SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of August 2024

Commission file number: 001-35223

BioLineRx Ltd.

(Translation of registrant's name into English)

2 HaMa'ayan Street
Modi'in 7177871, Israel
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ **Form 40-F ☐**

On August 15, 2024, the Registrant issued a press release announcing its financial results for the three and six months ended June 30, 2024. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of June 30, 2024 and for the three and six months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated August 15, 2024;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of June 30, 2024 and for the three and six months then ended; and

Exhibit 3: Registrant's operating and financial review as of June 30, 2024 and for the three and six months then ended.

This Form 6-K, the text under the heading "Second Quarter 2024 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 A. Serlin
Philip A. Serlin
Chief Executive Officer

Dated: August 15, 2024

Exhibit 99.1

FOR IMMEDIATE RELEASE

BioLineRx Reports Second Quarter 2024 Financial Results and Recent Corporate and Portfolio Updates

- Secured APHEXDA® *formulary placement among top 80 transplant centers representing ~37% of stem cell transplant procedures performed, surpassing stated goal for quarter; on-track to reach goal of ~60% by end of Q4 -*

- Doubled the number of centers ordering APHEXDA during the second quarter -

- Entered into clinical trial agreement with St. Jude Children's Research Hospital to evaluate motixafortide for hematopoietic stem cell mobilization for gene therapies in sickle cell disease -

- Management to host conference call today, August 15, at 8:30 am EDT -

TEL AVIV, Israel, August 15, 2024 – 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 second quarter ended June 30, 2024, and provided recent corporate and portfolio updates.

"We continue to demonstrate positive commercial launch momentum with APHEXDA, our best-in-class stem cell mobilization agent," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, among our targeted top 80 transplant centers, we've secured formulary placement to date at institutions representing ~37% of stem cell transplant procedures performed, surpassing our stated goal. Additionally, we doubled the number of transplant centers ordering APHEXDA during the second quarter, which is a strong leading indicator and, we believe, reflects centers' growing recognition of the value that APHEXDA offers relative to other mobilization agents. Our goal is to achieve formulary placement at institutions representing approximately 60% of procedures by the end of year, which will support continued revenue growth and ease burdens on patients, caregivers, and transplant centers.

"Our vision is to maximize the potential of APHEXDA by expanding into key areas with high unmet need. To that end, we announced our second clinical trial collaboration, with St. Jude Children's Research Hospital, evaluating APHEXDA for stem cell mobilization in patients with sickle cell disease (SCD) seeking gene therapy. This new collaboration complements the ongoing SCD stem cell mobilization Phase 1 trial at Washington University in St. Louis (Wash U.). APHEXDA has the potential to support the collection of the immense amount of stem cells needed for these complex gene therapies in a more predictable and condensed timeline for patients. The companies launching these new gene therapies for SCD report continued expansion of authorized treatment centers and increased numbers of patients initiating cell collection. We look forward to seeing early data from the Wash U. Phase 1 trial later this year."

APHEXDA Launch Updates

- Among top 80 transplant centers, secured formulary placement to date at institutions representing ~37% of stem cell transplant procedures performed, exceeding the company's stated goal for the quarter; on track to achieve ~60% by year-end 2024
- Saw double the number of centers ordering APHEXDA during the second quarter as compared to the first quarter, which contributed to quarter-over-quarter net revenue growth of 100%

Clinical Portfolio Updates

Motixafortide

Multiple Myeloma

- Presented a poster at the American Society for Apheresis (ASFA) 2024 Annual Meeting on April 17, 2024, demonstrating that transplant centers (averaging, for example, 20 transplants per month), when switching to G-CSF plus APHEXDA, could increase capacity by 52.0 patient days per month versus G-CSF alone, or by 12.3 patient days per month versus G-CSF in combination with plerixafor
- Presented a poster at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) on April 6, 2024, showing that even with APHEXDA's higher drug acquisition cost compared to other mobilization regimens, specifically G-CSF alone or G-CSF plus generic plerixafor, the combination of G-CSF plus APHEXDA may confer a similar or better overall financial impact while providing centers and patients with an improved mobilization experience
- Collaboration partner Gloria Biosciences' stem cell mobilization bridging study IND was filed and approved by the Center for Drug Evaluation of the National Medical Products Administration in China. Anticipate initiation of pivotal clinical trial in 2H 2024

Sickle Cell Disease (SCD) & Gene Therapy

- Entered into clinical trial agreement with St. Jude Children's Research Hospital to evaluate motixafortide for hematopoietic stem cell mobilization for gene therapies in sickle cell disease. The Phase 1 clinical trial is an open-label, multi-center study evaluating the safety, tolerability, and feasibility of single-agent motixafortide for the mobilization and collection of CD34+ HSCs in 12 patients (aged 18 and older) with SCD. Anticipate first patient dosed in September 2024 and initial data in 2025
- Reported continuing enrollment of patients into a Phase 1 clinical trial evaluating motixafortide as monotherapy and in combination with natalizumab for stem cell mobilization for gene therapies in sickle cell disease. The trial, in collaboration with Washington University School of Medicine in St. Louis, has been expanded from five to 10 patients. Anticipate initial data in 2H 2024

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Presented positive biopsy data from the completed pilot phase of the ongoing CheMo4METPANC Phase 2b clinical trial collaboration with Columbia University at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting held on June 1, 2024 in Chicago, IL. New analyses of paired pre- and on-treatment biopsy samples demonstrated a statistically significant increase in CD8+ T-cell density in tumors from all 11 patients treated with the combination therapy approach (P=0.007). Enrollment in the randomized trial targeting 108 patients continues with full enrollment anticipated in 2027
- Completed design of Phase 2b randomized clinical trial in China with collaboration partner Gloria Biosciences intended to assess motixafortide in combination with the PD-1 inhibitor zimberelimab and standard-of-care chemotherapy as first-line treatment in patients with metastatic pancreatic cancer. Anticipate clinical trial initiation in 2025

Second Quarter 2024 Financial Results

- Total revenue for the three months ended June 30, 2024 was $5.4 million. The Company did not record any revenue during the second quarter of 2023. Revenue for the quarter reflects a portion of the upfront payment from the Gloria Biosciences license, which amounted to $3.6 million, as well as $1.8 million of net revenue from product sales of APHEXDA in the U.S.
- Cost of revenue for the three months ended June 30, 2024 was $0.9 million. The Company did not record any cost of revenue during the second quarter of 2023. Cost of revenue for the quarter primarily reflects the amortization of intangible assets, royalties on net product sales of APHEXDA in the U.S., and cost of goods sold on product sales
- Research and development expenses for the three months ended June 30, 2024 were $2.2 million, compared to $3.0 million for the same period in 2023. The decrease resulted primarily from lower expenses related to motixafortide New Drug Application (NDA) supporting activities, termination of the development of AGI-134 and a decrease in share-based compensation
- Sales and marketing expenses for the three months ended June 30, 2024 were $6.4 million, compared to $5.6 million for the same period in 2023. The increase resulted primarily from the ramp-up in headcount costs associated with a fully hired field team
- General and administrative expenses for the three months ended June 30, 2024 were $1.6 million, compared to $1.3 million for the same period in 2023. The increase resulted primarily from an increase in legal and certain other expenses
- Net income for the three months ended June 30, 2024 was $0.5 million, compared to net loss of $18.5 million for the same period in 2023. The net income for the 2024 period included $7.8 million in non-operating income, compared to non-operating expenses of $7.7 million for the same period in 2023, both primarily related to the non-cash revaluation of warrants
- As of June 30, 2024, the Company had cash, cash equivalents, and short-term bank deposits of $40.1 million. The Company anticipates that this amount 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 August 19, 2024; 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 BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; 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 26, 2024. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

Contacts:

United States
John Lacey
BioLineRx
IR@biolinerx.com

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

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

	December 31, 2023	June 30, 2024
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	4,255	9,623
Short-term bank deposits	38,739	30,437
Trade receivables	358	3,179
Prepaid expenses	1,048	1,581
Other receivables	830	656
Inventory	1,953	3,634
Total current assets	47,183	49,110
NON-CURRENT ASSETS		
Property and equipment, net	473	344
Right-of-use assets, net	1,415	1,452
Intangible assets, net	14,854	13,690
Total non-current assets	16,742	15,486
Total assets	63,925	64,596
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,145	10,656
Contract liabilities	12,957	5,477
Accounts payable and accruals:		
Trade	10,869	6,266
Other	3,353	2,530
Current maturities of lease liabilities	528	500
Warrants	11,932	5,087
Total current liabilities	42,784	30,516
NON-CURRENT LIABILITIES		
Long-term loan, net of current maturities	6,628	18,790
Lease liabilities	1,290	1,309
Total non-current liabilities	7,918	20,099
CONTINGENT LIABILITIES		
Total liabilities	50,702	50,615
EQUITY		
Ordinary shares	31,355	34,411
Share premium	355,482	352,428
Warrants	1,408	1,408
Capital reserve	17,000	17,968
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(390,818)
Total equity	13,223	13,981
Total liabilities and equity	63,925	64,596

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	in USD thousands		in USD thousands	
REVENUES	-	5,393	-	12,248
COST OF REVENUES	-	(897)	-	(2,352)
GROSS PROFIT	-	4,496	-	9,896
RESEARCH AND DEVELOPMENT EXPENSES	(3,006)	(2,225)	(6,690)	(4,719)
SALES AND MARKETING EXPENSES	(5,604)	(6,415)	(9,478)	(12,757)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,305)	(1,629)	(2,603)	(3,015)
OPERATING LOSS	(9,915)	(5,773)	(18,771)	(10,595)
NON-OPERATING INCOME (EXPENSES), NET	(7,733)	7,807	(10,649)	12,297
FINANCIAL INCOME	440	535	977	1,100
FINANCIAL EXPENSES	(1,337)	(2,085)	(2,264)	(3,014)
NET INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)	(18,545)	484	(30,707)	(212)
	in USD		in USD	
EARNINGS (LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY SHAREHOLDERS				
BASIC	(0.02)	0.00	(0.03)	(0.00)
DILUTED	(0.02)	0.00	(0.03)	(0.00)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF EARNINGS (LOSS) PER SHARE				
BASIC	922,958,942	1,197,582,901	922,958,942	1,142,221,033
DILUTED	922,958,942	1,197,582,901	922,958,942	1,142,221,033

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, 2023	27,100	338,976	1,408	14,765	(1,416)	(329,992)	50,841
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2023:							
Employee stock options expired	-	69	-	(69)	-	-	-
Share-based compensation	-	-	-	920	-	-	920
Comprehensive loss for the period	-	-	-	-	-	(30,707)	(30,707)
BALANCE AT JUNE 30, 2023	27,100	339,045	1,408	15,616	(1,416)	(360,699)	21,054

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
				in USD thousands			
BALANCE AT JANUARY 1, 2024	31,355	355,482	1,408	17,000	(1,416)	(390,606)	13,223
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2024:							
Issuance of share capital and warrants, net	3,056	(3,056)	-	-	-	-	-
Employee stock options forfeiture				(66)			(66)
Share-based compensation expenses	-	-	-	1,036	-	-	1,036
Comprehensive loss for the period	-	-	-	-	-	(212)	(212)
BALANCE AT JUNE 30, 2024	34,411	352,426	1,408	17,970	(1,416)	(390,818)	13,981

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

	Six months ended June 30,	
	2023	2024
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(30,707)	(212)
Adjustments required to reflect net cash used in operating activities (see appendix below)	13,009	(25,226)
Net cash used in operating activities	(17,698)	(25,438)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(6,006)	(20,559)
Maturities of short-term deposits	24,000	28,660
Purchase of property and equipment	(99)	(59)
Purchase of intangible assets	(153)	-
Net cash provided by investing activities	17,742	8,042
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance cost	-	5,565
Net proceeds from loan	-	19,223
Repayments of loan		(1,547)
Repayments of lease liabilities	(183)	(256)
Net cash provided by (used in) financing activities	(183)	22,985
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(139)	5,589
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(344)	(221)
CASH AND CASH EQUIVALENTS - END OF PERIOD	10,104	9,623

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

	Six months ended June 30,	
	2023	2024
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	457	1,373
Exchange differences on cash and cash equivalents	344	221
Fair value adjustments of warrants	10,843	(12,845)
Share-based compensation	920	970
Interest on short-term deposits	(210)	201
Interest on loan	1,405	1,997
Exchange differences on lease liabilities	(75)	189
Issuance cost of warrants	-	642
	13,684	(7,252)
Changes in operating asset and liability items:		
Increase in trade receivables	-	(2,821)
Increase in prepaid expenses and other receivables	(958)	(359)
Increase in inventory	-	(1,681)
Increase (decrease) in accounts payable and accruals	283	(5,633)
Decrease in contract liabilities	-	(7,480)
	(675)	(17,974)
	13,009	(25,226)
Supplemental information on interest received in cash	761	931
Supplemental information on interest paid in cash	640	971
Supplemental information on non-cash transactions:		
Changes in right-of-use asset and lease liabilities	66	58
Warrant issuance costs	-	207

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2024

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2024

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Capital reserve	17,000	17,968
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(390,818)
Total equity	13,223	13,981
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The accompanying notes are an integral part of these condensed consolidated interim financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	in USD thousands		in USD thousands	
REVENUES	-	5,393	-	12,248
COST OF REVENUES	-	(897)	-	(2,352)
GROSS PROFIT	-	4,496	-	9,896
RESEARCH AND DEVELOPMENT EXPENSES	(3,006)	(2,225)	(6,690)	(4,719)
SALES AND MARKETING EXPENSES	(5,604)	(6,415)	(9,478)	(12,757)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,305)	(1,629)	(2,603)	(3,015)
OPERATING LOSS	(9,915)	(5,773)	(18,771)	(10,595)
NON-OPERATING INCOME (EXPENSES), NET	(7,733)	7,807	(10,649)	12,297
FINANCIAL INCOME	440	535	977	1,100
FINANCIAL EXPENSES	(1,337)	(2,085)	(2,264)	(3,014)
NET INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)	(18,545)	484	(30,707)	(212)
	in USD		in USD	
EARNINGS (LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY SHAREHOLDERS				
BASIC	(0.02)	0.00	(0.03)	(0.00)
DILUTED	(0.02)	0.00	(0.03)	(0.00)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF EARNINGS (LOSS) PER SHARE				
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DILUTED	922,958,942	1,197,582,901	922,958,942	1,142,221,033

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

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

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

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
				in USD thousands			
BALANCE AT JANUARY 1, 2024	31,355	355,482	1,408	17,000	(1,416)	(390,606)	13,223
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2024:							
Issuance of share capital and warrants, net	3,056	(3,056)	-	-	-	-	-
Employee stock options forfeiture				(66)			(66)
Share-based compensation expenses	-	-	-	1,036	-	-	1,036
Comprehensive loss for the period	-	-	-	-	-	(212)	(212)
BALANCE AT JUNE 30, 2024	34,411	352,426	1,408	17,970	(1,416)	(390,818)	13,981

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

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

	Six months ended June 30,	
	2023	**2024**
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(30,707)	(212)
Adjustments required to reflect net cash used in operating activities (see appendix below)	13,009	(25,226)
Net cash used in operating activities	(17,698)	(25,438)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(6,006)	(20,559)
Maturities of short-term deposits	24,000	28,660
Purchase of property and equipment	(99)	(59)
Purchase of intangible assets	(153)	-
Net cash provided by investing activities	17,742	8,042
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance cost	-	5,565
Net proceeds from loan	-	19,223
Repayments of loan		(1,547)
Repayments of lease liabilities	(183)	(256)
Net cash provided by (used in) financing activities	(183)	22,985
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(139)	5,589
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(344)	(221)
CASH AND CASH EQUIVALENTS - END OF PERIOD	10,104	9,623

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)

	Six months ended June 30,	
	2023	2024
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	457	1,373
Exchange differences on cash and cash equivalents	344	221
Fair value adjustments of warrants	10,843	(12,845)
Share-based compensation	920	970
Interest on short-term deposits	(210)	201
Interest on loan	1,405	1,997
Exchange differences on lease liabilities	(75)	189
Issuance cost of warrants	-	642
	13,684	(7,252)
Changes in operating asset and liability items:		
Increase in trade receivables	-	(2,821)
Increase in prepaid expenses and other receivables	(958)	(359)
Increase in inventory	-	(1,681)
Increase (decrease) in accounts payable and accruals	283	(5,633)
Decrease in contract liabilities	-	(7,480)
	(675)	(17,974)
	13,009	(25,226)
Supplemental information on interest received in cash	761	931
Supplemental information on interest paid in cash	640	971
Supplemental information on non-cash transactions:		
Changes in right-of-use asset and lease liabilities	66	58
Warrant issuance costs	-	207

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 U.S., and engaged in commercialization activities associated with the launch of motixafortide for stem-cell mobilization in the U.S.; 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 December 2023, the Company notified the former shareholders of Agalimmune Ltd. of its decision to terminate the development of AGI-134, the principal asset of Agalimmune Ltd., with an effective termination date of March 15, 2024.

In September 2023, the U.S. 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 U.S.

b. Israel-Hamas war

On October 7, 2023, an unprecedented invasion was launched against Israel from the Gaza Strip by terrorists from the Hamas terrorist organization that infiltrated Israel's southern border and other areas within the country, attacking civilians and military targets while simultaneously launching extensive rocket attacks on the Israeli civilian population. These attacks resulted in extensive deaths, injuries and the kidnapping of civilians and soldiers. In response, the Security Cabinet of the State of Israel declared war against Hamas, with commencement of a military campaign against the terrorist organization, in parallel to its continued rocket and terror attacks. In addition, Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, has attacked military and civilian targets in Northern Israel, to which Israel has responded, and the Islamic Republic of Iran launched an unprecedented missile attack against Israel in April 2024. To date, the State of Israel continues to be at war with Hamas and in an armed conflict with Hezbollah.

The Company's headquarters and principal development operations are located in the State of Israel. In addition, most of its key employees, officers and directors are residents of Israel. The ongoing war with Hamas has not, to date, materially impacted the Company's business or operations. Furthermore, the Company does not expect any disruption to its programs or operations as a result of this situation. Nevertheless, at this time, it is not possible to predict the intensity or duration of Israel's war against Hamas, nor how this conflict will ultimately affect the Company's ongoing business and operations, nor Israel's economy in general.

NOTE 1 – GENERAL INFORMATION (cont.)

c. Going concern

The Company has incurred accumulated losses in the amount of $391 million through June 30, 2024, 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 seeks to maintain liquidity balances at levels that are sufficient to meet its needs. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into 2025.

The execution of an independent commercialization plan for motixafortide in the U.S. 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 risks inherent in the Company's operations indicate that a material uncertainty exists that may cast significant doubt (or raise substantial doubt as contemplated by PCAOB standards) 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.

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.

d. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of June 30, 2024, and for the three and six months then ended, were approved by the Board of Directors on August 14, 2024, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer, and the Chief Financial Officer.

NOTE 2 – BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of June 30, 2024 and for the three and six months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair presentation of financial position, results of operations, and cash flows in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2023 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

The preparation of financial statements in conformity with IFRS requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity and expenses, as well as the related disclosures of contingent assets and liabilities, in the process of applying the Company's accounting policies. These inputs also consider, among other things, the implications of pandemics and wars across the globe (including the Israel-Hamas war) on the Company's activities, and the resulting effects on critical and significant accounting estimates, most significantly in relation to the value of intangible assets, license revenue recognition, fair value of warrants, and measurement of allowance for accruals of chargebacks, rebates and returns. In this regard, U.S. and global markets are currently experiencing volatility and disruption following the escalation of geopolitical tensions. As of the date of release of these financial statements, the Company estimates there are no material effects of those geopolitical tensions on its financial position and results of operations.

NOTE 3 – MATERIAL ACCOUNTING POLICIES

a. General

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, 2023 and for the year then ended, except for the reclassification of warrant liabilities to from non-current liabilities to current liabilities, as described in Note 3b.

NOTE 3 – MATERIAL ACCOUNTING POLICIES (cont.)

b. New international financial reporting standards, amendments to standards and new interpretations

Classification of Liabilities as Current or Non-Current (Amendment to IAS 1)

The narrow-scope amendments to IAS 1, "Presentation of Financial Statements," clarify that liabilities are classified as either current or noncurrent, depending on the rights that exist at the end of the reporting period. Classification is unaffected by the entity's expectations or events after the reporting date (e.g., the receipt of a waiver or a breach of covenant). The amendments also clarify what IAS 1 means when it refers to the 'settlement' of a liability. The amendments may affect the classification of liabilities, particularly for entities that previously considered management's intentions to determine classification and for some liabilities that can be converted into equity.

The Company adopted these amendments effective January 1, 2024. The impact on the Company's financial statements of these amendments was the reclassification of the Company's warrant liabilities from non-current to current as of its effective date. The Company has retrospectively applied the amendments in these interim financial statements and, accordingly, has retrospectively adjusted the comparative balance sheet for December 31, 2023 to reclassify its warrant liabilities ($11,932 as of December 31, 2023) from non-current to current. Adoption of the amendments had no other impact on the Company's financial statements.

IFRS 18, Presentation and Disclosure in the Financial Statements

This standard replaces the international accounting standard IAS 1, "Presentation of Financial Statements." As part of the new disclosure requirements, companies will be required to present new defined subtotals in the statements of income, as follows: (1) operating profit and (2) profit before financing and tax. In addition, income statement items will be classified into three defined categories: operating, investment and financing. The standard also includes a requirement to provide a separate disclosure in the financial statements regarding the use of management-defined performance measures ("non-GAAP measures"), and specific instructions were added for the grouping and splitting of items in the financial statements and in the notes to the financial statements. IFRS 18 is effective for annual reporting periods beginning on or after January 1, 2027, with an option for early adoption.

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

The Company maintains an ATM facility with H.C. Wainwright & Co., LLC ("HCW") pursuant to an ATM sales agreement entered into in September 2021. In accordance with the agreement, the Company is entitled, at its sole discretion, to offer and sell through HCW, acting as a sales agent, ADSs having an aggregate offering price of up to $25.0 million throughout the period during which the ATM facility remains in effect. The Company has agreed to pay HCW a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. During the six months ended June 30, 2024, no ADSs were issued by the Company. From the effective date of the agreement through the issuance date of this report, 2,109,858 ADSs have been sold under the program for total gross proceeds of approximately $4.4 million and total fees of approximately $0.1 million.

NOTE 5 – LONG-TERM LOAN

In September 2022, the Company entered into a $40 million loan agreement with BlackRock EMEA Venture and Growth Lending (previously Kreos Capital) ("BlackRock"). Pursuant to the agreement, the first tranche of $10 million was drawn down by the Company upon closing, with the remaining $30 million to 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. In April 2024, the Company completed a drawdown of the $20 million second tranche of the loan agreement.

Each tranche of the loan 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 bear interest at a fixed annual rate of 9.5% (~11.0%, including associated cash fees). As security for the loan, BlackRock 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, BlackRock is entitled to mid-to-high single-digit royalties on motixafortide sales in the U.S., up to a pre-defined cap.

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

NOTE 6 – CONTINGENT LIABILITIES

On January 5, 2023, a putative securities class action complaint was filed in the U.S. against the Company and its Chief Executive Officer. The complaint claims that the Company made false and materially misleading statements and failed to disclose material adverse facts pertaining to its financial position with regard to the development of motixafortide and that the Company would require a loan and a securities offering to commercialize motixafortide. The complaint asserted a putative class period of February 23, 2021 to September 19, 2022, inclusive, and seeked certification as a class action and an unspecified amount of damages. On July 5, 2023, an amended complaint was filed, alleging the same claims and adding the Company's Chief Financial Officer. On September 5, 2023, the Company, its Chief Executive Officer and its Chief Financial Officer filed a motion to dismiss the amended complaint in its entirety and, on July 15, 2024, the court granted the order to dismiss without prejudice. The Company also received, on February 5, 2023, a substantially similar lawsuit and motion to approve the lawsuit as a class action in the Tel Aviv District Court. The total amount claimed in Tel Aviv, if the lawsuit is certified as a class action, is approximately NIS 113.5 million (approximately $32 million). The outcome of the legal proceeding in the Tel Aviv District Court is uncertain at this point, although the Company anticipates it will likely be dismissed following dismissal of the U.S. claim. Notwithstanding, the Company believes that it is without merit and intends to vigorously defend itself against such action.

On June 16, 2024, Biokine Therapeutics Ltd. ("Biokine"), filed a complaint with the District Court of Jerusalem against the Company. The complaint alleges breach of contract and a purported failure to make certain payments to Biokine under the Company's in-licensing agreement with Biokine for motixafortide. The lawsuit seeks compensatory damages in the amount of approximately $6.5 million and a declaratory judgment in favor of Biokine. The Company believes the claim is without merit and intends to vigorously defend itself against such action.

NOTE 7 – EQUITY FINANCINGS

a. 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. The Company also 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 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. 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 $2,599,000 as of June 30, 2024 (December 31, 2023 - $11,905,000), and was based on the then current price of an ADS, a risk-free interest rate of 4.50%, an average standard deviation of 82.5%, and on the remaining contractual life of the warrants.

The changes in fair value for the six months ended June 30, 2024 of $9,306,000 have been recorded as non-operating income in the statement of comprehensive loss. As of June 30, 2024, 2,545,455 of these warrants had been exercised.

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

NOTE 7 – EQUITY FINANCINGS (cont.)

b. April 2024 offering

In April 2024, the Company completed a registered direct offering of 7,500,000 ADSs at a price of $0.80 per ADS. The Company also issued to investors in the offering unregistered warrants to purchase 7,500,000 ADSs. The warrants are exercisable immediately, expire five years from the date of issuance and have an exercise price of $0.80 per ADS. Gross proceeds from the offering totaled $6.0 million, with net proceeds of $5.4 million, after deducting fees and expenses.

The warrants have been classified as a 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 income (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 4.21%, and an average standard deviation of 84.7%. The fair value initially allocated to the investor warrants amounted to $6,250,000, with total issuance costs initially allocated to the warrants amounting to $642,000.

Due to a difference between the fair value at initial recognition and the transaction price ("day 1 loss"), upon initial recognition, the fair value of the warrants was adjusted by the amount of $250,000, to reflect the unrecognized day 1 loss. Following initial recognition, the unrecognized day 1 loss of the warrants is being amortized over its contractual life.

The fair value of the warrants amounted to $2,723,000 as of June 30, 2024, and was based on the then current price of an ADS, a risk-free interest rate of 4.30%, an average standard deviation of 87.6%, and on the remaining contractual life of the warrants. The changes in fair value through June 30, 2024, amounting to $3,526,000, have been recorded as a non-operating expense in the statement of comprehensive loss.

As of June 30, 2024, none of these warrants had been exercised.

NOTE 8 – SHAREHOLDERS' EQUITY

As of December 31, 2023 and June 30, 2024, share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2023	June 30, 2024
Authorized share capital	2,500,000,000	2,500,000,000
Issued and paid-up share capital	1,086,589,165	1,199,089,165

	In USD and NIS	
	December 31, 2023	June 30, 2024
Authorized share capital (in NIS)	250,000,000	250,000,000
Issued and paid-up share capital (in NIS)	108,658,916	119,908,916
Issued and paid-up share capital (in USD)	31,355,056	34,411,291

NOTE 9 – LICENSE AND SECURITIES PURCHASE AGREEMENTS

In October 2023, the Company closed on 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.

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, in October 2023, the Company closed on a securities purchase agreement (the "Purchase Agreement") with HST and Gloria, pursuant to which the Company sold in a private placement an aggregate of 6,829,137 ADSs of the Company, at a purchase price of $2.136 per ADS. Aggregate gross proceeds from the sale amounted to $14.6 million, with related issuance costs amounting to approximately $0.9 million. No warrants were issued in the transaction.

In accordance with IFRS 15, both agreements have been treated as a single unit of account, with the consideration combined and subsequently allocated between the Purchase Agreement and the License Agreement. Of the total consideration amounting to $29.6 million, $12.0 million were allocated to the Purchase Agreement, and $17.6 million were allocated to the License Agreement. Costs in the amount of $0.7 million directly attributable to the Purchase Agreement were recognized as a reduction in equity.

The Company has identified the following performance obligations in the contract, each to be recognized separately: (1) SCM license; (2) SCM support services; and (3) PDAC license and related support services.

With regard to PDAC, the Company determined that the license, together with the associated support services, should be combined into a single performance obligation, since the Licensee cannot benefit from the license without the associated support services. The support services are highly specialized for the licensed product in this indication. Licensing rights for other indications and related support were deemed immaterial.

The fixed transaction price has been allocated among the performance obligations based on similar price offers received by the Company, with the assistance of a valuation specialist. The variable consideration related to the performance obligations was not taken into account in the fixed transaction price due to uncertainty.

NOTE 9 – LICENSE AND SECURITIES PURCHASE AGREEMENTS (cont.)

Revenue has been/will be recognized in the Company's financial statements as follows:

a. Revenue for the SCM license was recognized in the fourth quarter of 2023, upon transfer of control over the license to the licensee, in the amount of approximately $2.0 million.

b. Revenue from providing the SCM support services is recognized using the input method, which is based on costs incurred and labor hours expended, expected to result in straight-line revenue recognition over six months, totaling approximately $0.1 million.

c. Revenue from the PDAC performance obligation is recognized over time, with the percentage of completion determined based on support hours incurred, and expected to be recognized through the end of 2024, in the total amount of $15.5 million.

Based on the above methodology, as well as the achievement of a specific regulatory milestone, the Company recognized revenues from the license agreement of approximately $3.6 million and $9.5 million in the three and six months ended June 30, 2024, respectively.

NOTE 10 – REVENUES AND COST OF REVENUES

a. Revenues

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	in USD thousands		in USD thousands	
License revenues (see Note 9)	-	3,550	-	9,481
Product sales, net	-	1,843	-	2,767
	-	5,393	-	12,248

b. Cost of revenues

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	in USD thousands		in USD thousands	
Amortization of intangible asset	-	482	-	1,128
Direct costs related to license revenues	-	155	-	388
License fees and royalties payable to licensor	-	175		683
Cost of product sales	-	85	-	153
	-	897	-	2,352

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/A filed on March 26, 2024 (the "Annual Report").

Forward Looking Statements

The following discussion contains "forward-looking statements," including statements regarding expectations, beliefs, intentions or strategies for the future. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, the potential benefits of APHEXDA®, the ongoing commercialization of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of APHEXDA, as well as its potential investigational uses. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions, and are subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those listed below as well as those discussed in the Annual Report (particularly those in "Item 3. Key Information – Risk Factors"). Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- the 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;
- 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;
- 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 commercialization of APHEXDA;
- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- competitive companies, technologies and our industry; and
- statements as to the impact of the political and security situation in Israel on our business, including the impact of Israel's war with Hamas and other militant groups, which may exacerbate the magnitude of the factors discussed above.

Overview

General

We are a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. Our primary commercialization pipeline consists of APHEXDA (motixafortide), a novel peptide for the treatment of stem-cell mobilization and solid tumors which, on September 8, 2023, was approved by the 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. We are also advancing the development of motixafortide for patients with sickle cell disease, or SCD, pancreatic cancer and other solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions.

We seek to develop and commercialize a pipeline of promising therapeutic candidates that exhibit distinct advantages over currently available therapies or address unmet medical needs. Our resources are focused on advancing our therapeutic candidates through development and toward commercialization. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. Our strategy includes commercializing our therapeutic candidates 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 in the U.S. for APHEXDA in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

We use "APHEXDA" when referring to our FDA approved drug, and "motixafortide" when referring to our development of APHEXDA for additional indications.

FDA Approval and U.S. Launch of APHEXDA

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 commenced commercialization of 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.

The FDA approval of APHEXDA is based on results from the 2-part, Phase 3 GENESIS trial, a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of APHEXDA plus G-CSF compared to placebo plus G-CSF, for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients. Top-line results announced in May 2021 showed highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in combination with G-CSF ($p<0.0001$). In addition, the combination was found to be safe and well tolerated.

During 2023, we completed the build-out of the infrastructure for commercial operations in the U.S. designed to support the commercialization of APHEXDA. In addition, we completed the onboarding of customer-facing personnel on our sales, medical affairs, and national account teams, which have engaged with transplant centers, physicians and payers. Patient-focused support has also been critical to our launch efforts with the creation of BioLineRx Connect, our internal patient support program, as well as the establishment of relationships with patient advocacy groups.

Our focus has been on the top 80 centers that perform 85% of the autologous stem cell transplantations, or ASCTs, in multiple myeloma in order to build the foundations for commercial expansion. Among this defined population, we have been granted formulary status for APHEXDA at hospitals representing approximately 37% of the total annual U.S. multiple myeloma transplant procedures at these centers as of June 30, 2024, and expect this number to grow as additional formulary reviews are scheduled. In addition, we have received inclusion of APHEXDA in the National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation Importantly, we have achieved positive coverage decisions by payers representing over 95% of all covered lives in the U.S. and received a Healthcare Common Procedure Coding System (HCPCS) J-Code to facilitate Medicare reimbursement for APHEXDA to transplant centers treating Medicare beneficiaries.

Out-Licensing of Motixafortide in Asia

In October 2023, we closed on 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.

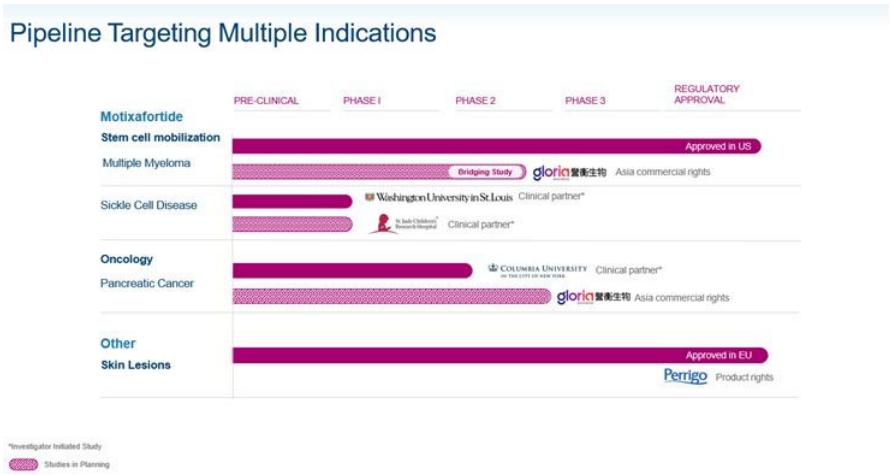
Pursuant to the terms of the License Agreement, the Licensee made a $15 million upfront payment upon the closing of the transaction. We are entitled to up to $49 million based on the achievement of certain development and regulatory milestones in China and Japan, and up to $197 million in sales milestones based on defined sales targets of motixafortide in the Territory. Additionally, we are eligible to receive tiered, double-digit royalties (ranging from 10-20%), on aggregate net sales of motixafortide in the Territory payable on a country-by-country basis 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 us are to be reduced by 50% following the end of the initial royalty term and are also to be reduced upon the occurrence of certain events, including, on a country-by-country basis, the entry of a generic product in such country.

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 2b study in first-line pancreatic adenocarcinoma.

In addition, in October 2023, we closed on a securities purchase agreement with HST and Gloria pursuant to which we issued in a private placement an aggregate of 6,829,137 of our American Depositary Shares, or ADSs, at a price of $2.136 per ADS. Aggregate gross proceeds from the sale were approximately $14.6 million. No warrants were issued in the transaction.

Our Product Pipeline

The table below summarizes key information about our products and our clinical programs:



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. CXCR4 is expressed by normal hematopoietic cells and overexpressed in various human cancers where its expression correlates with disease severity. CXCR4 is a chemokine receptor that mediates the homing and retention of hematopoietic stem cells, or HSCs, in the bone marrow, and also mediates tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of tumor to other organs) and survival. Before "motixafortide" was approved by the World Health Organization, or WHO, in 2019 as an International Nonproprietary Name, this therapeutic candidate was known as "BL-8040." In October 2021, we received WHO approval of the United States Adopted Name, or USAN, "motixafortide." The FDA-approved trade or brand name of motixafortide is APHEXDA.

Inhibition of CXCR4 by motixafortide leads to the mobilization of HSCs from the bone marrow to the peripheral blood, enabling their collection for subsequent autologous or allogeneic transplantation in cancer patients. Clinical data has demonstrated the ability of motixafortide to mobilize higher numbers of long-term engrafting HSCs (CD34+CD38-CD45RA-CD90+CD49f+) as compared to G-CSF.

Motixafortide also mobilizes cancer cells from the bone marrow, detaching them from their survival signals and sensitizing them to chemotherapy. In addition, motixafortide has demonstrated a direct anti-cancer effect by inducing apoptosis (cell death) and inhibiting proliferation in various cancer cell models (multiple myeloma, non-Hodgkin's lymphoma, leukemia, non-small-cell lung carcinoma, neuroblastoma and melanoma).

In the field of immuno-oncology, motixafortide mediates infiltration of T-cells while reducing immune regulatory cells in the tumor microenvironment, or TME. In clinical studies, the combination of motixafortide with immune checkpoint inhibitors, such as anti PD-1, has shown T-cell activation and a reduction in tumor cell numbers.

The following is a summary of our motixafortide principal development activities.

Stem cell mobilization

Multiple Myeloma

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.

In November 2023, we initiated pivotal bridging study preparation activities with Gloria, our Asia partner, to support potential approval and commercialization of motixafortide in stem-cell mobilization in China. In February 2024, an IND was filed with the Center for Drug Evaluation of the National Medical Products Administration in China, which was approved in May 2024. The trial in China is expected to commence in the second half of 2024 and data is expected in 2025.

Sickle Cell Disease

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 is being evaluated as a monotherapy and in combination with natalizumab (VLA-4 inhibitor), as novel regimens to mobilize CD34+ hematopoietic stem cells (HSC) for gene therapies SCD. The proof-of-concept investigator-initiated study planned to enroll five adults with a diagnosis of SCD who are receiving automated red blood cell exchanges via apheresis. In June 2024, the study was amended to increase enrollment from five to 10 adults. 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, with first patient dosed in December 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). Initial data from this study is expected in the second half of 2024.

In May 2024, we entered into a clinical collaboration with St. Jude Children's Research Hospital, Inc. to conduct a multi-center Phase 1 clinical trial to evaluate motixafortide for the mobilization of CD34+ hematopoietic stem cells (HSCs) used in the development of gene therapies for patients with SCD. The Phase 1 clinical trial is an open-label, multi-center study evaluating the safety, tolerability, and feasibility of single-agent motixafortide (CXCR4 inhibitor) for the mobilization and collection of CD34+ HSCs in 12 patients (aged 18 and older) with SCD. The trial's primary objective is to assess the safety and tolerability of motixafortide in SCD patients, as determined by the incidence of adverse events. Secondary objectives include understanding CD34+ kinetics after motixafortide administration in patients with SCD and determining the number of CD34+ HSCs collected via leukapheresis. The study is designed in two parts: Part A (N=6) will evaluate single dose motixafortide mobilization followed by one apheresis session; Part B (N=6) will evaluate daily motixafortide administration over a two-day mobilization and apheresis regimen. Additional objectives include phenotype and cell function characterization, as well as assessment of the gene modifying potential and senescence of CD34+ cells. First patient dosing is expected in September 2024 with data anticipated in 2025 (timelines, as well as other study related decisions, are ultimately controlled by the independent investigator-sponsor and are, therefore, subject to change).

Pancreatic Cancer

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 mechanism of action and safety of motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic PDAC. The study was an open-label, multicenter, single-arm trial designed to evaluate the mechanism of action, safety and tolerability, and clinical response of the combination of these therapies. The mechanistic evaluation consisted of 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 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 (CheMo4METPANC), led by Columbia University and supported equally by BioLineRx and Regeneron, initially enrolled 11 PDAC patients in a pilot phase. In September 2023, we reported data from the pilot phase of the study. As of July 2023, of those 11 patients, seven patients (64%) experienced a partial response (PR), of which six (55%) are now 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. Additionally, analysis of paired pre- and on-treatment biopsy samples demonstrated an increase in CD8+ T-cell density in tumors from all 11 patients treated (P = 0.007).

Based on the preliminary data from this pilot phase, the planned single-arm study was amended to a significantly larger, randomized multi-center study, with a new planned total of 108 patients. The amended Phase 2b study is evaluating the combination of motixafortide, PD-1 inhibitor cemiplimab, and standard of care chemotherapies gemcitabine and nab-paclitaxel, versus gemcitabine and nab-paclitaxel alone. The trial's primary endpoint is progression free survival and a pre-specified interim futility analysis will be conducted when 40% of progression free survival events are observed. Secondary objectives include safety, response rate, disease control rate, duration of clinical benefit and overall survival. In February 2024, the first patient was dosed, with full enrollment projected for 2027.

We are also advancing plans in collaboration with Gloria, our Asia partner, for a Phase 2b randomized study assessing motixafortide in combination with the PD-1 inhibitor zimberelimab and standard-of-care chemotherapy as first-line treatment in patients with metastatic pancreatic cancer. IND submission and protocol finalization is expected later in 2024 and study initiation in 2025.

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 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 was an investigator-initiated study, led by Wolfson Medical Center, in Israel, to evaluate motixafortide in patients hospitalized with ARDS. This study was terminated in June 2024, after reviewing the strategic and commercial viability of the project.

Other Studies

In addition to the above, from time to time a number of Company-sponsored and investigator-initiated studies may be conducted 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.

Orphan Drug Designations

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). Orphan Drug Designation is granted to therapeutics intended to treat rare diseases or conditions that affect not more than 200,000 people in the United States (or diseases or conditions that affect more than 200,000 people but where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States). If an Orphan Drug-Designated product subsequently receives FDA approval for the disease or condition for which it was designated, the product is entitled to a seven-year marketing exclusivity period, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances (such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues), for seven years. In addition, Orphan Drug Designation enables sponsors to apply for certain federal grants and tax credits for clinical trials and provides an exemption from the Prescription Drug User Fee so long, as the sponsor’s annual revenue is below $50,000,000.

In January 2020, the EMA granted an Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer. In addition, in December 2023, the EMA granted Orphan Drug Designation to motixafortide for treatment of patients undergoing hematopoietic stem cell transplantation. The EMA grants orphan medicinal product designation to investigational drugs intended to treat, prevent or diagnose a life-threatening or chronically debilitating disease affecting fewer than five in 10,000 people in the EU and for which no satisfactory treatment is available or, if such treatment exists, the medicine must be of significant benefit to those affected by the condition. Orphan medicinal product designation provides regulatory and financial incentives for companies to develop and market therapies, including ten years of market exclusivity, protocol assistance, fee reductions and EU-funded research.

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. It offers an alternative to painful, invasive and expensive removal treatments including cryotherapy, laser treatment and surgery. Since the treatment is non-invasive, it poses minimal infection risk and eliminates the need for anesthesia, antiseptic precautions and bandaging. The pre-filled device controls and standardizes the volume of solution applied to a lesion, ensuring accurate administration directly on the lesion and preventing both accidental exposure of the healthy surrounding tissue and unintentional dripping. It has an ergonomic design, making it easy to handle, and has been designed with a childproof cap. BL-5010 is applied topically on a skin lesion in a treatment lasting a few minutes with the pen-like applicator and causes the lesion to gradually dry out and fall off within one to four weeks.

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.

Israel-Hamas war

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. In addition, since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with the Hezbollah terror organization) and southern border (with the Houthi movement in Yemen). It is possible that hostilities with Hezbollah in Lebanon will escalate, and that other terrorist organizations, including Palestinian military organizations in the West Bank as well as other hostile countries will join the hostilities. In addition, Iran recently launched a direct attack on Israel involving hundreds of drones and missiles and has threatened to continue to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. Such clashes may escalate in the future into a greater regional conflict. We cannot currently predict the intensity or duration of Israel's war against Hamas, nor can we predict how this war will ultimately affect our business and operations or Israel's economy in general.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), payments received under our strategic licensing and collaboration arrangements, funding received from the Israel Innovation Authority, or IIA, 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 APHEXDA, 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 any other out-licensing transaction, interest earned on our investments, and additional capital to be raised through public or private equity offerings or debt financings. As of June 30, 2024, we had $40.1 million of cash, cash equivalents and short-term bank deposits.

Revenues

Our revenues to date have been generated primarily from milestone payments under out-licensing agreements and more recently, revenues from product sales of APHEXDA.

We expect our revenues, if any, for the next several years to be derived primarily from the independent commercialization of APHEXDA in stem cell mobilization in the U.S. and milestone payments from the license agreement with HST and Gloria, including future royalties on product sales from such out-licensing agreements.

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 and more recently, costs associated with the manufacture of APHEXDA and royalty payments to the licensor with respect to direct product sales of APHEXDA. Prior to receiving FDA approval for APHEXDA in September 2023, we expensed such manufacturing and material costs as research and development expenses.

We expect our cost of revenues, if any, for the next several years to be derived primarily from the costs associated with the manufacture of APHEXDA, 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 therapeutic 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 motixafortide.

There is no extra space

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.	Commercialization ongoing
	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 6 (55%) 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 Phase 2b trial of 108 patients	2.	First patient dosed in February 2024 and currently enrolling*
	3.	Phase 1 study for gene therapies in SCD (with Washington University School of Medicine in St. Louis)	3.	First patient dosed in December 2023 and initial data from the study is expected in the second half of 2024*
	4.	Phase 1 study for gene therapies in SCD (with St. Jude Children's Research Hospital, Inc.)	4.	First patient dosing is expected in September 2024, with data anticipated in 2025*
	5.	IND approved in China for initiation of pivotal bridging study in SCM under license agreement with Gloria	5.	Initiation of the study is expected in second half of 2024 and data is expected in 2025
	6.	Phase 2b randomized study in first-line PDAC in China under license agreement with Gloria	6.	IND submission and protocol finalization expected in 2024 and study initiation in 2025

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

We expect that a large percentage of our research and development 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 motixafortide 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 motixafortide and any other therapeutic candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each such 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 the U.S. commercialization of motixafortide, and a life-cycle expansion and management program for other therapeutic indications for motixafortide, our future research and development expenses will depend on the clinical success of motixafortide in these other indications, and of each potential 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 therapeutic candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees in 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 remain 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, 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, September 2022 and April 2024. 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 BlackRock; 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, 2023. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

Our consolidated financial statements are prepared in conformity with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. In preparing our consolidated financial statements, we make judgements, estimates and assumptions about the application of our accounting policies which affect the reported amounts of assets, liabilities, revenue and expenses. Our critical accounting judgements and sources of estimation uncertainty are described in Note 4 to the consolidated financial statements included in our Annual Report.

Results of Operations

Comparison of the three-month and six-month periods ended June 30, 2024 to the three-month and six-month periods ended June 30, 2023

Revenues

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
License revenues	-	3,550	3,550	-	9,481	9,481
Product sales, net	-	1,843	1,843	-	2,767	2,767
Total revenues	-	5,393	5,393	-	12,248	12,248

Comparison of three-month periods ended June 30, 2024 and 2023

Revenues for the three-month period ended June 30, 2024 were $5.4 million. We did not record any revenues during the three-month period ended June 30, 2023. The revenues in 2024 primarily reflect a portion of the up-front payment received by us under the License Agreement which amounted to $3.6 million, as well as $1.8 million of net revenues from product sales of APHEXDA in the U.S.

Comparison of six-month periods ended June 30, 2024 and 2023

Revenues for the six-month period ended June 30, 2024 were $12.2 million. We did not record any revenues during the six-month period ended June 30, 2023. The revenues in 2024 primarily reflect a portion of the up-front payment received by us under the License Agreement and a milestone payment achieved under the License Agreement, which collectively amounted to $9.5 million, as well as $2.8 million of net revenues from product sales of APHEXDA in the U.S.

Cost of revenues

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
Amortization of intangible asset	-	482	482	-	1,128	1,128
Direct costs related to license revenues	-	155	155	-	388	388
License fees and royalties payable to licensor	-	175	175	-	683	683
Cost of product sales	-	85	85	-	153	153
Total cost of revenues	-	897	897	-	2,352	2,352

Comparison of three-month periods ended June 30, 2024 and 2023

Cost of revenues for the three-month period ended June 30, 2024 was $0.9 million. We did not record any cost of revenues during the three-month period ended June 30, 2023. The cost of revenues in 2024 primarily reflects the amortization of intangible assets, royalties on net product sales of APHEXDA in the U.S. and cost of goods sold on product sales.

Compari 1 space *4 and 2023*

Cost of revenues for the six-month period ended June 30, 2024 was $2.4 million. We did not record any cost of revenues during the six-month period ended June 30, 2023. The cost of revenues in 2024 primarily reflects the amortization of intangible assets, sub-license fees on a milestone payment received under the License Agreement, royalties on net product sales of APHEXDA in the U.S. and cost of goods sold on product sales.

Research and development expenses

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses	3,006	2,225	(781)	6,690	4,719	(1,971)

Comparison of three-month periods ended June 30, 2024 and 2023

Research and development expenses for the three months ended June 30, 2024 were $2.2 million, a decrease of $0.8 million, or 26.0%, compared to $3.0 million for the three months ended June 30, 2023. The decrease resulted primarily from lower expenses related to New Drug Application-supporting activities related to motixafortide, the termination of the development of AGI-134 and a decrease in share-based compensation.

Comparison of six-month periods ended June 30, 2024 and 2023

Research and development expenses for the six months ended June 30, 2024 were $4.7 million, a decrease of $2.0 million, or 29.5%, compared to $6.7 million for the six months ended June 30, 2023. The reason for the decrease is similar to the aforementioned decrease in the three-month period.

Sales and marketing expenses

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	5,604	6,415	811	9,478	12,757	3,279

Comparison of three-month periods ended June 30, 2024 and 2023

Sales and marketing expenses for the three months ended June 30, 2024 were $6.4 million, an increase of $0.8 million, or 14.5%, compared to $5.6 million for the three months ended June 30, 2023. The increase resulted primarily from the ramp-up in headcount costs associated with fully hired field teams.

Comparison of six-month periods ended June 30, 2024 and 2023

Sales and marketing expenses for the six months ended June 30, 2024 were $12.8 million, an increase of $3.3 million, or 34.6%, compared to $9.5 million for the six months ended June 30, 2023. The reason for the increase is similar to the aforementioned increase in the three-month period.

General and administrative expenses

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	1,305	1,629	324	2,603	3,015	412

Comparison of three-month periods ended June 30, 2024 and 2023

General and administrative expenses for the three months ended June 30, 2024 were $1.6 million, an increase of $0.3 million, or 24.8%, compared to $1.3 million for the three months ended June 30, 2023. The increase resulted primarily from an increase in legal and certain other expenses during the corresponding 2023 period.

Comparison of six-month periods ended June 30, 2024 and 2023

General and administrative expenses for the six months ended June 30, 2024 were $3.0 million, an increase of $0.4 million, or 15.8%, compared to $2.6 million for the six months ended June 30, 2023. The reason for the increase is similar to the aforementioned increase in the three-month period.

Non-operating income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	(7,733)	7,807	15,540	(10,649)	12,297	22,946

Comparison of three-month and six-months periods ended June 30, 2024 and 2023

Non-operating income for the three and six months ended June 30, 2024 primarily relates to fair-value adjustments of warrant liabilities on our balance sheet, as a result of changes in our share price, offset by warrant offering expenses. Non-operating expenses for the three and six months ended June 30, 2023 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet.

Financial income (expenses), net

	Three months ended June 30,			Six months ended June 30,		
	2023	2024	Increase (decrease)	2023	2024	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	440	535	95	977	1,100	123
Financial expenses	(1,337)	(2,085)	(748)	(2,264)	(3,014)	(750)
Net financial income (expenses)	(897)	(1,550)	(653)	(1,287)	(1,914)	(627)

Comparison of three-month periods ended June 30, 2024 and 2023

Net financial expenses for the three months ended June 30, 2024 were $1.6 million, compared to net financial expenses of $0.9 million for the three months ended June 30, 2023. Net financial expenses for both periods primarily relate to interest paid on loans, which increased in 2024 due to the drawdown of the second tranche of the BlackRock loan in April 2024, partially offset by investment income earned on our bank deposits.

Comparison of six-month periods ended June 30, 2024 and 2023

Net financial expenses for the six months ended June 30, 2024 were $1.9 million, compared to net financial expenses of $1.3 million for the six months ended June 30, 2023. 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, proceeds from debt financings, interest earned on investments and funding from the IIA. As of June 30, 2024, we held $40.1 million of cash, cash equivalents and short-term bank deposits. We have invested substantially all our available cash funds in short-term bank deposits.

In April 2024, we completed the issuance and sale in a registered direct offering of 7,500,000 of our ADSs and warrants to purchase up to an aggregate of 7,500,000 ADSs, or the April 2024 Warrants, to certain institutional investors at a combined purchase price of $0.80 per ADS and accompanying April 2024 Warrant, for aggregate net proceeds of approximately $5.4 million, after deducting the fees of the placement agent and offering expenses payable by us, and excluding any proceeds that may be received upon exercise of the April 2024 Warrants.

In September 2022, we entered into a loan agreement, or the Loan Agreement, with BlackRock, with an aggregate principal amount of up to $40 million comprised of three tranches of up to $10 million, $20 million and $10 million. We drew down the initial tranche of $10 million following execution of the Loan Agreement in September 2022 and we drew down the second tranche of $20 million in April 2024, following fulfilment of the requisite milestones. The third tranche will be available for drawdown upon achievement of certain milestones and until October 1, 2024.

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 2,109,858 of our ADSs for total gross proceeds of approximately $4.4 million under the ATM program.

Net cash used in operating activities was $25.4 million for the six months ended June 30, 2024, compared to net cash used in operating activities of $17.7 million for the six months ended June 30, 2023. The increase was primarily the result of an increase in sales and marketing expenses (primarily for commercialization) and repayment of outstanding payables from December 2023.

Net cash provided by investing activities was $8.0 million for the six months ended June 30, 2024, compared to net cash provided by investing activities of $17.7 million for the six months ended June 30, 2023. 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 $23.0 million for the six months ended June 30, 2024, compared to net cash provided by financing activities of $0.2 million for the six months ended June 30, 2023. The cash flows in 2024 primarily reflect the net proceeds of a loan from BlackRock and the net proceeds of a registered direct offering of our ADSs in April 2024, offset by repayments of the loan from BlackRock and the repayments of lease liabilities. The cash flows provided by financing activities in 2023 primarily reflect the repayments of lease liabilities.

We have incurred accumulated losses in the amount of $391 million through June 30, 2024, 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 seeks to maintain 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, which management has concluded indicate that a material uncertainty exists, may cast significant doubt on our ability to continue as a going concern. Similarly, our independent registered public accounting firm included a “going concern” explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2023.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Based on our current projected cash requirements, we believe that our existing cash and investment balances and other sources of liquidity, including net product revenues from product sales of APHEXDA and milestone payments from the License Agreement, will be sufficient to meet our capital requirements into 2025. We expect to also continue to seek to finance our operations through other sources, including commercialization in the United States for APHEXDA, 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 therapeutic candidates;
- the magnitude of our general and administrative expenses;
- interest and principal payments on the loan from BlackRock;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates;
- market conditions;
- payments to the IIA; and
- the impact of any resurgence of the COVID-19 pandemic and the 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.

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

Share and per-share information in ADSs and ordinary shares are presented in the tables below. Each ADS represents 15 ordinary shares.

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	(in U.S. dollars)			
Earnings (loss) per ADS – basic and diluted	(0.30)	0.00	(0.50)	(0.00)
Earnings (loss) per ordinary share – basic and diluted	(0.02)	0.00	(0.03)	(0.00)

	December 31, 2023	June 30, 2024
	(in number of ADSs)	
Authorized share capital	166,666,667	166,666,667
Issued and paid-up capital	72,439,278	79,939,278

Legal Proceedings

Securities Class Action Complaints

On January 5, 2023, a putative securities class action complaint captioned Winston Peete v. BioLineRx Ltd. and Philip A. Serlin (Case no: Case 2:23-cv-00041 was filed in the U.S. District Court for the District of New Jersey by purported shareholder Winston Peete, naming us and our chief executive officer, Mr. Serlin, as defendants. The complaint asserted violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, claiming that the defendants made false and materially misleading statements and failed to disclose material adverse facts pertaining to our financial position with regard to the development of motixafortide and that we would require a loan and a securities offering to commercialize motixafortide. The complaint asserted a putative class period of February 23, 2021 to September 19, 2022, inclusive, and sought certification as a class action and an unspecified amount of damages. On July 5, 2023, plaintiffs filed an amended complaint alleging the same claims and adding the Company's Chief Financial Officer, Mali Zeevi, as a defendant. On September 5, 2023, defendants filed a motion to dismiss the amended complaint in its entirety, and on July 15, 2024, the court granted the order to dismiss without prejudice. We are not aware of an amended claim being filed by the plaintiffs by the deadline, which passed on August 14, 2024. In addition, on February 5, 2023, we received a lawsuit and motion to approve the lawsuit as a class action lawsuit pursuant to the Class Action Lawsuits Law 5766-2006, which was filed against us and Mr. Serlin in the Tel Aviv District Court (Economic Division). The motion asserts substantially similar allegations as the U.S. action described above. The motion asserts to define the class as all shareholders who held the company's securities traded on the TASE, on September 19, 2022 and the class period relates to the company's statements between February 23, 2021, and September 19, 2022. The total amount claimed, if the lawsuit is certified as a class action, as set forth in the motion is approximately NIS 113.5 million (approximately $32 million). The outcome of the legal proceeding in the Tel Aviv District Court (Economic Division) is uncertain at this point, although we anticipate it will likely be dismissed following the dismissal of the U.S. claim. Notwithstanding, we believe that it is without merit and intend to vigorously defend ourselves against such action.

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Biokine Claim

On June 16, 2024, Biokine Therapeutics Ltd. ("Biokine"), filed a complaint with the District Court of Jerusalem against us. The complaint alleges br[illegible]ake certain payments to Biokine under our in-licensing agreement with Biokine for motixafortide. The lawsuit seeks compensatory damages in the amount of approximately $6.5 million and a declaratory judgment in favor of Biokine. We believe the claim is without merit and intend to vigorously defend ourselves against such action.