by-country basis, on aggregate net sales of motixafortide in the Territory during the initial royalty term of at least 15 years, with a reduction of the royalties payable following the end of the initial royalty term as well as upon the occurrence of certain events. In the event that the Company does not receive FDA approval of motixafortide from the FDA by end of 2023, the development and regulatory milestones will only be partially payable, and all royalty rates will be reduced to single digit royalties.

The License Agreement provides that the Company will supply motixafortide to the Licensee during the term on a cost plus basis for commercial supply, while supply for development purposes will be on a cost-plus basis except that in certain limited circumstances the supply will be at a reduced cost, with the Company bearing a portion of the cost to be applied against any future royalties. The Licensee has a right but not an obligation after the effective date of the License Agreement to select to manufacture motixafortide itself or through a designated party.

NOTE 8 – SUBSEQUENT EVENTS (cont.)

In connection with the entry into the License Agreement, on August 27, 2023, the Company also entered into a share purchase agreement (the "Purchase Agreement") with the Purchaser Parties, pursuant to which the Company agreed to sell and issue in a private placement an aggregate of 6,829,137 ADSs of the Company, at a purchase price of $2.136 per ADS. Aggregate gross proceeds from the sale are expected to be approximately $14.6 million and are to be deposited into escrow pending closing. The closing is subject to certain closing conditions including, among other things, receipt of the IIA consent and effectiveness of the License Agreement, actual receipt by the Company in its bank account of the purchase price for the ADSs following release from escrow, as well as other customary closing conditions. No warrants were issued in the transaction.

Exhibit 3

OPERATING AND FINANCIAL REVIEW

You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this 6-K, as well as in our Annual Report on Form 20-F filed on March 22, 2023 (the "Annual Report").

Forward Looking Statements

Various statements in this discussion concerning our future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, our planned and ongoing clinical trials, the plans and objectives of management for future operations, regulatory filings submitted to the FDA (including potential timing of the FDA's review of the NDA for motixafortide), commercial potential of motixafortide, expectations regarding the announced license agreement, statements relating to the private placement, including, as to the consummation of the private placement and license agreement, and our financial condition and results of operations. These forward-looking 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 such 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, including our ability to secure adequate and viable pricing and reimbursement coverage of any marketed product;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate and academic collaborations and licensees, including the collaboration contemplated in the license;
- our ability to integrate new therapeutic candidates and new personnel;
- the interpretation or characterization 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, Asia or elsewhere;
- competitive companies, technologies and our industry, including generic entrants;
- risks related to unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and
- statements as to the impact of the political and security situation in Israel on our business.

Overview

General

We are a pre-commercial-stage biopharmaceutical company focused 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 and solid tumors, 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 by way of out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently. In this regard, we are currently executing on an independent commercialization plan for motixafortide in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

Motixafortide

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 and solid tumors.

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 granulocyte colony-stimulating factor, or 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 completed 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 generally well tolerated with a favorable safety profile.

  We continue to follow-up on the GENESIS study patients for relapse-free and overall survival, according to the statistical analysis plan agreed upon with the U.S. Food and Drug Administration, or FDA. In December 2021, we held a pre-New Drug Application, or NDA, meeting with the FDA. The purpose of the meeting was to obtain agreement from the FDA on the content of the proposed NDA, and, in particular, to confirm that our single Phase 3 pivotal study, GENESIS, is sufficient to support an NDA submission. During the pre-NDA meeting, the FDA agreed that the proposed data package is sufficient to support an NDA submission. In September 2022, we submitted an NDA to the FDA for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients and in November 2022, the FDA accepted for review the NDA and assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of September 9, 2023.

- In October 2021, we announced positive results from a pharmacoeconomic study evaluating the cost-effectiveness of using motixafortide as a primary stem cell mobilization agent on top of G-CSF, versus G-CSF alone, in multiple myeloma patients undergoing autologous stem-cell transplantation (ASCT). The study was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA, and was a pre-planned study conducted in parallel with the GENESIS Phase 3 trial. The study concluded that the addition of motixafortide to G-CSF (the current standard of care) is associated with a statistically significant decrease in health resource utilization (HRU) during the ASCT process, compared to G-CSF alone. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show quality-adjusted-life-year (QALY) benefits and net cost savings of ~$19,000 (not including the cost of motixafortide), versus G-CSF alone.

- In March 2022, we announced results from a follow-on pharmacoeconomic study performed by the HEOR team of IQVIA. This study indirectly evaluated the cost-effectiveness of using motixafortide as a primary stem cell mobilization agent in combination with G-CSF, against plerixafor in combination with G-CSF, in multiple myeloma patients undergoing ASCT. The additional study results show that motixafortide in combination with G-CSF, versus plerixafor in combination with G-CSF, demonstrates a statistically significant decrease in HRU during the ASCT process. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show QALY benefits and net cost savings of ~$30,000 (not including the cost of motixafortide), versus plerixafor plus G-CSF. The study findings strengthen the assessment that the use of motixafortide in combination with G-CSF, as the potential new standard of care in mobilization for ASCT, would be a cost-effective option in the United States, based on accepted willingness-to-pay (WTP) values for healthcare payers.

- We believe these results, together with the highly significant and clinically meaningful data from the GENESIS trial, strongly support the potential use of motixafortide, on top of G-CSF, as the standard of care in stem cell mobilization for autologous stem cell transplantation. In this regard, in June 2022, we appointed biopharmaceutical veteran executive, Holly W. May, as our Chief Commercial Officer and in September 2022 we announced our U.S. commercialization plan for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients and appointed Ms. May as President of our U.S. subsidiary, with responsibility for the commercial planning, positioning, and launch oversight for motixafortide in the stem cell mobilization indication across the U.S. market, assuming FDA approval. If approved, we intend to commercialize motixafortide in the U.S. independently in order to accelerate its availability to patients and to maximize the value of this innovative therapeutic candidate.

- In March 2023, we entered into a clinical collaboration with Washington University School of Medicine in St. Louis to advance a Phase 1 clinical trial in which motixafortide will be evaluated as a monotherapy and in combination with natalizumab (VLA-4 inhibitor), as novel regimens to mobilize CD34+ hematopoietic stem cells for gene therapies in Sickle Cell Disease (SCD). The study will enroll five adults with a diagnosis of SCD who are receiving automated red blood cell exchanges via apheresis. The trial's primary objective is to assess the safety and tolerability of motixafortide alone and in combination with natalizumab in SCD patients, defined by dose-limiting toxicities. Secondary objectives include determining the number of CD34+ hematopoietic stem and progenitor cells (HSPCs) mobilized via leukapheresis; and determining the pharmacokinetics of CD34+ HSPCs mobilization to peripheral blood in response to motixafortide alone and motixafortide plus natalizumab in SCD patients. The study is anticipated to begin enrollment in 2023 (although timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change).

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 the recruiting of 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.

- 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, single-arm study, led by Columbia University, initially enrolled 10 PDAC patients in a pilot phase. In July 2023, we announced initiation of an amended randomized study, based on preliminary pre-defined data from the single-arm pilot phase, in a total of 102 patients. The primary endpoint of the study is progression free survival. Secondary endpoints include safety and tolerability, duration of clinical benefit and overall survival. Data from the pilot stage of the study is planned for submission to a congress later this year.

- In June 2022, we entered into a collaboration agreement with GenFleet Therapeutics, or GenFleet, an immuno-oncology focused biopharmaceutical company based in China, to advance motixafortide through a randomized Phase 2b clinical trial in PDAC. On August 29, 2023, the Company and Genfleet mutually agreed to terminate their collaboration agreement.

ARDS secondary to COVID-19 and other viral infections

- During the first half of 2020, we initiated the evaluation of motixafortide as a potential therapy for acute respiratory distress syndrome, or ARDS, resulting from COVID-19 and other viral infections In this regard, substantial data is emerging regarding the involvement of neutrophils, neutrophil extracellular traps (NETs), monocytes and macrophages in the development of ARDS secondary to COVID-19 and other viral infections; as well as the key involvement of CXCR4 as a mediator of those cells in the inflamed pulmonary tissue. Based on the scientific data indicating the importance of blocking the CXCR4/CXCL12 axis during ARDS, we believe that motixafortide may be of potential benefit for patients with ARDS. Following our initial evaluation, in November 2020, we announced initiation of a Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections. The study is an investigator-initiated study, led by Wolfson Medical Center, in Israel, to evaluate motixafortide in patients hospitalized with ARDS. The primary endpoint of the study is to assess the safety of motixafortide in these patients; respiratory parameters and inflammatory biomarkers will be assessed as exploratory endpoints. Up to 25 patients will be enrolled in the study, with a preliminary analysis planned after ten patients have completed the initial treatment period. Results of the preliminary analysis are expected in 2023 (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 potentially 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.

- In September 2022, the FDA approved APHEXDA as motixafortide's trade name.

Out licensing of Motixafortide in Asia

On August 27, 2023, we entered into a License Agreement or the License Agreement, with Hong Seng Technology Limited, or HST, and Guangzhou Gloria Biosciences Co., Ltd., or Gloria and/or with HST, the Licensee, pursuant to which we granted HST an exclusive, royalty-bearing, sublicensable license with respect to the intellectual property rights and know-how associated with motixafortide in order to develop and commercialize motixafortide in Asia (other than Israel and certain other countries), or the Territory, and to engage and authorize Gloria to perform services under the License Agreement in the Territory. Effectiveness of the License Agreement is conditioned, among other things, upon obtaining the consent of the Israeli Innovation Authority, or the IIA, within four months from the execution of the License Agreement.

Pursuant to the terms of the License Agreement, the Licensee is required to deposit a $15 million upfront payment in escrow within seven days after the execution of the License Agreement, which under the terms of the License Agreement will be released from escrow and transferred to the Company on the date that consent of the License Agreement is provided by the IIA, so long as that consent is obtained within four months from the execution of the License Agreement. The Company is also entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. Additionally, the Company is eligible to receive tiered double-digit royalties (ranging from 10-20%), on a country-by-country basis, on aggregate net sales of motixafortide in the Territory until the longer of (i) fifteen years from the date of the first sale of motixafortide by Licensee, (ii) the last to expire valid claim of any licensed patents with respect to motixafortide in such country and (iii) the expiration of motixafortide's orphan drug status in such country. The royalties payable by Licensee to the Company shall be reduced by 50% following the end of the initial royalty term and shall also be reduced upon the occurrence of certain events, including, on a country-by-country basis, the entry of a generic product in such country. In the event that the Company does not receive FDA approval of motixafortide from the FDA by the end of 2023, the development and regulatory milestones will only be partially payable and all royalty rates will be reduced to single digit royalties.

In connection with the entry into the License Agreement, on August 27, 2023, we also entered into a securities purchase agreement, or the Purchase Agreement, with HST and Gloria, or the Purchaser Party, pursuant to which we agreed to sell and issue in a private placement an aggregate of 6,829,137 of our ADSs. Aggregate gross proceeds from the sale are expected to be $14.6 million and are to be deposited into escrow pending closing. The closing is subject to certain closing conditions including, among other things, receipt of the IIA consent and effectiveness of the License Agreement, actual receipt by us in our bank account of the purchase price for the ADSs following release from escrow, as well as other customary closing conditions. No warrants were issued in the transaction.

The License Agreement includes various development obligations for the Licensee pursuant to an agreed-upon development plan, including the execution of a registrational study in stem-cell mobilization and the execution of a randomized Phase 2/3 study in first-line pancreatic adenocarcinoma.

AGI-134

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 is designed to not only kill the tumor cells at the site of injection, but also to bring 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 in unresectable metastatic solid tumors. The multi-center, open-label study was carried out in the United Kingdom, Spain 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 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, and in January 2022, we completed enrollment. In December 2022, we announced results from the study. The study met its primary endpoint of AGI-134's safety and tolerability. Generations of an immune response and markers of clinical efficacy were assessed as secondary endpoints. Most patients analyzed showed an increase in alpha-Gal antibodies, indicating increased overall immune activity. Additionally, increases in antigen presenting cells (APCs) were observed in most tissue samples analyzed, and T cell and macrophage tumor infiltration was seen in approximately one-third of evaluable patients' injected tumors, and in approximately half of evaluable patients' un- injected lesions. Radiological assessments found that 29 percent of patients in the trial achieved a best overall response of stable disease. We plan to seek publication of our data at a medical congress in 2023, and in consultation with our scientific advisory board, we will determine the next steps for the program during 2023.

Scientific Advisory Board

In December 2021, we established a Scientific Advisory Board (SAB) to provide insight and guidance on our activities in the field of immuno-oncology. The SAB is comprised of recognized leaders in cancer immunology, intra-tumoral injections and clinical development.

Listed in alphabetical order, the founding SAB members are: Ronald Levy, MD, the Robert K. and Helen K. Summy Professor and Director of the Lymphoma Program at Stanford University School of Medicine, Palo Alto, CA; Aurélien Marabelle, MD, PhD, Clinical Director, Cancer Immunotherapy Program, Gustave Roussy, Paris, France and Director, Translational Research Laboratory in Immunotherapy, INSERM, Paris, France; Ignacio Melero MD, PhD, Professor of Immunology at the Academic Hospital of Navarra, Spain and at the Center for Applied Medical Research (CIMA) of the University of Navarra, Spain; Jon Wigginton, MD, Chair of the SAB and Senior Advisor at Cullinan Oncology, former Chief Medical Officer of MacroGenics, and former Therapeutic Area Head, Immuno-Oncology, Early Clinical Research at Bristol-Myers Squibb; and Leisha Emens, MD, PhD, Professor of Medicine, Director of Translational Immunotherapy for the Women's Cancer Research Center Co-Leader, Hillman Cancer Immunology/Immunotherapy Program at the UPMC Hillman Cancer Center, Pittsburgh, PA.

BL-5010

Our commercialized, legacy therapeutic product, BL-5010, is a customized, proprietary pen-like applicator containing a novel, acidic, aqueous solution for the non-surgical removal of skin lesions. In December 2014, we entered into an exclusive out-licensing arrangement with Perrigo Company plc, or Perrigo, for the rights to BL-5010 for over-the-counter, or OTC, indications in Europe, Australia and additional selected countries. In March 2016, Perrigo received CE Mark approval for BL-5010 as a novel OTC treatment for the non-surgical removal of warts. The commercial launch of products for treatment of this first OTC indication (warts/verrucas) commenced in Europe in the second quarter of 2016. Since then, Perrigo has invested in improving the product and during 2019 launched an improved version of the product in several European countries. In March 2020, we agreed that Perrigo could relinquish its license rights for certain countries that had been included in its territory according to the original license agreement, and was also no longer obligated to develop, obtain regulatory approval for, and commercialize products for a second OTC indication. In turn, in March 2020, we agreed with our licensor of the rights to BL-5010, Innovative Pharmaceutical Concepts (IPC) Inc., or IPC, to return to IPC those license rights no longer out-licensed to Perrigo as a result of the agreement described in the preceding sentence, in consideration of the payment to us of royalties or fees on sublicense receipts.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the Israel Innovation Authority, or IIA, payments received under out-licensing arrangements, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, the commercialization of our lead therapeutic candidate, motixafortide, if approved, 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, potential revenues that we may receive from the direct commercialization of 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 June 30, 2023, we held $32.8 million of cash, cash equivalents and short-term bank deposits. This amount does not include $29.6 million in total funding from the exclusive license agreement and securities purchase agreement entered into on August 27, 2023, which we anticipate closing following formal transaction approval by the Israeli Innovation Authority and other closing conditions.

Other

On August 29, 2023, Tami Rachmilewitz, M.D., resigned as our Chief Medical Officer, effective October 31, 2023, after serving in the position since January 2023. Dr. Rachmilewitz's resignation was not the result of a disagreement with us on any matter relating to our operations, policies or practices. We anticipate initiating a search for a replacement candidate in the near future.

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 the independent commercialization of motixafortide in stem cell mobilization, if approved by the FDA, as well as payments from any out- licensing agreements 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 one of our primary expenses 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 in May 2021 showed highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in combination with G-CSF ($p<0.0001$). In addition, the combination was found to be safe and well tolerated. Pharmaco-economic studies showed positive results regarding the cost-effectiveness of using motixafortide versus both G-CSF alone and plerixafor in combination with G-CSF. NDA submission made in September 2022, and in November 2022 the FDA accepted for review the NDA with a PDUFA target action date of September 9, 2023.	1. FDA decision on NDA filing expected in third quarter of 2023
	2. Investigator-initiated randomized clinical trial in first-line metastatic PDAC patients, based on preliminary data from the single-arm pilot phase.	2. Data from the pilot stage of the Phase 2 study is planned for submission to a congress later in 2023
	3. Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections	3. Data from the study is anticipated in 2023*
	.	.
	4. Phase 1 study for gene therapies in SCD	4. Initiation of the study is expected in 2023*
AGI-134	Phase 1/2a study completed. Results announced December 2022. The study met its primary endpoint of safety and tolerability. Generation of an immune response and markers of clinical efficacy were assessed as secondary endpoints.	Determination of next steps for the program during 2023

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

The table above does not include a registrational study in stem-cell mobilization, as well as a randomized Phase 2/3 study in first-line pancreatic adenocarcinoma, both of which the Licensee has committed to execute pursuant to the exclusive License Agreement in Asia for motixafortide which we entered into on August 27, 2023.

We expect that a large percentage of our research and development expenses 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 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, as well as the U.S. commercialization of motixafortide, 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, and are eligible to participate, in the clinical trials;
- the duration of patient follow-up;
- whether the patients require hospitalization or can be treated on an outpatient basis;
- the development stage of the therapeutic candidate; and
- the efficacy and safety profile of the therapeutic candidate.

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, commercialization and marketing functions. Other significant sales and marketing costs include costs for marketing and communication materials, pre-commercialization and market access activities, professional fees for outside market research and consulting, legal services related to potential business development transactions and travel costs.

We expect our sales and marketing expenses to become our most significant cost as we advance our U.S. commercialization plan for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including accounting, finance, legal, compliance, 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 February 2019, May-June 2020 and September 2022. 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 an “at-the-market” offering agreement, or ATM Agreement, between us and H.C. Wainwright & Co., LLC, or HCW, entered into in September 2021, 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 loans 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, 2022.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board. 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 and six-month periods ended June 30, 2023 and 2022.

Cost of revenues

We did not record any cost of revenues during each of the three-month and six-month periods ended June 30, 2023 and 2022.

Operating Results Comparison between Periods

Research and development expenses

	Three months ended June 30,			Six months ended June 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	5,395	3,006	(2,389)	9,830	6,690	(3,140)

Comparison of three-month periods ended June 30, 2023 and 2022

Research and development expenses for the three months ended June 30, 2023 were $3.0 million, a decrease of $2.4 million, or 44.3%, compared to $5.4 million for the three months ended June 30, 2022. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide as well as lower expenses associated with the completed AGI-134 clinical trial.

Comparison of six-month periods ended June 30, 2023 and 2022

Research and development expenses for the six months ended June 30, 2023 were $6.7 million, a decrease of $3.1 million, or 31.9%, compared to $9.8 million for the six months ended June 30, 2022. The reason for the decrease is similar to the aforementioned decrease in the three-month period.

Sales and marketing expenses

	Three months ended June 30,			Six months ended June 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	1,158	5,604	4,446	1,795	9,478	7,683

Comparison of three-month periods ended June 30, 2023 and 2022

Sales and marketing expenses for the three months ended June 30, 2023 were $5.6 million, an increase of $4.4 million, or 383.9% compared to $1.2 million for the three months ended June 30, 2022. The increase resulted primarily from the ramp-up of pre-commercialization activities related to motixafortide.

Comparison of six-month periods ended June 30, 2023 and 2022

Sales and marketing expenses for the six months ended June 30, 2023 were $9.5 million, an increase of $7.7 million, or 428.0% compared to $1.8 million for the six months ended June 30, 2022. The reason for the increase is similar to the aforementioned increase in the three-month period.

General and administrative expenses

	Three months ended June 30,			Six months ended June 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
	(in thousands of U.S. dollars)					
General and administrative expenses	1,049	1,305	256	2,056	2,603	547

Comparison of three-month periods ended June 30, 2023 and 2022

General and administrative expenses for the three months ended June 30, 2023 were $1.3 million, an increase of $0.3 million, or 24.4% compared to $1.0 million for the three months ended June 30, 2022. The increase resulted primarily from an increase in payroll and related expenses due to a small increase in headcount and share-based compensation, as well as small increases in a number of G&A expenses.

Comparison of six-month periods ended June 30, 2023 and 2022

General and administrative expenses for the six months ended June 30, 2023 were $2.6 million, an increase of $0.5 million, or 26.6% compared to $2.1 million for the six months ended June 30, 2022. The reason for the increase is similar to the aforementioned increase in the three-month period.

Non-operating income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
	(in thousands of U.S. dollars)					
Non-operating income (expenses), net	458	(7,733)	(8,191)	1,726	(10,649)	(12,375)

Comparison of three-month periods ended June 30, 2023 and 2022

We recognized net non-operating expenses of $7.7 million for the three months ended June 30, 2023, compared to net non-operating income of $0.5 million for the three months ended June 30, 2022. Non-operating income (expenses) for both periods primarily relates to fair-value adjustments of warrant liabilities on our balance sheet.

Comparison of six-month periods ended June 30, 2023 and 2022

We recognized net non-operating expense of $10.6 million for the six months ended June 30, 2023, compared to net non-operating income of $1.7 million for the six months ended June 30, 2022. Non-operating income (expenses) for both periods primarily relates to fair-value adjustments of warrant liabilities on our balance sheet.

Financial income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
	(in thousands of U.S. dollars)					
Financial income	80	440	360	147	977	830
Financial expenses	(379)	(1,337)	(958)	(565)	(2,264)	(1,699)
Net financial income (expenses)	(299)	(897)	(598)	(418)	(1,287)	(869)

Comparison of three-month periods ended June 30, 2023 and 2022

We recognized net financial expenses of $0.9 million for the three months ended June 30, 2023, compared to net financial expenses of $0.3 million for the three months ended June 30, 2022. Net financial expenses for both periods primarily relate to interest paid on loan and losses recorded on foreign currency (primarily NIS) cash balances due to the strengthening of the US dollar during the period, offset by investment income earned on our bank deposits.

Comparison of six-month periods ended June 30, 2023 and 2022

We recognized net financial expenses of $1.3 million for the six months ended June 30, 2023, compared to net financial expenses of $0.4 million for the six months ended June 30, 2022. The composition of the expenses is similar to the aforementioned composition detailed in the three-month period.

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 June 30, 2023, we held $32.8 million of cash, cash equivalents and short-term bank deposits. We have invested substantially all our available cash funds in short-term bank deposits.

In August 2023, we entered into an exclusive license agreement and securities purchase agreement providing for total initial funding of $29.6 million, which we anticipate closing following formal transaction approval by the Israeli Innovation Authority and other closing conditions.

In September 2022, we entered into a loan agreement, or the Loan Agreement, with Kreos Capital VII Aggregator SCSp, or Kreos Capital. Under the Loan Agreement, Kreos Capital will provide the Company with access to term loans in an aggregate principal amount of up to $40 million in three tranches as follows: (a) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon closing of the Loan Agreement and until April 1, 2023, (b) a loan in the aggregate principal amount of up to $20 million, available for drawdown upon achievement of certain milestones and until April 1, 2024, and (c) a loan in the aggregate principal amount of up to $10 million, available for drawdown upon achievement of certain milestones and until October 1, 2024. We drew down the initial tranche of $10 million following execution of the agreement in September 2022.

In September 2021, we entered into the ATM Agreement with HCW pursuant to which we may offer and sell, at our option, up to $25.0 million of our ADSs through an at-the- market equity program under which HCW agreed to act as sales agent. This agreement replaced a substantially identical ATM program that we previously had with HCW. As of the issuance date of this report, we have sold 608,651 of our ADSs for total gross proceeds of approximately $1.4 million under the ATM program.

Net cash used in operating activities was $18.4 million for the six months ended June 30, 2023, compared with net cash used in operating activities of $11.9 million for the six months ended June 30, 2022. The $6.5 million increase in net cash used in operating activities was primarily the result of an increase in sales and marketing expenses.

Net cash provided by investing activities was $18.4 million for the six months ended June 30, 2023, compared to net cash provided by investing activities of $15.1 million for the six months ended June 30, 2022. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash used in financing activities was $0.2 million for the six months ended June 30, 2023, compared to net cash used in financing activities of $1.6 million for the six months ended June 30, 2022. The cash flows in 2023 primarily reflect the repayments of lease liabilities. The cash flows in 2022 primarily reflect the repayments of a previous loan from Kreos Capital.

We have incurred accumulated losses in the amount of $361 million through June 30, 2023, and we expect to continue incurring losses and negative cash flows from operations until our product or products reach commercial profitability. Management monitors rolling forecasts of our liquidity reserves on the basis of anticipated cash flows and maintains liquidity balances at levels that are sufficient to meet its needs. The execution of an independent commercialization plan for motixafortide in the United States implies an increased level of expenses prior to and following launch of the product. However, as is common with FDA approvals of innovative pharmaceutical products, there is significant uncertainty regarding the receipt of approval, as well as the timing and scope of any potential approval ultimately received in order to launch commercialization of the product. Therefore, our cash flow projections are subject to various risks and uncertainties concerning their fulfilment, and these factors and the risk inherent in our operations may cast significant doubt on our ability to continue as a going concern. Our independent registered public accounting firm included a “going concern” explanatory paragraph in its report on our financial statements for the year ended December 31, 2022.

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 (which estimate does not take into account the $29.6 million in total funding from the aforementioned exclusive license agreement and securities purchase agreement entered into on August 27, 2023, which we anticipate closing following formal transaction approval by the Israeli Innovation Authority and other closing conditions), we will require additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. We expect to also continue to seek to finance our operations through other sources, including commercialization, if approved, in the United States for motixafortide, our lead therapeutic candidate, out-licensing arrangements for the development and commercialization of our therapeutic candidates or other partnerships or joint ventures, as well as grants from government agencies and foundations. 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, if any, 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;
- our success in effecting out-licensing arrangements with third parties;
- the ability of our collaborators and licensees to achieve development milestones, marketing approval and other events or developments under our collaboration and out-licensing 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;
- payments to the IIA; and
- the impact of any resurgence of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above.

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 June 30,		Six months ended June 30,	
	2022	2023	2022	2023
	(in U.S. dollars)			
Loss per ADS – basic and diluted	(0.16)	(0.30)	(0.26)	(0.50)

	December 31, 2022	June 30, 2023
	(in number of ADSs)	
Authorized share capital	166,666,667	166,666,667
Issued and paid-up capital	61,530,596	61,530,596