SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of November 2022

Commission file number: 001-35223

_____

BioLineRx Ltd.

(Translation of registrant's name into English)

_____

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

_____

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

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):_____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):_____

On November 15, 2022, the Registrant issued a press release announcing its financial results for the three and nine months ended September 30, 2022. The Registrant is also publishing its unaudited interim consolidated financial statements, as well as its operating and financial review, as of September 30, 2022 and for the three and nine months then ended. Attached hereto are the following exhibits:

Exhibit 1: Registrant's press release dated November 15, 2022;

Exhibit 2: Registrant's condensed consolidated interim financial statements as of September 30, 2022 and for the three and nine months then ended; and

Exhibit 3: Registrant's operating and financial review as of September 30, 2022 and for the three and nine months then ended.

This Form 6-K, the text under the heading "Financial Results for the Quarter Ended June 30, 2022" in Exhibit 1, and Exhibit 2 and Exhibit 3 are hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

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

BioLineRx Ltd.

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

Dated: November 15, 2022

Exhibit 1

For Immediate Release

BioLineRx Reports Third Quarter 2022 Financial Results and Recent Corporate and Portfolio Updates

***- Announced FDA acceptance of APHEXDA® (motixafortide) New Drug Application (NDA) in stem cell mobilization* with Prescription Drug User Fee Act (PDUFA) target action date of September 9, 2023 -**

- Introduced plan to commercialize APHEXDA® independently in the U.S., if approved, and named Holly May, President, BioLineRx USA -

- Completed $40M debt financing agreement and $15M equity offering to support aggressive commercial U.S. launch of APHEXDA®

- Management to hold conference call today, November 15, at 10:00 am EST -

TEL AVIV, Israel, November 15, 2022 – (PRNewswire) – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today reported third quarter financial results and recent corporate and portfolio updates.

"The Company delivered outstanding performance during the third quarter and subsequent period. Last week's FDA acceptance of our new drug application for APHEXDA® (motixafortide) substantially advances our twin goals of delivering an important new therapy for the mobilization of stem cells in preparation for autologous transplantation in patients with multiple myeloma, and in parallel, transitioning to a commercial stage company," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, we took steps that allow us to rapidly commercialize APHEXDA®, if approved, including securing financing, building out our U.S. operations, and progressing our launch strategy. We believe that APHEXDA® has the potential to become the standard-of-care mobilizing agent for multiple myeloma patients."

"Additionally, working with our collaborators, we advanced motixafortide development programs for pancreatic cancer, reflecting motixafortide's potential broad clinical utility. Finally, we anticipate sharing data from the Phase 1/2a trial of our solid tumor investigational immunotherapy AGI-134 prior to year-end. We believe we are well-positioned to execute across all of our programs and continue to aggressively plan for the potential launch of APHEXDA® next year," Mr. Serlin concluded.

Recent Corporate Updates

- Completed $40 million non-dilutive debt financing agreement with Kreos Capital and $15 million registered direct offering to support commercial launch of APHEXDA® in the U.S.
- Announced APHEXDA® U.S. commercialization plan and named Holly May, President, BioLineRx USA

Portfolio Execution

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Announced FDA acceptance of APHEXDA® NDA in stem cell mobilization for autologous transplantation in multiple myeloma patients. PDUFA target action date set for September 9, 2023
- Announced presentation of cost-effectiveness analysis of motixafortide versus plerixafor in stem cell mobilization for autologous transplantation in patients with multiple myeloma at the American Society of Hematology (ASH) 64th Annual Meeting, which is being held December 10-13, 2022, in New Orleans, Louisiana

Pancreatic Ductal Adenocarcinoma (PDAC)

- Began Phase 2b PDAC randomized clinical trial preparation activities with collaboration partner GenFleet. Anticipate clinical trial initiation in 2023. The collaboration agreement allows BioLineRx to retain global rights to motixafortide in all indications
- Continued collaboration progress in Columbia University investigator-initiated Phase 2 study of motixafortide in combination with an anti-PD-1 and standard-of-care chemotherapy in first-line PDAC patients

Sickle Cell Disease & Gene Therapy

- Announced presentation of clinical trial study design of novel stem cell mobilization regimen with motixafortide to support gene therapy development for sickle cell patients at the ASH Annual Meeting, which is being held December 10-13, 2022, in New Orleans, Louisiana

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Advanced biomarker analysis from the Phase 1/2a trial of AGI-134 in solid tumors and anticipate announcing results from Part 2 of the trial by year-end

Third Quarter 2022 Financial Results

- Research and development expenses for the quarter ended September 30, 2022, were $4.4 million compared to $4.9 million for the same period in 2021; the decrease resulted primarily from lower expenses related to motixafortide NDA supporting activities, as well as lower expenses associated with the completed motixafortide GENESIS clinical trial, offset by an increase in payroll and related expenses
- Sales and marketing expenses for the quarter ended September 30, 2022, were $1.3 million compared to $0.2 million for the same period in 2021; the increase resulted primarily from initiation of pre-commercialization activities related to motixafortide, as well as an increase in market research
- General and administrative expenses for the quarter ended September 30, 2022, were $1.4 million compared to $1.0 million for the same period in 2021; the increase resulted primarily from an increase in share-based compensation and small increases across several G&A expenses
- Net loss for the quarter ended September 30, 2022, was $6.8 million, compared to $5.7 million for the same period in 2021
- As of September 30, 2022, the Company had cash, cash equivalents, and short-term bank deposits of $57.3 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Tuesday, November 15 at 10:00 a.m. EST. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. The call will also be available via webcast and can be accessed through the Investor Relations page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast. A replay of the conference call will be available approximately two hours after completion of the live conference call on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until November 17, 2022; please dial +1-888-295-2634 from the US or +972-3-925-5903 internationally.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation in multiple myeloma patients, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., and has had its NDA submission accepted by the FDA with a PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy. A randomized phase 2b study with 200 patients in combination with PD1 and chemotherapy as a first-line PDAC therapy will initiate in 2023. BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study. For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

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 forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and 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 and the Russian invasion of Ukraine, 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 16, 2022. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2022	2021	2022
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,923)	(4,369)	(14,340)	(14,199)
SALES AND MARKETING EXPENSES	(247)	(1,317)	(731)	(3,112)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,047)	(1,392)	(3,108)	(3,448)
OPERATING LOSS	(6,217)	(7,078)	(18,179)	(20,759)
NON-OPERATING INCOME (EXPENSES), NET	710	389	(4,068)	2,115
FINANCIAL INCOME	52	109	299	256
FINANCIAL EXPENSES	(261)	(267)	(802)	(832)
NET LOSS AND COMPREHENSIVE LOSS	(5,716)	(6,847)	(22,750)	(19,220)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.01)	(0.04)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	708,473,164	740,767,492	646,427,790	723,805,390

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

	December 31, 2021	September 30, 2022
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	12,990	13,105
Short-term bank deposits	44,145	44,157
Prepaid expenses	127	537
Other receivables	142	143
Total current assets	57,404	57,942
NON-CURRENT ASSETS		
Property and equipment, net	952	726
Right-of-use assets, net	1,331	1,289
Intangible assets, net	21,704	21,716
Total non-current assets	23,987	23,731
Total assets	81,391	81,673
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	2,757	802
Accounts payable and accruals:		
Trade	5,567	5,829
Other	1,227	1,351
Current maturities of lease liabilities	168	151
Total current liabilities	9,719	8,133
NON-CURRENT LIABILITIES		
Warrants	1,859	8,156
Long-term loan, net of current maturities	-	8,353
Lease liabilities	1,726	1,507
Total non-current liabilities	3,585	18,016
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	13,304	26,149
EQUITY		
Ordinary shares	21,066	27,098
Share premium	339,346	338,841
Warrants	975	1,408
Capital reserve	13,157	13,854
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(305,041)	(324,261)
Total equity	68,087	55,524
Total liabilities and equity	81,391	81,673

Exhibit 2

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2022

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2022

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BioLineRx Ltd.

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(UNAUDITED)

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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 LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2022	2021	2022
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,923)	(4,369)	(14,340)	(14,199)
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GENERAL AND ADMINISTRATIVE EXPENSES	(1,047)	(1,392)	(3,108)	(3,448)
OPERATING LOSS	(6,217)	(7,078)	(18,179)	(20,759)
NON-OPERATING INCOME (EXPENSES), NET	710	389	(4,068)	2,115
FINANCIAL INCOME	52	109	299	256
FINANCIAL EXPENSES	(261)	(267)	(802)	(832)
NET LOSS AND COMPREHENSIVE LOSS	(5,716)	(6,847)	(22,750)	(19,220)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.01)	(0.04)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	708,473,164	740,767,492	646,427,790	723,805,390

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, 2021	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2021:							
Issuance of share capital and warrants, net	8,764	39,569	975	-	-	-	49,308
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options expired	-	233	-	(233)	-	-	-
Share-based compensation	-	-	-	1,104	-	-	1,104
Comprehensive loss for the period	-	-	-	-	-	(22,750)	(22,750)
BALANCE AT SEPTEMBER 30, 2021	20,874	338,051	975	13,154	(1,416)	(300,737)	70,901

	Ordinary Shares	Share premium	Warrants	Capital reserve	Other Comprehensive Loss	Accumulated deficit	Total
				in USD thousands			
BALANCE AT JANUARY 1, 2022	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087
CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2022:							
Issuance of share capital and warrants, net	6,030	(1,008)	433	-	-	-	5,455
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	491	-	(491)	-	-	-
Share-based compensation	-	-	-	1,200	-	-	1,200
Comprehensive loss for the period	-	-	-	-	-	(19,220)	(19,220)
BALANCE AT SEPTEMBER 30, 2022	27,098	338,841	1,408	13,854	(1,416)	(324,261)	55,524

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

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

	Nine months ended September 30,	
	2021	2022
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(22,750)	(19,220)
Adjustments required to reflect net cash used in operating activities (see appendix below)	4,680	(1,337)
Net cash used in operating activities	(18,070)	(20,557)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(70,000)	(36,000)
Maturities of short-term deposits	27,813	36,232
Purchase of property and equipment	-	(74)
Purchase of intangible assets	(35)	(14)
Net cash provided by (used in) investing activities	(42,222)	144
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	49,308	14,359
Exercise of warrants	10,907	-
Employee stock options exercised	7	2
Repayments of loan	(2,502)	(2,832)
Proceeds of long-term loan, net of issuance costs	-	9,126
Repayments of lease liabilities	(145)	(126)
Net cash provided by financing activities	57,575	21,085
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,717)	672
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	16,831	12,990
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(37)	(557)
CASH AND CASH EQUIVALENTS - END OF PERIOD	14,077	13,105

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

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 30,	
	2021	2022
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	529	467
Exchange differences on cash and cash equivalents	37	557
Fair value adjustments of warrants	4,090	(2,778)
Share-based compensation	1,104	1,200
Warrant issuance costs	-	171
Interest and exchange differences on short-term deposits	(185)	(244)
Interest on loans	245	104
Exchange differences on lease liability	(3)	(233)
Long-term loan issuance costs	-	(556)
	5,817	(1,312)
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(348)	(411)
Increase (decrease) in accounts payable and accruals	(789)	386
	(1,137)	(25)
	4,680	(1,337)
Supplemental information on interest received in cash	77	244
Supplemental information on interest paid in cash	541	307
Supplemental information on warrant issuance costs paid in cash	-	591
Supplemental information on non-cash transactions:		
Changes in right-of-use asset	143	123
Warrant issuance costs	-	262
Exercise of warrants (portion related to accumulated fair value adjustments)	10,295	-

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

NOTE 1 – GENERAL INFORMATION

a. General

BioLineRx Ltd. ("BioLineRx"), headquartered in Modi'in, Israel, was incorporated and commenced operations in April 2003. BioLineRx and its subsidiaries (collectively, the "Company") are engaged in the development of therapeutics, primarily in pre-commercialization and clinical stages, with a focus on the field of oncology.

The Company's American Depositary Shares ("ADSs") are traded on the NASDAQ Capital Market, and its ordinary shares are traded on the Tel Aviv Stock Exchange ("TASE"). Each ADS represents 15 ordinary shares.

In March 2017, the Company acquired Agalimmune Ltd. ("Agalimmune"), a privately held company incorporated in the United Kingdom, with a focus on the field of immuno-oncology. In April 2022, the Company re-activated BioLineRx USA, Inc., a previously inactive subsidiary incorporated in the US, to engage in pre-commercialization and commercialization activities associated with the potential launch of Motixafortide for stem-cell mobilization in the US.

Although the Company has succeeded in generating significant revenues from a number of out-licensing transactions in the past, it cannot determine with reasonable certainty if and when it will become profitable on a current basis. Management believes that the Company's current cash and other resources will be sufficient to fund its projected cash requirements into the first half of 2024. However, in the event that the Company does not begin to generate sustainable cash flows from its operating activities in the future, the Company will need to carry out significant cost reductions or raise additional funding.

b. Approval of financial statements

The condensed consolidated interim financial statements of the Company as of September 30, 2022, and for the three and nine months then ended, were approved by the Board of Directors on November 14, 2022, and signed on its behalf by the Chairman of the Board, the Chief Executive Officer and the Chief Financial Officer.

NOTE 2 – BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of September 30, 2022 and for the three and nine months then ended (the "interim financial statements") have been prepared in accordance with International Accounting Standard No. 34, "Interim Financial Reporting" ("IAS 34"). These interim financial statements, which are unaudited, do not include all disclosures necessary for a fair statement of financial position, results of operations, and cash flows in conformity with International Financial Reporting Standards ("IFRS"). The condensed consolidated interim financial statements should be read in conjunction with the Company's annual financial statements as of December 31, 2021 and for the year then ended and their accompanying notes, which have been prepared in accordance with IFRS. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

The preparation of financial statements in conformity with IFRS requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity and expenses, as well as the related disclosures of contingent assets and liabilities, in the process of applying the Company's accounting policies. These inputs also consider, among other things, the implications of pandemics and wars across the globe on the Company's activities, and the resultant effects on critical and significant accounting estimates, most significantly in relation to the value of intangible assets. In this regard, U.S. and global markets are currently experiencing volatility and disruption following the escalation of geopolitical tensions and the ongoing military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict are highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and the capital markets. As of the date of release of these financial statements, the Company estimates there are no material effects of this conflict on its financial position and results of operations.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of these interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2021 and for the year then ended.

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

The Company maintains an ATM facility with H.C. Wainwright & Co., LLC ("HCW") pursuant to an ATM sales agreement entered into in September 2021. In accordance with the agreement, the Company is entitled, at its sole discretion, to offer and sell through HCW, acting as a sales agent, ADSs having an aggregate offering price of up to $25.0 million throughout the period during which the ATM facility remains in effect. The Company has agreed to pay HCW a commission of 3.0% of the gross proceeds from the sale of ADSs under the facility. During the nine months ended September 30, 2022, the Company issued a total of 206,324 ADSs under the program for total gross proceeds of approximately $0.3 million. From the effective date of the agreement through the issuance date of this report, 608,651 ADSs have been sold under the program for total gross proceeds of approximately $1.4 million.

NOTE 5- LONG-TERM LOAN

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

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

NOTE 6 – REGISTERED DIRECT OFFERING

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

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

The fair value of the warrants is computed using the Black-Scholes option pricing model. 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 $8.1 million as of September 30, 2022, and was based on the then current price of an ADS, a risk-free interest rate of 4.06%, an average standard deviation of 82.8%, and on the remaining contractual life of the warrants.

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

NOTE 7 – SHAREHOLDERS' EQUITY

As of December 31, 2021, and September 30, 2022, the Company's share capital is composed of ordinary shares, as follows:

	Number of ordinary shares	
	December 31, 2021	September 30, 2022
Authorized share capital	1,500,000,000	2,500,000,000
Issued and paid-up share capital	715,156,008	922,867,375

	In USD and NIS	
	December 31, 2021	September 30, 2022
Authorized share capital (in NIS)	150,000,000	250,000,000
Issued and paid-up share capital (in NIS)	71,515,600	92,286,737
Issued and paid-up share capital (in USD)	21,066,368	27,097,603

Exhibit 3

OPERATING AND FINANCIAL REVIEW

You should read the following discussion of our operating and financial condition and prospects in conjunction with the financial statements and the notes thereto included elsewhere in this 6-K, as well as in our Annual Report on Form 20-F filed on March 16, 2022, as amended on September 9, 2022 (the "Annual Report").

Forward Looking Statements

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

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

- the initiation, timing, progress and results of our preclinical studies, clinical trials and other therapeutic candidate development efforts;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory approvals for our therapeutic candidates and the timing of other regulatory filings and approvals;
- the clinical development, commercialization and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- our ability to integrate new therapeutic candidates and new personnel;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues, capital requirements and our needs for and ability to access sufficient additional financing;
- risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- competitive companies, technologies and our industry;
- statements as to the impact of the political and security situation in Israel on our business; and
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above.

Risk Factors

Except as set forth below, there are no material changes to the risk factors previously disclosed in our Annual Report on Form 20-F for the year ended December 31, 2021.

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our ADSs may be delisted and the price of our ADSs stock and our ability to access the capital markets could be negatively impacted.

Nasdaq has established certain standards for the continued listing of a security on the Nasdaq Capital Market. The standards for continued listing include, among other things, that the minimum bid price for the listed securities not fall below $1.00 per share for a period of 30 consecutive trading days.

On November 2, 2022, we were notified in a letter, or the Notification Letter, by the Nasdaq Listing Qualifications that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2), or the Rule, for continued listing on The Nasdaq Capital Market.

The Notification Letter provides that the Company has 180 calendar days, or until May 1, 2023, to regain compliance with the Rule. To regain compliance, the bid price of our ADSs must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. In the event we do not regain compliance by May 1, 2023, we may then be eligible for additional 180 days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second compliance period, then Nasdaq will notify us of its determination to delist our ADSs, at which point we will have an opportunity to appeal the delisting determination to a Hearings Panel

No assurance can be given that we will be able to regain compliance with the Rule. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our ADSs. A delisting of our ADSs from Nasdaq could materially reduce the liquidity of our ADSs and result in a corresponding material reduction in the price of our ADSs. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

Overview

General

We are a pre-commercial-stage biopharmaceutical company focused on oncology. Our current development and commercialization pipeline consists of two clinical-stage therapeutic candidates – motixafortide (BL-8040), a novel peptide for the treatment of stem-cell mobilization, solid tumors and acute myeloid leukemia, or AML, and AGI-134, an immuno-oncology agent in development for solid tumors. In addition, we have an off-strategy, legacy therapeutic product called BL-5010 for the treatment of skin lesions. We have generated our pipeline by systematically identifying, rigorously validating and in-licensing therapeutic candidates that we believe exhibit a high probability of therapeutic and commercial success. To date, except for BL-5010, none of our therapeutic candidates have been approved for marketing or sold commercially. Our strategy includes commercializing our therapeutic candidates through out-licensing arrangements with biotechnology and pharmaceutical companies and evaluating, on a case-by-case basis, the commercialization of our therapeutic candidates independently. In this regard, we are currently executing on an independent commercialization plan for motixafortide in stem cell mobilization for autologous bone marrow transplantation in multiple myeloma patients.

Motixafortide

Motixafortide is a novel, short peptide that functions as a high-affinity antagonist for CXCR4, which we are developing for the treatment of stem-cell mobilization, solid tumors and AML.

Stem cell mobilization

- In March 2015, we reported successful top-line results from a Phase 1 safety and efficacy trial for the use of motixafortide as a novel stem cell mobilization treatment for allogeneic bone marrow transplantation at Hadassah Medical Center in Jerusalem.

- In March 2016, we initiated a Phase 2 trial for motixafortide in allogeneic stem cell transplantation, conducted in collaboration with the Washington University School of Medicine, Division of Oncology and Hematology. In May 2018, we announced positive top-line results of this study showing, among other things, that a single injection of motixafortide mobilized sufficient amounts of CD34+ cells required for transplantation at a level of efficacy similar to that achieved by using 4-6 injections of G-CSF, the current standard of care.

- In December 2017, we commenced a randomized, placebo-controlled Phase 3 registrational trial for motixafortide, known as the GENESIS trial, for the mobilization of HSCs, for autologous transplantation in patients with multiple myeloma. The trial began with a lead-in period for dose confirmation, which was to include 10-30 patients and then progress to the placebo-controlled main part, which was designed to include 177 patients in more than 25 centers. Following review of the positive results from treatment of the first 11 patients, the Data Monitoring Committee, or DMC, recommended that the lead-in part of the study be stopped and that we should move immediately to the second part. Additional positive results from the lead-in period were reported at the annual meeting of the European Society for Blood and Marrow Transplantation held in March 2019, where it was announced that HSCs mobilized by motixafortide in combination with G-CSF were successfully engrafted in all 11 patients.

- In August 2020, we announced a decision to perform an interim analysis on approximately 65% of the original study sample size, primarily based on a significantly lower-than-anticipated patient-dropout rate in the study. In October 2020, we announced positive results from the interim analysis. Based on the statistically significant evidence favoring treatment with motixafortide, the study's independent DMC issued a recommendation to us that patient enrollment may be ceased immediately, without the need to recruit all 177 patients originally planned for the study. In accordance with the DMC's recommendation, study enrollment was complete at 122 patients. In May 2021, we announced positive top-line results from the Phase 3 trial. Based on an analysis of data on all 122 enrolled patients (the intent to treat population) we found highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in addition to G-CSF, as compared to placebo plus G-CSF ($p<0.0001$). The addition of motixafortide to G-CSF also allowed 88.3% of patients to undergo transplantation after only one apheresis session, compared to 10.8% in the G-CSF arm – an 8.2-fold increase. The combination was also found to be safe and well tolerated. We continue to follow-up on the GENESIS study patients for relapse-free and overall survival, according to the statistical analysis plan agreed upon with the U.S. Food and Drug Administration, or FDA.

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

- In December 2021, we held a pre-New Drug Application, or NDA, meeting with the FDA. The purpose of the meeting was to obtain agreement from the FDA on the content of the proposed NDA, and, in particular, to confirm that our single Phase 3 pivotal study, GENESIS, is sufficient to support an NDA submission. During the pre-NDA meeting, the FDA agreed that the proposed data package is sufficient to support an NDA submission.

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

- In September 2022, we submitted an NDA to the FDA for motixafortide in stem cell mobilization for autologous bone marrow transplantation for multiple myeloma patients and in November 2022, the FDA accepted for review the NDA and assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of September 9, 2023.

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

Solid tumors

- In January 2016, we entered into a clinical collaboration with MSD (a tradename of Merck & Co., Inc., Kenilworth, New Jersey) in the field of cancer immunotherapy. Based on this collaboration, in September 2016 we initiated a Phase 2a study, known as the COMBAT/KEYNOTE-202 study, focusing on evaluating the safety and efficacy of motixafortide in combination with KEYTRUDA® (pembrolizumab), MSD's anti-PD-1 therapy, in 37 patients with metastatic pancreatic adenocarcinoma, or PDAC. The study was an open-label, multicenter, single-arm trial designed to evaluate the clinical response, safety and tolerability of the combination of these therapies as well as multiple pharmacodynamic parameters, including the ability to improve infiltration of T-cells into the tumor and their reactivity. Top-line results showed that the dual combination demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor, while reducing the number of immune regulatory cells.

- In July 2018, we announced the expansion of the COMBAT/KEYNOTE-202 study under the collaboration to include a triple combination arm investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA ® and chemotherapy. We initiated this arm of the trial in December 2018. In December 2019, we announced that preliminary data from the study indicated that the triple combination therapy showed a high level of disease control, including seven partial responders and 10 patients with stable disease out of 22 evaluable patients. In February 2020, we completed recruiting a total of 43 patients for the study and in December 2020, we announced the final results of the study. The results of the study showed substantial improvement as compared to comparable historical results of other pancreatic cancer studies across all study endpoints. Of the 38 evaluable patients, median overall survival was 6.5 months, median progression free survival was 4.0 months, confirmed overall response rate was 13.2%, overall response rate was 21.2% and disease control rate was 63.2%. The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event and severe adverse event profiles were as expected with chemotherapy-based treatment regimens.

- In August 2016, in the framework of an agreement with MD Anderson Cancer Center, or MD Anderson, we entered into an additional collaboration for the investigation of motixafortide in combination with KEYTRUDA in pancreatic cancer. The focus of this study, in addition to assessing clinical response, was the mechanism of action by which both drugs might synergize, as well as multiple assessments to evaluate the biological anti-tumor effects induced by the combination. We supplied motixafortide for this Phase 2b study, which commenced in January 2017. Final results from this study (based on a cut-off in July 2019 from 20 enrolled patients out of which 15 were evaluable) showed that the dual combination demonstrated clinical activity and encouraging overall survival in patients with metastatic pancreatic cancer. In addition, assessment of patient biopsies supported motixafortide's ability to induce infiltration of tumor-reactive T-cells into the tumor.

- In October 2020, we announced that motixafortide will be tested in combination with the anti-PD-1 cemiplimab (LIBTAYO®) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line PDAC. This investigator-initiated Phase 2 study, led by Columbia University, will initially enroll 10-12 PDAC patients, and will be expanded to a total of 40 patients following an evaluation of the initial 10-12 patients based on pre-defined criteria. The primary endpoint of the study is the overall response rate. Secondary endpoints include safety and tolerability, progression free survival, duration of clinical benefit and overall survival. Data from the study is now anticipated during 2023 (although timelines are ultimately controlled by the independent investigator and are therefore subject to change).

- In June 2022, we entered into a collaboration agreement with GenFleet Therapeutics, an immuno-oncology focused biopharmaceutical company based in China, to advance motixafortide through a randomized Phase 2b clinical trial in PDAC. Under the terms of the agreement, GenFleet will fully fund, design and execute a randomized Phase 2b clinical trial that will enroll approximately 200 first-line metastatic PDAC patients in China. This randomized controlled study will aim to evaluate the superiority of motixafortide in combination with an anti-PD-1 and chemotherapy compared to chemotherapy alone, the current standard of care, and is expected to commence in 2023. As part of the collaboration, we will supply motixafortide, while GenFleet will supply the other study drugs for the trial. Trial oversight will be administered by a Joint Development Committee. GenFleet will be eligible to receive low-to-mid-single digit tiered percentage royalties on future motixafortide sales, if approved.

AML

- During 2016, we completed and reported on a Phase 2a proof-of-concept trial for the treatment of relapsed or refractory acute myeloid leukemia, or r/r AML, which was conducted on 42 patients at six world-leading cancer research centers in the United States and at five premier sites in Israel. The study included both a dose-escalation and a dose-expansion phase. Results from the trial showed positive safety and response rate data for subjects treated with a combination of motixafortide and high-dose cytarabine (Ara-C), or HiDAC. At the annual meeting of the European Hematology Association, or EHA, in June 2018, we presented positive overall survival data from the long-term follow-up part of this study. In March 2021, we completed the monitoring of long-term survival data for patients in the study and, in parallel, are evaluating our next clinical development steps in this indication.

- In August 2015, we conducted a double-blind, placebo-controlled, randomized, multi-center, Phase 2b trial in Germany, in collaboration with the German Study Alliance Leukemia Group, to assess the efficacy of motixafortide in addition to standard consolidation therapy (cytarabine) in AML patients who have responded to standard induction treatment and are in complete remission. During 2020, we finalized plans with our collaboration partners to conduct an interim analysis on 2/3 (N=128) of the 194 patients originally planned in the study, all of which had already completed treatment. Based on the interim analysis, the investigational arm of motixafortide combined with cytarabine did not demonstrate a statistically significant effect in the study's primary endpoint, and therefore, the DMC recommended not to continue the study. We continue to believe in the relevance of CXCR4 as a viable target in other AML treatment lines, such as rr/AML and induction treatment, and we intend to decide on next steps in AML once we have had an opportunity to review and analyze the unblinded data, including detailed biomarker and subpopulation data, from the study.

ARDS secondary to COVID-19 and other viral infections

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

Other matters

- In addition to the above, we are currently conducting, or planning to conduct, a number of investigator-initiated, open-label studies in a variety of indications, to support the interest of the scientific and medical communities in exploring additional uses for motixafortide. These studies serve to further elucidate the mechanism of action for motixafortide. The results of studies such as these are presented from time to time at relevant professional conferences.

- Motixafortide has been granted three Orphan Drug Designations by the FDA: for use to mobilize HSCs from the bone marrow to peripheral blood for collection in autologous or allogeneic transplantation (granted in July 2012); for the treatment of AML (granted in September 2013); and for the treatment of pancreatic cancer (granted in February 2019). In January 2020, the European Medicines Agency, or EMA, granted Orphan Drug Designation to motixafortide for the treatment of pancreatic cancer.

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

AGI-134

AGI-134, a clinical therapeutic candidate in-licensed by our subsidiary, Agalimmune Ltd., is a synthetic alpha-Gal glycolipid immunotherapy in development for solid tumors. AGI-134 harnesses the body's pre-existing, highly abundant, anti-alpha-Gal antibodies to induce a hyper-acute, systemic, specific anti-tumor response to the patient's own tumor neo-antigens. This response not only kills the tumor cells at the site of injection, but also brings about a durable, follow-on, anti-metastatic immune response. In August 2018, we initiated a Phase 1/2a clinical study for AGI-134 that is primarily designed to evaluate the safety and tolerability of AGI-134 in unresectable metastatic solid tumors. The multi-center, open-label study is currently being carried out in the United Kingdom, Spain and Israel. Initial safety results from the first part of the study were announced at the beginning of September 2019; at the end of the same month, the second part of the study was commenced. Due to clinical operating issues associated with the COVID-19 pandemic, in April 2020, enrollment to the clinical trial was temporarily suspended. In August 2020, we renewed study enrollment, and in January 2022, we completed enrollment. Initial proof-of-mechanism of action and efficacy results are expected by the end of 2022.

Scientific Advisory Board

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

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

BL-5010

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

Departure of Chief Medical Officer

On November 13, 2022, Abi Vainstein-Haras, our Chief Medical Officer, notified us of her resignation from the Company in order to relocate to the United States. Dr. Vainstein-Haras' resignation will take effect on December 31, 2022. Dr. Vainstein-Haras is expected to continue to provide consulting services to the Company following her resignation, including full support during the FDA review process.

Funding

We have funded our operations primarily through the sale of equity securities (both in public and private offerings), funding received from the Israel Innovation Authority, or IIA, payments received under out-licensing arrangements, and interest earned on investments. We expect to continue to fund our operations over the next several years through our existing cash resources, potential future milestone and royalty payments that we may receive from our existing out-licensing agreement, potential future upfront, milestone or royalty payments that we may receive from out-licensing transactions for our other therapeutic candidates, potential revenues that we may receive from the direct commercialization of our other therapeutic candidates, interest earned on our investments, and additional capital to be raised through public or private equity offerings or debt financings. As of September 30, 2022, we held $57.3 million of cash, cash equivalents and short-term bank deposits.

Revenues

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

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

Research and Development

Our research and development expenses consist primarily of salaries and related personnel expenses, fees paid to external service providers, up-front and milestone payments under our license agreements, patent-related legal fees, costs of preclinical studies and clinical trials, drug and laboratory supplies and costs for facilities and equipment. We primarily use external service providers to manufacture our product candidates for clinical trials and for the majority of our preclinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

The following table identifies our current major research and development projects:

Project	Status	Expected Near Term Milestones
motixafortide	1. Phase 3 registration study in autologous stem cell mobilization (GENESIS) completed; top-line results announced May 2021 showed highly statistically significant evidence across all primary and secondary endpoints favoring motixafortide in combination with G-CSF ($p<0.0001$). In addition, the combination was found to be safe and well tolerated. Pharmaco-economic studies showed positive results regarding the cost-effectiveness of using motixafortide versus both G-CSF alone and plerixafor in combination with G-CSF. NDA submission made in September 2022, and in November 2022 the FDA accepted for review the NDA with a PDUFA target action date of September 9, 2023.	1. FDA decision on NDA filing expected in third quarter of 2023
	2. Phase 2 investigator-initiated study in first-line metastatic PDAC patients	2. Data from the study is anticipated in 2023*
	3. Phase 1b study in patients with ARDS secondary to COVID-19 and other respiratory viral infections	3. Data from the study is anticipated in 2023*
	4. Phase 2b randomized clinical trial in first-line metastatic PDAC patients under collaboration with GenFleet	4. Initiation of the study is expected in 2023
AGI-134	Phase 1/2a study, ongoing	Initial proof-of-mechanism of action and efficacy results expected by end of 2022

*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 the therapeutic candidates in our pipeline for commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for each product candidate. If we are not able to enter into an out-licensing arrangement with respect to any therapeutic candidate prior to the commencement of later stage clinical trials, we may fund the trials for the therapeutic candidate ourselves.

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

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

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

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

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

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Non-Operating Expense and Income

Non-operating expense and income includes fair-value adjustments of liabilities on account of the warrants issued in equity financings we carried out in February 2019, May-June 2020 and September 2022. These fair-value adjustments are highly influenced by our share price at each period end (revaluation date). Non-operating expense and income also includes issuance expenses of the ATM sales agreements between us and H.C. Wainwright & Co., LLC, or HCW, entered into in September 2020 and September 2021, and the pro-rata share of issuance expenses from the placements related to the warrants. Sales-based royalties and other revenue from the license agreement with Perrigo have also been included as part of non-operating income, as the out-licensed product is not an integral part of our strategy and the amounts are not material.

Financial Expense and Income

Financial expense and income consist of interest earned on our cash, cash equivalents and short-term bank deposits; interest expense related to our loans from Kreos Capital; bank fees and other transactional costs. In addition, it may also include gains/losses on foreign exchange hedging transactions, which we carry out from time to time to protect against a portion of our NIS-denominated expenses (primarily compensation) in relation to the dollar.

Critical Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2021. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepare in accordance with IFRS. The preparation of these financial statements requires us to make estimates using assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates, including those described in greater detail below. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which impact the carrying value of our assets and liabilities that are not readily apparent from other sources. Actual results will differ from these estimates and such differences may be significant.

Results of Operations

Revenues

We did not record any revenues during each of the three-month and nine-month periods ended September 30, 2022 and 2021.

Cost of revenues

We did not record any cost of revenues during each of the three-month and nine-month periods ended September 30, 2022 and 2021.

Operating Results Comparison between Periods

Research and development expenses

	Three months ended September 30,			Nine months ended September 30,		
	2021	2022	Increase (decrease)	2021	2022	Increase (decrease)
			(in thousands of U.S. dollars)			
Research and development expenses, net	4,923	4,369	(554)	14,340	14,199	(141)

Comparison of three-month periods ending September 30, 2022 and 2021

Research and development expenses for the three months ended September 30, 2022 were $4.4 million, a decrease of $0.5 million, or 11.3%, compared to $4.9 million for the three months ended September 30, 2021. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide, as well as lower expenses associated with the completed motixafortide GENESIS clinical trial, offset by an increase in payroll and related expenses.

Comparison of nine-month periods ending September 30, 2022 and 2021

Research and development expenses for the nine months ended September 30, 2022 were $14.2 million, a decrease of $0.1 million, or 1.0%, compared to $14.3 million for the nine months ended September 30, 2021. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide, as well as lower expenses associated with the completed motixafortide GENESIS clinical trial, offset by an increase in expenses associated with the AGI-134 study.

Sales and marketing expenses

	Three months ended September 30,			Nine months ended September 30,		
	2021	2022	Increase (decrease)	2021	2022	Increase (decrease)
			(in thousands of U.S. dollars)			
Sales and marketing expenses	247	1,317	1,070	731	3,112	2,381

Comparison of three-month periods ending September 30, 2022 and 2021

Sales and marketing expenses for the three months ended September 30, 2022 were $1.3 million, an increase of $1.1 million, or 433.2% compared to $0.2 million for the three months ended September 30, 2021. The increase resulted primarily from initiation of pre-commercialization activities related to motixafortide, as well as an increase in market research.

Comparison of nine-month periods ending September 30, 2022 and 2021

Sales and marketing expenses for the nine months ended September 30, 2022 were $3.1 million, an increase of $2.4 million, or 325.7% compared to $0.7 million for the nine months ended September 30, 2021. The reason for the increase is similar to the aforementioned increase in the three-month period.

General and administrative expenses

	Three months ended September 30,			Nine months ended September 30,		
	2021	2022	Increase (decrease)	2021	2022	Increase (decrease)
			(in thousands of U.S. dollars)			
General and administrative expenses	1,047	1,392	345	3,108	3,448	340

Comparison of three-month periods ending September 30, 2022 and 2021

General and administrative expenses for the three months ended September 30, 2022 were $1.4 million, an increase of $0.3 million, or 32.9% compared to $1.0 million for the three months ended September 30, 2021. The increase resulted primarily from an increase in share-based compensation and small increases in a number of G&A expenses.

Comparison of nine-month periods ending September 30, 2022 and 2021

General and administrative expenses for the nine months ended September 30, 2022 were $3.4 million, an increase of $0.3 million, or 10.9% compared to $3.1 million for the nine months ended September 30, 2021. The reason for the increase is similar to the aforementioned increase in the three-month period.

Non-operating income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2021	2022	Increase (decrease)	2021	2022	Increase (decrease)
			(in thousands of U.S. dollars)			
Non-operating income (expenses), net	710	389	(321)	(4,068)	2,115	6,183

Comparison of three-month and nine-months periods ending September 30, 2022 and 2021

Non-operating income for the three and nine months ended September 30, 2022 primarily relates to fair-value adjustments of warrant liabilities on our balance sheet, offset by warrant offering expenses. Non-operating income (expenses) for the three and nine months ended September 30, 2021 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet and issuance expenses of the ATM.

Financial income (expenses), net

	Three months ended September 30,			Nine months ended September 30,		
	2021	2022	Increase (decrease)	2021	2022	Increase (decrease)
			(in thousands of U.S. dollars)			
Financial income	52	109	57	299	256	(43)
Financial expenses	(261)	(267)	(6)	(802)	(832)	(30)
Net financial income (expenses)	(209)	(158)	51	(503)	(576)	(73)

Comparison of three-month periods ending September 30, 2022 and 2021

We recognized net financial expenses of $0.2 million for the three months ended September 30, 2022, similar to the three months ended September 30, 2021. Net financial expenses for the 2022 period primarily relate to interest paid on loan and losses recorded on foreign currency (primarily NIS) cash balances due to the strengthening of the US dollar during the period, offset by investment income earned on our bank deposits. Net financial expenses for the 2021 period primarily relate to interest paid on loans, offset by investment income earned on our bank deposits.

Comparison of nine-month periods ending September 30, 2021 and 2020

We recognized net financial expenses of $0.6 million for the nine months ended September 30, 2022, compared to net financial expenses of $0.5 million for the nine months ended September 30, 2021. The composition of the expenses is similar to the aforementioned composition detailed in the three-month period.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through public and private offerings of our equity securities, payments received under our strategic licensing and collaboration arrangements, interest earned on investments and funding from the IIA. As of September 30, 2022, we held $57.3 million of cash, cash equivalents and short-term bank deposits. We have invested substantially all of our available cash funds in short-term bank deposits.

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

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

In September 2022, we entered into definitive agreements with certain institutional investors providing for the issuance and sale in a registered direct offering of 13,636,365 of our ADSs and warrants to purchase up to an aggregate of 13,636,365 ADSs at a combined purchase price of $1.10 per ADS and associated investor warrant, for aggregate gross proceeds of approximately $15 million. The transaction closed in September 2022.

Net cash used in operating activities was $20.6 million for the nine months ended September 30, 2022, compared with net cash used in operating activities of $18.1 million for the nine months ended September 30, 2021. The $2.5 million increase in net cash used in operating activities in 2022 was primarily the result of an increase in sales and marketing expenses.

Net cash provided by investing activities was $0.1 million for the nine months ended September 30, 2022, compared to net cash used in investing activities of $44.2 million for the nine months ended September 30, 2021. 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 $21.1 million for the nine months ended September 30, 2022, compared to net cash provided by financing activities of $57.6 million for the nine months ended September 30, 2021. The cash flows in 2022 primarily reflect the underwritten public offering of our ADSs in September 2022 and the net proceeds of a loan from Kreos Capital, offset by repayments of a previous loan from Kreos Capital. The cash flows in 2021 primarily reflect the underwritten public offering of our ADSs in January 2021, warrant exercises, and net proceeds from the ATM Facility, offset by repayments of a loan from Kreos Capital.

Developing drugs, conducting clinical trials and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. Although we believe our existing cash and other resources will be sufficient to fund our current projected cash requirements into the first half of 2024, we will require additional financing in the future to fund our operations. Additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under our collaboration or licensing arrangements;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval of our therapeutic candidates;
- the ability of our collaborators to achieve development milestones, marketing approval and other events or developments under our collaboration agreements;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of establishing sales and marketing capabilities or contracting with third parties to provide these capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future product candidates;
- the magnitude of our general and administrative expenses;
- interest and principal payments on the loan from Kreos Capital;
- any cost that we may incur under current and future licensing arrangements relating to our therapeutic candidates;
- market conditions;
- payments to the IIA; and
- the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through payments received under our collaborations, debt or equity financings, or by out-licensing other product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, or at all.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

Off-Balance Sheet Arrangements

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

Share and per-share information in ADSs

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2022	2021	2022
	(in U.S. dollars)			
Loss per ADS – basic and diluted	(0.12)	(0.14)	(0.53)	(0.39)

	December 31, 2021	September 30, 2022
	(in number of ADSs)	
Authorized share capital	100,000,000	166,666,667
Issued and paid-up capital	47,677,067	61,524,492