SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of November 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 November 20, 2023, the Registrant issued a press release announcing its financial results for the three and nine months ended September 30, 2023. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2023 and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 20, 2023;

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

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

This Form 6-K, the text under the heading "Third Quarter 2023 Financial Results" in Exhibit 1, Exhibit 2 and Exhibit 3 are hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioLineRx Ltd.

By: /s/ Philip Serlin
Philip Serlin
Chief Executive Officer

Dated: November 20, 2023

Exhibit 1

FOR IMMEDIATE RELEASE

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

- Received FDA Approval of APHEXDA® (motixafortide) in Combination with Filgrastim (G-CSF) to Mobilize Hematopoietic Stem Cells for Collection and Subsequent Autologous Transplantation in Patients with Multiple Myeloma -

- Closed Exclusive License Agreement for Motixafortide in Asia Region with Concurrent Strategic Equity Investment -

- Presented Encouraging Data at AACR from Pilot Phase of Randomized Phase 2 Combination Trial with Motixafortide in Patients with First Line PDAC -

- Began Enrollment of Phase 1 Trial Evaluating Motixafortide for CD34+ Hematopoietic Stem Cell Mobilization for Gene Therapies in Sickle Cell Disease -

- Management to host conference call today, November 20, at 10:00 a.m. EST -

TEL AVIV, Israel, November 20, 2023 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today reported its unaudited financial results for the third quarter ended September 30, 2023, and provided corporate and portfolio updates.

“FDA approval of APHEXDA® in September was a transformative event for the company, and our U.S. commercial team is now working with payers and providers to make this important innovation available to patients,” said Philip Serlin, Chief Executive Officer of BioLineRx. “We were pleased that APHEXDA® was recently added to the NCCN guidelines, and we believe that as centers adjust their protocols to include and gain experience with APHEXDA®, transplant teams will gain a deep appreciation for the efficiencies that it can provide, and more importantly, the improved treatment journey patients experience as they navigate their essential transplant process.

“In addition, the company also closed its motixafortide licensing agreement covering the important Asia market. The agreement, which provided significant upfront funding, will first advance potential indications in the region for stem cell mobilization and pancreatic cancer, areas of high unmet need. We continue to evaluate additional commercial partnership opportunities in other markets.

“Lastly, exciting data were presented at AACR from the single-arm pilot phase of the randomized Phase 2 combination clinical trial with motixafortide in first-line pancreatic cancer by the study’s lead investigator at Columbia University. The highly encouraging data triggered a change in the protocol, from a small, single-arm study to a much larger randomized study. This study, as well as the enrolling Phase 1 study evaluating motixafortide for stem cell mobilization in patients with sickle cell disease seeking gene therapy, highlight the potential versatility of motixafortide and the tremendous progress we are making to realize the full promise of this novel molecule for patients around the world,” Mr. Serlin concluded.

Corporate Updates

- Received U.S. Food and Drug Administration approval of APHEXDA® (motixafortide) in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma

- Closed exclusive license agreement to develop and commercialize motixafortide in Asia, alongside strategic equity investment:

    - License agreement included $15 million upfront payment, up to $50 million in potential development and regulatory milestones, up to $200 million in potential commercial milestones, and tiered double-digit royalties on sales
    - Straight common equity investment of $14.6 million in BioLineRx American Depository Shares (ADSs)
    - Gloria Biosciences expected to begin pivotal bridging study to support potential approval and commercialization of motixafortide in stem cell mobilization in China
    - Gloria Biosciences planning randomized Phase 2/3 first-line pancreatic cancer clinical trial evaluating motixafortide in combination with PD-1 inhibitor zimberelimab and standard of care combination chemotherapy

Clinical Portfolio Updates

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Received inclusion of APHEXDA® in the National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation
- Received acceptance of an abstract on combination premedication benefits in the Phase 3 GENESIS trial, further educating on the use of APHEXDA at transplant centers. The poster will be presented at the American Society of Hematology (ASH) 65th Annual Meeting on December 10, 2023, in San Diego, California
- Initiated pivotal bridging study preparation activities with Gloria Biosciences to support potential approval and commercialization of motixafortide in stem cell mobilization in China

Pancreatic Ductal Adenocarcinoma

- Presented data from the single-arm pilot phase of the investigator-initiated CheMo4METPANC Phase 2 combination clinical trial in first-line pancreatic cancer (PDAC) at the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer. Of 11 patients with metastatic pancreatic cancer enrolled, 7 patients (64%) experienced a partial response (PR), of which 5 (45%) were confirmed PRs with one patient experiencing resolution of the hepatic (liver) metastatic lesion. Three patients (27%) experienced stable disease, resulting in a disease control rate of 91%. Based on these encouraging results, the study was substantially revised to a multi-institution, randomized trial of 108 patients
- Initiated preparation activities with Gloria Biosciences to support the development of a randomized Phase 2/3 clinical trial evaluating motixafortide in combination with the PD-1 inhibitor zimberelimab and standard of care combination chemotherapy in first-line pancreatic cancer

Sickle Cell Disease & Gene Therapy

- Began enrollment in investigator-initiated Phase 1 pilot study led by Washington University School of Medicine in St. Louis evaluating motixafortide as monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell mobilization for gene therapies in sickle cell disease. Anticipate data in 2H of 2024

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Evaluating next development pathways for AGI-134 program. The Phase 1/2a first-in-human, single-agent study, results of which were announced in Q4 2022, met the primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers

Third Quarter 2023 Financial Results

- Research and development expenses for the three months ended September 30, 2023 were $2.7 million, a decrease of $1.6 million, or 37.6%, compared to $4.3 million for the three months ended September 30, 2022. The decrease resulted primarily from lower expenses associated with 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 September 30, 2023 were $8.1 million, an increase of $6.8 million, or 517.4% compared to $1.3 million for the three months ended September 30, 2022. The increase resulted primarily from the ramp-up of pre-commercialization activities related to motixafortide
- General and administrative expenses for the three months ended September 30, 2023 were $1.5 million, an increase of $0.1 million, or 7.7% compared to $1.4 million for the three months ended September 30, 2022. The increase resulted from small increases in a number of individual G&A expenses
- Non-operating expenses for the three months ended September 30, 2023 were $3.1 million, an increase of $3.5 million, compared to non-operating income of $0.4 million for the three months ended September 30, 2022. The increase relates primarily to the revaluation of outstanding warrants resulting from an increase in the company’s share price during the 2023 period
- Net loss for the three months ended September 30, 2023 was $16.0 million, compared to $6.8 million for the three months ended September 30, 2022. Net loss for the nine months ended September 30, 2023 amounted to $46.7 million, compared to $19.2 million for the nine months ended September 30, 2022. The increases in net loss for both the three- and nine-month periods in 2023 were primarily due to the significant non-operating expenses (which were also non-cash) related to revaluation of outstanding warrants, as well as the significant increases in sales and marketing expenses related to pre-commercialization and commercialization activities, which were partially offset by a decrease in research and development expenses
- As of September 30, 2023, we held $26.0 million of cash, cash equivalents and short-term bank deposits. We anticipate that this amount, as well as the consideration from the exclusive license agreement and the securities purchase agreement of $29.6 million that was received in October 2023, will be sufficient to fund operations, as currently planned, into 2025

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 November 22, 2023; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company’s first approved product is APHEXDA® (motixafortide) with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma. BioLineRx is advancing a pipeline of investigational medicines for patients with sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., the company 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, the potential benefits of APHEXDA, the execution of the launch of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of motixafortide, as well as its potential investigational uses. 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; whether the clinical trial results for APHEXDA will be predictive of real-world results; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; BioLineRx's ability to establish, operationalize and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the commercial launch of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic, the Russian invasion of Ukraine, the declared war by Israel against Hamas and the military campaigns against Hamas and other terrorist organizations, which may exacerbate the magnitude of the factors discussed above. 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.

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	December 31, 2022	September 30, 2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	7,727
Short-term bank deposits	40,495	18,241
Inventory	-	1,352
Prepaid expenses	198	1,170
Other receivables	721	315
Total current assets	52,001	28,805
NON-CURRENT ASSETS		
Property and equipment, net	726	561
Right-of-use assets, net	1,772	1,462
Intangible assets, net	21,885	22,027
Total non-current assets	24,383	24,050
Total assets	76,384	52,855
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	1,542	3,078
Accounts payable and accruals:		
Trade	6,966	8,438
Other	1,744	2,683
Current maturities of lease liabilities	427	526
Total current liabilities	10,679	14,725
NON-CURRENT LIABILITIES		
Warrants	4,509	15,287
Long-term loan, net of current maturities	8,626	8,458
Lease liabilities	1,729	1,251
Total non-current liabilities	14,864	24,996
Total liabilities	25,543	39,721
EQUITY		
Ordinary shares	27,100	28,332
Share premium	338,976	345,462
Warrants	1,408	1,408
Capital reserve	14,765	16,070
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(376,722)
Total equity	50,841	13,134
Total liabilities and equity	76,384	52,855

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2023	2022	2023
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,369)	(2,727)	(14,199)	(9,417)
SALES AND MARKETING EXPENSES	(1,317)	(8,131)	(3,112)	(17,609)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,392)	(1,499)	(3,448)	(4,102)
OPERATING LOSS	(7,078)	(12,357)	(20,759)	(31,128)
NON-OPERATING INCOME (EXPENSES), NET	389	(3,141)	2,115	(13,790)
FINANCIAL INCOME	109	312	256	1,289
FINANCIAL EXPENSES	(267)	(837)	(832)	(3,101)
NET LOSS AND COMPREHENSIVE LOSS	(6,847)	(16,023)	(19,220)	(46,730)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.02)	(0.03)	(0.05)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	740,767,492	929,058,619	723,805,390	925,014,511

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 NINE MONTHS ENDED SEPTEMBER 30, 2022:							
Issuance of share capital and warrants, net	6,030	(1,008)	433	-	-	-	5,455
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	491	-	(491)	-	-	-
Share-based compensation	-	-	-	1,200	-	-	1,200
Comprehensive loss for the period	-	-	-	-	-	(19,220)	(19,220)
BALANCE AT SEPTEMBER 30, 2022	27,098	338,841	1,408	13,854	(1,416)	(324,261)	55,524

	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 NINE MONTHS ENDED SEPTEMBER 30, 2023:							
Issuance of share capital, net	361	1,535	-	-	-	-	1,896
Warrants exercised	865	4,855	-	-	-	-	5,720
Employee stock options exercised	6	18	-	(9)	-	-	15
Employee stock options expired	-	78	-	(78)	-	-	-
Share-based compensation	-	-	-	1,392	-	-	1,392
Comprehensive loss for the period	-	-	-	-	-	(46,730)	(46,730)
BALANCE AT SEPTEMBER 30, 2023	28,332	345,462	1,408	16,070	(1,416)	(376,722)	13,134

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

	Nine months ended September 30,	
	2022	2023
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(19,220)	(46,730)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,337)	19,131
Net cash used in operating activities	(20,557)	(27,599)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(36,000)	(13,882)
Maturities of short-term deposits	36,232	36,000
Purchase of property and equipment	(74)	(100)
Purchase of intangible assets	(14)	(179)
Net cash provided by investing activities	144	21,839
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	14,359	1,896
Exercise of warrants	-	2,530
Employee stock options exercised	2	15
Proceeds of long-term loan, net of issuance costs	9,682	-
Repayments of loan	(2,832)	(802)
Repayments of lease liabilities	(126)	(323)
Net cash provided by financing activities	21,085	3,316
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	672	(2,444)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(557)	(416)
CASH AND CASH EQUIVALENTS - END OF PERIOD	13,105	7,727

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 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	467	678
Exchange differences on cash and cash equivalents	557	416
Fair value adjustments of warrants	(2,778)	13,968
Share-based compensation	1,200	1,392
Warrant issuance costs	171	-
Interest and exchange differences on short-term deposits	(244)	136
Interest on loan	104	2,170
Exchange differences on lease liability	(233)	(122)
Long-term loan issuance cost	(566)	-
	(1,312)	18,638
Changes in operating asset and liability items:		
Increase in inventory	-	(1,352)
Increase in prepaid expenses and other receivables	(411)	(566)
Increase in accounts payable and accruals	386	2,411
	(25)	493
	(1,337)	19,131
Supplemental information on interest received in cash	244	1,268
Supplemental information on interest paid in cash	307	833
Supplemental information on warrant issuance costs paid in cash	591	-
Supplemental information on non-cash transactions:		
Changes in right-of-use asset	123	66
Warrant issuance costs	262	-
Exercise of warrants (portion related to accumulated fair value adjustments)	-	3,190

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2023

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2023

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BioLineRx Ltd.

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Capital reserve	14,765	16,070
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(376,722)
Total equity	50,841	13,134
Total liabilities and equity	76,384	52,855

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

BioLineRx Ltd.
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(UNAUDITED)

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WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	740,767,492	929,058,619	723,805,390	925,014,511

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BioLineRx Ltd.
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Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	491	-	(491)	-	-	-
Share-based compensation	-	-	-	1,200	-	-	1,200
Comprehensive loss for the period	-	-	-	-	-	(19,220)	(19,220)
BALANCE AT SEPTEMBER 30, 2022	27,098	338,841	1,408	13,854	(1,416)	(324,261)	55,524

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Warrants exercised	865	4,855	-	-	-	-	5,720
Employee stock options exercised	6	18	-	(9)	-	-	15
Employee stock options expired	-	78	-	(78)	-	-	-
Share-based compensation	-	-	-	1,392	-	-	1,392
Comprehensive loss for the period	-	-	-	-	-	(46,730)	(46,730)
BALANCE AT SEPTEMBER 30, 2023	28,332	345,462	1,408	16,070	(1,416)	(376,722)	13,134

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(UNAUDITED)

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Issuance of share capital and warrants, net of issuance costs	14,359	1,896
Exercise of warrants	-	2,530
Employee stock options exercised	2	15
Proceeds of long-term loan, net of issuance costs	9,682	-
Repayments of loan	(2,832)	(802)
Repayments of lease liabilities	(126)	(323)
Net cash provided by financing activities	21,085	3,316
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	672	(2,444)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(557)	(416)
CASH AND CASH EQUIVALENTS - END OF PERIOD	13,105	7,727

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

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

	Nine months ended September 30,	
	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	467	678
Exchange differences on cash and cash equivalents	557	416
Fair value adjustments of warrants	(2,778)	13,968
Share-based compensation	1,200	1,392
Warrant issuance costs	171	-
Interest and exchange differences on short-term deposits	(244)	136
Interest on loan	104	2,170
Exchange differences on lease liability	(233)	(122)
Long-term loan issuance cost	(566)	-
	(1,312)	18,638
Changes in operating asset and liability items:		
Increase in inventory	-	(1,352)
Increase in prepaid expenses and other receivables	(411)	(566)
Increase in accounts payable and accruals	386	2,411
	(25)	493
	(1,337)	19,131
Supplemental information on interest received in cash	244	1,268
Supplemental information on interest paid in cash	307	833
Supplemental information on warrant issuance costs paid in cash	591	-
Supplemental information on non-cash transactions:		
Changes in right-of-use asset	123	66
Warrant issuance costs	262	-
Exercise of warrants (portion related to accumulated fair value adjustments)	-	3,190

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 (primarily in clinical stages) and commercialization of therapeutics, with a focus on the fields of oncology and hematology.

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.

The Company has two substantially wholly owned subsidiaries: (i) BioLineRx USA, Inc., incorporated in the US, and engaged in commercialization activities associated with the launch of motixafortide for stem-cell mobilization in the US; and (ii) Agalimmune Ltd., incorporated in the United Kingdom, and engaged in clinical development activities with a focus on the field of immuno-oncology.

In September 2023, the US Food and Drug Administration ("FDA") approved motixafortide in stem cell mobilization for autologous transplantation for multiple myeloma patients, and the Company has begun to independently commercialize motixafortide in the US.

b. Going concern

The Company has incurred accumulated losses in the amount of $377 million through September 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 (including the consideration from the license agreement and the securities purchase agreement as detailed in Note 8) and other resources will be sufficient to fund its projected cash requirements into 2025.

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, as well as uncertainty regarding the timing of commercial profitability. 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.

NOTE 1 – GENERAL INFORMATION (cont.)

b. Going concern (cont.)

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.

Management's plans include the independent commercialization of the Company's product, as aforementioned, 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 September 30, 2023, and for the three and nine months then ended, were approved by the Board of Directors on November 17, 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 September 30, 2023 and for the three and nine months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair 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 nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 2 – BASIS OF PREPARATION (cont.)

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.

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.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas and other terrorist organizations in parallel to their continued rocket and terror attacks. As of the date of release of these financial statements, the Company estimates there are no material effects of this war on its current financial position and results of operations. Nevertheless, the Company cannot predict the intensity or duration of the war, nor can it predict how the war will ultimately affect the Company's business and operations in Israel or Israel's economy in general.

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, except with regard to inventory, as a result of the recent FDA approval and launch of the Company's first product (see Note 1).

Inventory is measured at the lower of cost or net realizable value. The cost of inventories includes purchase costs, packaging and labeling costs, and other costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price of the inventories in the ordinary course of business, less the estimated costs necessary to make the sale. Pre-launch inventory is recorded as an asset only when there is a high probability of regulatory approval for the relevant product. Prior to that point, inventory costs are recorded as research and development expenses.

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 nine months ended September 30, 2023, the Company issued a total of 917,640 ADSs under the agreement for total gross proceeds of $1.9 million. From the effective date of the agreement through the issuance of this report, 1,890,325 ADSs have been sold under the program for total gross proceeds of approximately $3.8 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 $15,282,000 as of September 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 4.7%, (4.1% as of December 31, 2022), an average standard deviation of 88.2%, (85.5% as of December 31, 2022), and on the remaining contractual life of the warrants. As of September 30, 2023, 2,200,000 of these warrants had been exercised.

The changes in fair value from December 31, 2022 through September 30, 2023 of $13,968,000 have been recorded as non-operating expenses in the statement of comprehensive loss.

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 September 30, 2023, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2022	September 30, 2023
Authorized share capital	2,500,000,000	2,500,000,000
Issued and paid-up share capital	922,958,942	969,918,007

	In USD and NIS	
	December 31, 2022	September 30, 2023
Authorized share capital (in NIS)	250,000,000	250,000,000
Issued and paid-up share capital (in NIS)	92,295,894	96,991,801
Issued and paid-up share capital (in USD)	27,100,201	28,332,050

NOTE 8 – SUBSEQUENT EVENT - LICENSE AND SECURITIES PURCHASE AGREEMENTS

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. The License Agreement became effective on October 12, 2023, following fulfillment of all closing conditions.

Pursuant to the terms of the License Agreement, the Licensee paid an upfront payment of $15 million, which was received by the Company at closing. 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 connection with the License Agreement, on August 27, 2023, the Company also entered into a securities purchase agreement (the "Purchase Agreement") with HST and Gloria, pursuant to which the Company agreed to sell in a private placement an aggregate of 6,829,137 ADSs of the Company, at a purchase price of $2.136 per ADS. The Purchase Agreement became effective on October 12, 2023, following fulfillment of all closing conditions. Aggregate gross proceeds from the sale, which were received by the Company at closing, amounted to $14.6 million, with related issuance costs amounting to approximately $0.9 million. 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, the potential benefits of APHEXDA, the timing and execution of the launch of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of motixafortide, as well as its potential investigational uses. 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;
- whether the clinical trial results for APHEXDA will be predictive of real-world results;
- our receipt of regulatory approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients;
- whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors;
- our ability to establish, manage, and maintain corporate collaborations, as well as the ability of our collaborators to execute on their development and commercialization plans;
- our ability to integrate new therapeutic candidates and new personnel, as well as new collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection that 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 need for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercial launch of APHEXDA;

- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;

- competitive companies, technologies and our industry;

- statements as to the impact of the political and security situation in Israel on our business, including the impact of Israel's war with Hamas and other militant groups, which may exacerbate the magnitude of the factors discussed above.

Risk Factors

Except as set forth below, there are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2022.

Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations

Because part of our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks.

The intensity and duration of Israel's current war against Hamas is difficult to predict, as are such war's economic implications on the Company's business and operations and on Israel's economy in general.

Overview

General

We are a commercial-stage biopharmaceutical company focused on oncology. Our current development and commercialization pipeline consists of motixafortide (BL-8040), a novel peptide for the treatment of stem-cell mobilization and solid tumors, which on September 8, 2023, was approved by the U.S. Food and Drug Administration, or FDA, for use in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma, 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 motixafortide and BL-5010, none of our therapeutic candidates have been approved for marketing or commercial sale. 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 FDA.

- 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) was 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 showed quality-adjusted-life-year (QALY) benefits and net cost savings of ~$19,000 (not including the cost of motixafortide), versus G-CSF alone.

- 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, was 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 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 showed that motixafortide in combination with G-CSF, versus plerixafor in combination with G-CSF, demonstrated 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 showed QALY benefits and net cost savings of ~$30,000 (not including the cost of motixafortide), versus plerixafor plus G-CSF. The study findings strengthened 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.

- 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.

- 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. As anticipated, the study began enrolling in 2023 and is ongoing (timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change).

- In September 2023, the FDA approved motixafortide in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. Following this approval, we have begun to commercialize motixafortide in the U.S. independently, as planned, in order to accelerate its availability to patients and to maximize the value of this innovative therapeutic candidate.

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 11 PDAC patients in a pilot phase. In September 2023, we reported data from the pilot phase of the study. As of May 2023 (the cutoff date of the reported data), of those 11 patients, seven patients (64%) experienced a partial response (PR), of which five (45%) were confirmed PRs, with one patient experiencing resolution of the hepatic (liver) metastatic lesion. Three patients (27%) experienced stable disease, resulting in a disease control rate of 91%. These findings compare favorably to historic partial response and disease control rates of 23% and 48%, respectively, reported with the chemotherapy combination of gemcitabine and nab-paclitaxel. Based on this data, the planned single-arm study was amended to a significantly larger, randomized study, based on preliminary pre-defined data from the single-arm pilot phase, with a new planned total of 108 patients. The primary endpoint of the study is progression free survival. Secondary endpoints include safety and tolerability, duration of clinical benefit and overall survival. The randomized study is expected to begin enrollment in the first half of 2024.

- On August 29, 2023, following the Company's out-licensing agreement with Gloria (as defined below), the Company and GenFleet Therapeutics, an immuno-oncology focused biopharmaceutical company based in China, mutually agreed to terminate their collaboration agreement originally entered into in June 2022. See "Out licensing of Motixafortide in Asia" below for additional information.

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 now expected in 2024 (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, generate data about motixafortide's potential use in other indications, and inform the life-cycle management process of 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 the trade or brand name of motixafortide.

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.

Pursuant to the terms of the License Agreement, the Licensee made a $15 million upfront payment in October 2023, upon the closing of the transaction. The Company is 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 are to be reduced by 50% following the end of the initial royalty term and to 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 connection with the License Agreement, on August 27, 2023, we also entered into a securities purchase agreement with HST and Gloria 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 were approximately $14.6 million. The private placement closed in October 2023. 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, in consultation with our scientific advisory board, to determine the next steps for the program during 2024.

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, 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 September 30, 2023, we held $26.0 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 in Asia and securities purchase agreement with Gloria, which closed in October 2023. See “Out licensing of Motixafortide in Asia” above for additional information.

Revenues

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

We expect our revenues, if any, for the next several years to be derived primarily from the independent commercialization of motixafortide in stem cell mobilization in the US, as well as payments from any out- licensing agreements, including the out-licensing agreement with Gloria mentioned above, and other potential collaboration arrangements, including future royalties on product sales.

Cost of Revenues

Our cost of revenues to date have consisted of sub-license payments to the licensors in respect of upfront and milestone payments associated with out-licensing agreements.

We expect our cost of revenues, if any, for the next several years to be derived primarily from the cost of goods sold related to the independent commercialization of motixafortide in stem cell mobilization in the US, royalties payable to the licensors stemming from direct product sales related to the independent commercialization as set forth above, as well as from sub-license payments to the licensors in respect of out-licensing agreements and other potential collaboration arrangements, including future royalties on product sales from such out-licensing agreements.

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 expenses 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. FDA approval received on September 8, 2023 for stem-cell mobilization in multiple myeloma patients.	1. Commercial product launch of motixafortide in the United States
	2. Reported data from single-arm pilot phase of the investigator-initiated Phase 2 combination trial in first-line PDAC. Of 11 patients with metastatic pancreatic cancer enrolled, 7 patients (64%) experienced partial response (PR), of which 5 (45%) were confirmed PRs with one patient experiencing resolution of the hepatic (liver) metastatic lesion. 3 patients (27%) experienced stable disease, resulting in a disease control rate of 91%. Based on these encouraging results, study was substantially revised to a multi-institution, randomized trial of 108 patients	2. Initiation of randomized study expected in first half of 2024*
	3. Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections	3. Data from the study is now anticipated in 2024*
	4. Phase 1 study for gene therapies in SCD	4. Data from the study is expected in the second half of 2024*
	5. Pivotal bridging study in SCM in China under license agreement with Gloria	5. Initiation of the study is expected in 2024
	6. Phase 2/3 randomized study in first-line PDAC in China under license agreement with Gloria	6. IND submission and protocol finalization expected in 2024
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 2024

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

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 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 nine-month periods ended September 30, 2023 and 2022.

Cost of revenues

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

Operating Results Comparison between Periods

Research and development expenses

	Three months ended September 30,			Nine months ended September 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	4,369	2,727	(1,642)	14,199	9,417	(4,782)

Comparison of three-month periods ending September 30, 2023 and 2022

Research and development expenses for the three months ended September 30, 2023 were $2.7 million, a decrease of $1.6 million, or 37.6%, compared to $4.3 million for the three months ended September 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 nine-month periods ending September 30, 2023 and 2022

Research and development expenses for the nine months ended September 30, 2023 were $9.4 million, a decrease of $4.8 million, or 33.7%, compared to $14.2 million for the nine months ended September 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 September 30,			Nine months ended September 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	1,317	8,131	6,814	3,112	17,609	14,497

Comparison of three-month periods ending September 30, 2023 and 2022

Sales and marketing expenses for the three months ended September 30, 2023 were $8.1 million, an increase of $6.8 million, or 517.4% compared to $1.3 million for the three months ended September 30, 2022. The increase resulted primarily from the ramp-up of pre-commercialization activities related to motixafortide.

Comparison of nine-month periods ending September 30, 2023 and 2022

Sales and marketing expenses for the nine months ended September 30, 2023 were $17.6 million, an increase of $14.5 million, or 465.8% compared to $3.1 million for the nine months ended September 30, 2022. The reason for the increase is similar to the aforementioned decrease in the three-month period.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	1,392	1,499	107	3,448	4,102	654

Comparison of three-month periods ending September 30, 2023 and 2022

General and administrative expenses for the three months ended September 30, 2023 were $1.5 million, an increase of $0.1 million, or 7.7% compared to $1.4 million for the three months ended September 30, 2022. The increase resulted primarily from small increases in a number of G&A expenses.

Comparison of nine-month periods ending September 30, 2023 and 2022

General and administrative expenses for the nine months ended September 30, 2023 were $4.1 million, an increase of $0.7 million, or 19.0% compared to $3.4 million for the nine months ended September 30, 2022. The increase resulted primarily from an increase in professional services and legal expenses, as well as an increase in share-based compensation.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	389	(3,141)	(3,530)	2,115	(13,790)	(15,905)

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

Non-operating expenses for the three and nine months ended September 30, 2023 primarily relates to non-cash fair-value adjustments of warrant liabilities on our balance sheet. Non-operating income for the three and nine months ended September 30, 2022 primarily relates to non-cash fair-value adjustments of warrant liabilities on our balance sheet, offset by warrant offering expenses.

Financial income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2022	2023	Increase (decrease)	2022	2023	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	109	312	203	256	1,289	1,033
Financial expenses	(267)	(837)	(570)	(832)	(3,101)	(2,269)
Net financial income (expenses)	(158)	(525)	(367)	(576)	(1,812)	(1,236)

Comparison of three-month periods ending September 30, 2023 and 2022

We recognized net financial expenses of $0.5 million for the three months ended September 30, 2023, compared to net financial expenses of $0.2 million for the three months ended September 30, 2022. Net financial expenses for both periods primarily relate to interest paid on loans 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 nine-month periods ending September 30, 2023 and 2022

We recognized net financial expenses of $1.8 million for the nine months ended September 30, 2023, compared to net financial expenses of $0.6 million for the nine months ended September 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 September 30, 2023, we held $26.0 million of cash, cash equivalents and short-term bank deposits. This amount does not take into account $29.6 million of aggregate gross proceeds received in October 2023, upon the closing of an exclusive license agreement and share purchase agreement. See “Out licensing of Motixafortide in Asia” above for additional information. We have invested substantially all our available cash funds in short-term bank deposits.

In September 2022, we entered into a loan agreement, or the Loan Agreement, with Kreos Capital VII Aggregator SCS, 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 2022, we entered into definitive agreements with certain institutional investors providing for the issuance and sale in a registered direct offering of 13,636,365 of our ADSs and warrants to purchase up to an aggregate of 13,636,365 ADSs at a combined purchase price of $1.10 per ADS and associated investor warrant, for aggregate gross proceeds of approximately $15 million. The transaction closed 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. As of the issuance date of this report, we have sold 1,890,325 of our ADSs for total gross proceeds of approximately $3.8 million under the ATM program.

Net cash used in operating activities was $27.6 million for the nine months ended September 30, 2023, compared with net cash used in operating activities of $20.6 million for the nine months ended September 30, 2022. The $7.0 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 $21.8 million for the nine months ended September 30, 2023, compared to net cash provided by investing activities of $0.1 million for the nine months ended September 30, 2022. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was $3.3 million for the nine months ended September 30, 2023, compared to net cash provided by financing activities of $21.1 million for the nine months ended September 30, 2022. The cash flows in 2023 primarily reflect warrant exercises and net proceeds from the ATM facility, offset by repayments of the loan from Kreos Capital and the repayments of lease liabilities. The cash flows in 2022 primarily reflect the underwritten public offering of our ADSs in September 2022 and the net proceeds of a loan from Kreos Capital, offset by repayments of a previous loan from Kreos Capital.

We have incurred accumulated losses in the amount of $377 million through September 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. 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 (including the consideration from the license agreement and the securities purchase agreement of $29.6 million) and other resources will be sufficient to fund our current projected cash requirements into 2025, 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 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, the Russian invasion of Ukraine, and the military campaigns by Israel against Hamas and other terrorist organizations (including the declaration of war by Israel against Hamas), 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 September 30,		Nine months ended September 30,	
	2022	2023	2022	2023
	(in U.S. dollars)			
Loss per ADS – basic and diluted	(0.14)	(0.26)	(0.39)	(0.76)

	December 31, 2022	September 30, 2023
	(in number of ADSs)	
Authorized share capital	166,666,667	166,666,667
Issued and paid-up capital	61,530,596	61,667,634