UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

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

For the Month of: August 2023 (Report No. 2)

Commission File Number: 001-38428

PolyPid Ltd.
(Translation of registrant's name into English)

18 Hasivim Street
Petach Tikva 495376, Israel
(Address of principal executive office)

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

CONTENTS

This Report of Foreign Private Issuer on Form 6-K consists of PolyPid Ltd.'s (the "Registrant"): (i) Unaudited Interim Condensed Consolidated Financial Statements as of June 30, 2023, which is attached hereto as Exhibit 99.1; and (ii) Management's Discussion and Analysis of Financial Condition and Results of Operations for the six months ended June 30, 2023, which is attached hereto as Exhibit 99.2.

The contents of this Form 6-K are incorporated by reference into the Registrant's registration statements on Form F-3 (File No. 333-257651) and Form S-8 (File No. 333-239517 and File No. 333-271060), filed with the Securities and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit No.	
99.1	PolyPid Ltd.'s Unaudited Interim Condensed Financial Statements as of June 30, 2023.
99.2	PolyPid Ltd.'s Management's Discussion and Analysis of Financial Condition and Results of Operation for the Six Months Ended June 30, 2023.
101	The following financial information from the Registrant's Unaudited Interim Condensed Financial Statements as of June 30, 2023, formatted in XBRL (eXtensible Business Reporting Language): (i) Interim Condensed Consolidated Balance Sheets, (ii) Interim Condensed Consolidated Statements of Operations, (iii) Interim Condensed Consolidated Statements of Shareholders' Equity; (iv) Interim Condensed Consolidated Statements of Cash Flows, and (v) Notes to Interim Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

POLYPID LTD.

Date: August 9, 2023

By: /s/ Dikla Czaczkes Akselbrad
Name: Dikla Czaczkes Akselbrad
Title: Chief Executive Officer

Exhibit 99.1

POLYPID LTD.
AND ITS SUBSIDIARIES

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF JUNE 30, 2023

U.S. DOLLARS IN THOUSANDS

UNAUDITED

INDEX

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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30, 2023 Unaudited	December 31, 2022 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,396	$ 8,552
Short-term deposits	11,710	4,042
Restricted deposits	503	511
Prepaid expenses and other current assets	144	1,089
Total current assets	15,753	14,194
LONG-TERM ASSETS:		
Property and equipment, net	8,529	9,247
Operating lease right-of-use assets	1,892	2,431
Other long-term assets	89	99
Total long-term assets	10,510	11,777
Total assets	$ 26,263	$ 25,971

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

INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	June 30, 2023	December 31, 2022
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt	$ 2,068	$ 4,024
Accrued expenses and other current liabilities	1,842	2,429
Trade payables	903	1,141
Current maturities of operating lease liabilities	638	959
Total current liabilities	5,451	8,553
LONG-TERM LIABILITIES:		
Long-term debt	8,538	7,574
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	933	1,173
Other liabilities	446	294
Total long-term liabilities	12,465	11,589
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares with no par value - Authorized: 107,800,000 and 47,800,000 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively; Issued and outstanding: 49,048,703 and 19,851,833 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively	-	-
Additional paid-in capital	234,696	220,273
Accumulated deficit	(226,349)	(214,444)
Total shareholders' equity	8,347	5,829
Total liabilities and shareholders' equity	$ 26,263	$ 25,971

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Six Months Ended June 30,		Three Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development, net	$ 7,754	$ 17,095	$ 3,960	$ 8,398
Marketing and business development	742	1,698	357	923
General and administrative	3,112	4,723	1,503	2,243
Operating loss	11,608	23,516	5,820	11,564
Financial expense, net	262	203	7	281
Loss before income tax	11,870	23,719	5,827	11,845
Income tax expenses	35	-	10	-
Net loss	$ 11,905	$ 23,719	$ 5,837	$ 11,845
Basic and diluted loss per ordinary share	$ 0.36	$ 1.23	$ 0.13	$ 0.61
Weighted average number of ordinary shares used in computing basic and diluted loss per share	32,910,446	19,222,423	44,383,474	19,505,246

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share and per share data)

Three Months Ended June 30, 2023	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of March 31, 2023	38,694,171	$ 231,919	$ (220,512)	$ 11,407
Share-based compensation	-	841	-	841
Modification of warrants	-	31	-	31
Reclassification of pre-funded warrants to Equity	-	1,905	-	1,905
Cashless exercise of pre-funded warrants	10,354,532	-	-	-
Net loss	-	-	(5,837)	(5,837)
Balances as of June 30, 2023 (unaudited)	49,048,703	$ 234,696	$ (226,349)	$ 8,347

Three Months Ended June 30, 2022	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of March 31, 2022	19,470,757	$ 215,606	$ (186,761)	$ 28,845
Share-based compensation	-	1,266	-	1,266
Issuance of ordinary shares, net (1)	57,722	285	-	285
Issuance of warrants	-	468	-	468
Exercise of options	22,694	91	-	91
Loss	-	-	(11,845)	(11,845)
Balances as of June 30, 2022 (unaudited)	19,551,173	$ 217,716	$ (198,606)	$ 19,110

(1) Net of issuance cost of $21 in cash.

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share and per share data)

Six Months Ended June 30, 2023	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of January 1, 2023	19,851,833	$ 220,273	$ (214,444)	$ 5,829
Share-based compensation	-	1,970	-	1,970
Issuance of Ordinary shares, net (1)	18,808,029	8,627	-	8,627
Issuance of pre-funded warrants, net (2)	-	3,987	-	3,987
Modification of warrants	-	31	-	31
Reclassification of pre-funded warrants to Liabilities	-	(2,106)	-	(2,106)
Reclassification of pre-funded warrants to Equity	-	1,905	-	1,905
Cashless exercise of pre-funded warrants	10,354,532	-	-	-
Exercise of options	34,309	9	-	9
Net loss	-	-	(11,905)	(11,905)
Balances as of June 30, 2023 (unaudited)	49,048,703	$ 234,696	$ (226,349)	$ 8,347

(1) Net of issuance cost of $734.
(2) Net of issuance cost of $362.

Six Months Ended June 30, 2022	Number of Ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of January 1, 2022	18,756,570	$ 210,847	$ (174,887)	$ 35,960
Share-based compensation	-	2,539	-	2,539
Issuance of shares, net (1)	768,622	3,754	-	3,754
Issuance of warrants	-	468	-	468
Exercise of options	25,981	108	-	108
Loss	-	-	(23,719)	(23,719)
Balances as of June 30, 2022 (unaudited)	19,551,173	$ 217,716	$ (198,606)	$ 19,110

(1) Net of issuance cost of $162.

Year Ended December 31, 2022	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of January 1, 2022	18,756,570	$ 210,847	$ (174,887)	$ 35,960
Share-based compensation	-	4,307	-	4,307
Issuance of ordinary shares, net (1)	1,065,057	4,423	-	4,423
Issuance of warrants	-	588	-	588
Exercise of options	30,206	108	-	108
Net loss	-	-	(39,557)	(39,557)
Balances as of December 31, 2022 (audited)	19,851,833	$ 220,273	$ (214,444)	$ 5,829

(1) Net of issuance costs of $222.

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six Months Ended June 30,	
	2023	**2022**
	Unaudited	
Cash flows from operating activities:		
Net loss	$ (11,905)	$ (23,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	913	805
Non-cash financial expenses, net	813	146
Remeasurement of warrants classified as a liability	(201)	-
Share-based compensation expenses	1,970	2,539
Changes in assets and liabilities:		
Prepaid expenses and other assets	950	1,584
Operating lease liabilities and right-of-use-assets, net	(22)	-
Trade payables	(238)	(1,748)
Accrued expenses and other liabilities	(561)	51
Net cash used in operating activities	(8,281)	(20,342)
Cash flows from investing activities:		
Short-term and long-term deposits, net	(7,668)	10,245
Purchase of property and equipment	(195)	(1,185)
Net cash provided (used) by investing activities	(7,863)	9,060
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares, net	8,627	3,754
Proceeds from long-term debt, net	-	9,331
Payments due to long-term debt	(1,522)	(406)
Payment of fees due to modification of debt	(125)	-
Proceeds from issuance of pre-funded warrants	3,987	468
Proceeds from exercise of options	9	108
Net cash provided by financing activities	10,976	13,255
Increase (decrease) in cash, cash equivalents and restricted cash	**(5,168)**	**1,973**
Cash, cash equivalents and restricted cash at the beginning of the period	9,142	10,456
Cash, cash equivalents and restricted cash at the end of the period	$ 3,974	$ 12,429

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six Months Ended June 30,	
	2023	2022
	Unaudited	
Non-cash activities:		
Modification of warrants	$ 31	$ -
Credit line derivative	$ 127	$ -
Property and equipment acquired by credit	$ -	$ 42
Supplemental disclosures of cash flows:		
Interest paid	$ 492	$ 77
Supplemental disclosures of cash flow information:		
Cash and cash equivalents	$ 3,396	$ 11,640
Restricted cash	503	576
Restricted cash included in other long-term assets	75	213
Cash, cash equivalents and restricted cash at the end of the period	$ 3,974	$ 12,429

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

NOTE 1:- GENERAL

a. PolyPid Ltd. (the "Company") was incorporated under the laws of Israel and commenced operations on February 28, 2008. The Company is a Phase 3 biopharmaceutical company focused on developing targeted, locally administered, and prolonged-release therapeutics using its proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology. The Company's product candidates are designed to address unmet medical needs by delivering active pharmaceutical ingredients, locally at predetermined release rates and durations over extended periods ranging from days to several months. The Company is initially focused on the development of its lead product candidate, D-PLEX, which incorporates an antibiotic for the prevention of surgical site infections ("SSIs") in bone and soft tissue. Through June 30, 2023, the Company has been primarily engaged in research and development.

The Company's wholly owned subsidiaries include a subsidiary in the United States (the "US Subsidiary") and a subsidiary in Romania. The US Subsidiary's operation focuses on marketing and business development of the Company's operation in the United States.

b. The Company's activities since inception have consisted of performing research and development activities. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations is dependent on future events, including, among other things, its ability to secure financing; obtain marketing approval from regulatory authorities; access potential markets; build a sustainable customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. The Company's operations are funded by its shareholders and research and development grants and the Company intends to seek further private or public financing as well as make applications for further research and development grants for continuing its operations. Although management believes that the Company will be able to successfully fund its operations, there can be no assurance that the Company will be able to do so or that the Company will ever operate profitably.

In September 2022, the Company announced top-line results from the Surgical site Hospital acquired Infection prEvention with Local D-PLEX$_{100}$ ("SHIELD") I Phase 3 trial. SHIELD I did not achieve its primary endpoint of reduction in SSIs, re-interventions due to SSIs and mortality: in the Intent to Treat population, the local administration of D-PLEX$_{100}$ and standard of care ("SoC"), (n=485) resulted in a decrease in the primary endpoint of 23 percent compared to SoC alone (n=489) (p=0.1520).

The Company expects to continue to incur substantial losses over the next several years during its clinical development phase. To fully execute its business plan, the Company will need to complete Phase 3 clinical studies and certain development activities as well as manufacture the required clinical and commercial production batches in the pilot manufacturing plant. Further, the Company's product candidates will require regulatory approval prior to commercialization, and the Company will need to establish sales, marketing and logistic infrastructures. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company.

As of June 30, 2023, the Company's cash, cash equivalents and short-term deposits amounted to a total of $15,106. During the six-month period ended June 30, 2023, the Company incurred a loss of $11,905 and had negative cash flows from operating activities of $8,281. In addition, the Company had an accumulated deficit of $226,349 as of June 30, 2023.

NOTE 1:- GENERAL (CONT.)

Management plans to seek additional equity financing through private and public offerings or strategic partnerships and, in the longer term, by generating revenues from product sales.

The Company's future operations are highly dependent on a combination of factors, including (i) completion of all required clinical studies; (ii) the success of its research and development activities; (iii) manufacture of all required clinical and commercial production batches; (iv) marketing approval by the relevant regulatory authorities; and (v) market acceptance of the Company's product candidates.

There can be no assurance that the Company will succeed in achieving the clinical, scientific and commercial milestones as detailed above.

Based on the abovementioned, as of the approval date of these interim consolidated financial statements, the Company has not raised the necessary funding in order to continue its activity for a period of at least one year. Therefore, these factors raise a substantial doubt about the Company's ability to continue as a going concern. The interim condensed consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that might result should the Company be unable to continue as a going concern.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation and summary of significant accounting policies:

The accompanying interim condensed consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States and are consistent in all material respects with those applied in the Company's Annual Report on Form 20-F for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 31, 2023.

The preparation of interim condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and judgments that affect the amounts reported in the interim condensed consolidated financial statements and accompanying notes. Significant items subject to such estimates and assumptions, but are not limited to, the fair value of financial assets and liabilities, the useful lives of property and equipment and the determination of the fair value of the Company's share-based compensation. The Company bases these estimates on historical and anticipated results, trends and various other assumptions that it believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ from those estimates.

The interim financial information is unaudited, but reflects all normal recurring adjustments that are, in the opinion of management, necessary to fairly present the information set forth herein. The interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes included in the Company's Annual Report on Form 20-F for the year ended December 31, 2022 (the "2022 Consolidated Financial Statements"). Interim results are not necessarily indicative of the results for a full year.

There have been no material changes in the Company's significant accounting policies as compared to the significant accounting policies described in the Company's Annual Report on Form 20-F for the year ended December 31, 2022.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

b. Basic and diluted loss per share:

The Company's basic loss per share is calculated by dividing the loss attributable to ordinary shareholders by the weighted-average number of shares of ordinary shares outstanding for the period, without consideration of potentially dilutive securities. The diluted loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted loss per share is the same as basic loss per share in periods when the effects of potentially dilutive shares of ordinary shares are anti-dilutive.

c. Fair value of financial instruments:

Under U.S. GAAP, fair value is defined as the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants and requires that assets and liabilities carried at fair value are classified and disclosed in the following three categories:

Level 1 Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities.
-
Level 2 Include other inputs that are directly or indirectly observable in the marketplace.
-
Level 3 Unobservable inputs which are supported by little or no market activity.
-

The carrying amounts of cash and cash equivalents, restricted cash, short-term deposits, long-term deposits, other current assets, trade payables, accrued expenses and other current and non-current liabilities approximate their fair value due to the short-term maturity of such instruments.

Fair value estimates are made at a specific point in time, based on relevant market information and information about the financial instruments. These estimates are subjective in nature and involve uncertainties and matters of significant judgment and, therefore, cannot be determined with precision. Changes in assumptions could significantly affect these estimates.

d. Recently adopted accounting pronouncements:

As an "Emerging Growth Company", the Jumpstart Our Business Startups Act ("JOBS Act") allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act.

The Company has reviewed recent accounting pronouncements and concluded that they are either not applicable to its business or that no material effect is expected on the condensed consolidated financial statements as a result of their future adoption.

U.S. dollars in thousands (except share and per share data)

NOTE 3:- LEASES

The Company leases substantially all of its office space and vehicles under operating leases. The Company's leases have original lease periods expiring between 2023 and 2027. Some leases include one or more options to renew. The Company does not assume renewals in its determination of the lease term unless the renewals are deemed to be reasonably certain. Lease payments included in the measurement of the lease liability are comprised of the following: the fixed non-cancelable lease payments, payments for optional renewal periods, where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

The following is a summary of weighted average remaining lease terms and discount rates for all of the Company's operating leases as of June 30, 2023:

Weighted average remaining lease term (years)	3.26
Weighted average discount rates	9.16%

For the six months ended June 30, 2023, the total operating lease cost and cash payments for operating leases were as follows:

Operating lease cost	$	582
Cash payments for operating leases	$	524

Minimum lease payments over the remaining lease periods as of June 30, 2023, are as follows:

The remainder of 2023	$	479
2024		403
2025		358
2026		349
2027		177
Total undiscounted lease payments		1,766
Less - imputed interest		(195)
Present value of lease liabilities	$	1,571

NOTE 4:- LINE OF CREDIT ARRANGEMENT

Further to the discussion in Note 7 in the 2022 Consolidated Financial Statements regarding the secured line of credit agreement signed on April 5, 2022, with Kreos Capital VI (Expert Fund) LP ("Kreos") (the "Credit Line" or "debt"), the Company entered into an amendment to the Credit Line on March 29, 2023 (the "Amendment").

Pursuant to the Amendment, 70% of the remaining principal and interest repayments will be delayed and repaid on a monthly equal basis from August 2024 to May 2026. The amended secured credit line now bears an interest at the rate of 10%. In addition, the Company will pay to Kreos a restructuring fee consisting of 1% on the closing date of the Amendment and an incremental 3% at the maturity of the Amendment. In return for this additional deferral of repayment, Kreos has the right to receive a potential claw-back payment on account of the then outstanding principal amount (the "Claw-Back"). This Claw-Back mechanism will be triggered by additional incoming funds from future collaboration and partnership agreements or additional funding. If triggered, the minimum Claw-Back to be paid will be $1,500, but will not exceed $3,000.

The Company evaluated the amendment under ASC 470-50, "*Debt - modification and extinguishment*", and concluded that the terms of the new debt and the original debt are not substantially different, therefore the debt restructuring is accounted as debt modification where no gain or loss was recognized.

During the six-month period ended on June 30, 2023, the Company recognized $813 of interest expenses related to the Credit Line, which were included as part of financial expenses in the Company's statements of operations.

In addition, the Company's debt includes Claw-Back feature that meets the definition of embedded derivative under ASC 815. Consequently, the embedded derivative was bifurcated and accounted for separately at fair value. The fair value of the derivative amounted to $127 as of March 29, 2023, and June 30, 2023. Changes in the fair value of the derivative liabilities are determined at each period end. The liability due to the derivative was classified under other long-term liabilities in the consolidated balance sheet as of June 30, 2023.

Further to the above, the outstanding warrants issued to Kreos were repriced and as a result bear an exercise price of $0.42 per share. As a result of the modification, the Company recorded an incremental value in the amount of $31, that was calculated based on the Black-Scholes option pricing model, which increased the additional paid-in capital against an offset of the long-term debt due to the Credit Line.

The Company incurred debt restructuring costs, which were fully paid in cash, and are presented as a direct deduction against the carrying amount of the debt and amortized to interest expense using the effective interest method.

NOTE 5:- COMMITMENTS AND CONTINGENT LIABILITIES

In connection with its research and development programs, through June 30, 2023, the Company received participation payments from the Israel Innovation Authority of the Ministry of Economy in Israel ("IIA") in the aggregate amount of $4,888. In return for IIA's participation, the Company is committed to pay royalties at a rate of 3% of sales of the developed products, up to 100% of the amount of grants received plus interest at LIBOR rate.

Through June 30, 2023, no royalties have been paid or accrued.

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' EQUITY

a. Ordinary share capital (with no par value) is composed as follows:

	June 30, 2023		December 31, 2022	
	Unaudited		Audited	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares	107,800,000	49,048,703	47,800,000	19,851,833

b. In July 2021, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell, from time to time, its Ordinary shares, no par value (the "Ordinary Shares"), through the Agent in an At The Market offering ("ATM'"), as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, for an aggregate offering price of up to $45,000, which was subsequently reduced to $8,707 on May 19, 2023.

During the six-month period ended June 30, 2023, the Company sold 1,949,029 Ordinary Shares under the ATM for a total amount of $2,212, net of issuance cost in the amount of $68.

c. On March 29, 2023, the Company entered into a private placement of unregistered pre-funded warrants to purchase up to 10,357,139 Ordinary shares (the "PFW"), at a price of $0.4199 per PFW with certain of the Company's existing shareholders. The PFWs have an exercise price of $0.0001 per Ordinary share. Accordingly, the consideration for the PFWs amounted to $3,987, net of related placement fees and other offering expenses which amounted to a total of $362. In accordance with ASC No. 480, "*Distinguishing Liabilities from Equity*" ("ASC 480"), and ASC No. 815-40, "*Derivatives and Hedging*" ("ASC 815"), the PFWs were qualified for equity accounting.

On March 31, 2023, the Company closed a public offering which was comprised of 16,859,000 Ordinary shares (inclusive of 2,199,000 Ordinary shares pursuant to the full exercise of an overallotment option granted to the underwriters), at a public offering price of $0.42 per share (the "Public Offering"). The proceeds to the Company from the Public Offering were $6,415, net of underwriting commissions and other offering expenses which amounted to $666.

Following the Public Offering, the Company did not have a sufficient number of authorized Ordinary shares to cover 5,013,446 PFWs, and as a result, in accordance with ASC 815-40, these PFWs, which amounted to $2,106, were classified as a liability at fair value.

On May 5, 2023, the shareholders of the Company approved to increase the Company's authorized share capital by 60,000,000, from 47,800,000 to 107,800,000 Ordinary shares, and as a result, in accordance with ASC 480 and 815-40, these PFWs were classified under equity accounting at their fair value, which amounted to $1,905. The change in the PFWs fair value was accounted for as financial expenses in the amount of $201.

On May 11, 2023, all of the PFWs were exercised into 10,354,532 Ordinary shares on a cashless basis.

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' EQUITY (CONT.)

d. Share option plan:

Through June 30, 2023, the Company authorized through its 2012 Share Option Plan the grant of 4,672,094 options to Ordinary shares to its officers, directors, advisors, management and other employees. The options granted generally have a four-year or three-year vesting period and expire ten years after the date of grant. Options granted under the Company's option plan that are cancelled or forfeited before expiration become available for future grant.

As of June 30, 2023, 1,206,447 of the Company's options were available for future grants.

During the first quarter of 2023, the Company decreased the exercise price of 2,021,599 options granted to all employees and a consultant under the 2012 Share Option Plan. As of the modification date, the options can be exercised for $0.77 (the "Repricing"). Following the Repricing the Company accounted for an incremental value in the total amount of $562, in which $307 was recognized as of the modification date due to vested options, and the rest of the amount will be expensed based on the vesting conditions of each grant.

On May 5, 2023, the Company's board of directors also approved a similar exercise price decrease of 504,169 options previously granted to the Company's Chief Executive Officer and board members. Therefore, the Company accounted for an incremental value in the total amount of $63, of which $50 was recognized as of the modification date due to vested options, and the rest of the amount will be expensed based on the vesting conditions of each grant.

A summary of the status of options to employees under the Company's 2012 Share Option Plan as of and for the six-month period ended June 30, 2023, and changes during the period then ended is presented below (unaudited):

	Number of options	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at beginning of period	3,303,346	$ 1.92	$ 115	6.14
Granted	114,500	$ 0.71	-	
Exercised	(34,309)	$ 0.23	$ 12	
Forfeited and expired	(795,172)	$ 3.65		
Outstanding at end of period	**2,588,365**	**$ 1.36**	**$ -**	**6.39**
Exercisable options	**1,569,578**	**$ 1.74**	**$ -**	**4.94**
Vested and expected to vest	**2,588,365**	**$ 1.36**	**$ -**	**6.39**

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' EQUITY (CONT.)

d. Share option plan: (Cont.)

The Black-Scholes option pricing model assumptions used to value the employee share options at the grant dates are presented in the following table for the six-month period ended June 30, 2023:

Dividend yield (%)	0
Expected volatility (%)	92.59-95.67
Risk-free interest rate (%)	3.38-3.73
Expected term (in years)	5.7-6.1

The total share-based compensation expense recognized by the Company's departments:

	Six Months Ended June 30,	
	2023	2022
	Unaudited	
Research and development	$ 1,022	$ 1,193
Marketing and business development	191	199
General and administrative	757	1,147
	$ 1,970	$ 2,539

As of June 30, 2023, there were unrecognized compensation costs of $4,692, which are expected to be recognized over a weighted average period of approximately 2.15 years.

e. Options issued to non-employees (including directors and consultants):

Outstanding options granted to non-employees as of June 30, 2023, were as follows (unaudited):

Grant date	Options outstanding as of June 30, 2023	Average Exercise price per share ($)	Options exercisable as of June 30, 2023	Exercisable through
April 2016	5,975	$ 3.10	5,975	April 2026
December 2016	7,170	$ 3.93	7,170	December 2026
June 2017	197,722	$ 4.10	197,722	June 2027
November 2017	17,925	$ 0.77	17,925	November 2027
August 2019	71,700	$ 0.77	71,700	August 2029
June 2020	64,530	$ 2.84	64,530	June 2030
April 2021	62,741	$ 2.03	62,741	April 2031
August 2021	15,000	$ 0.77	8,719	August 2031
December 2021	10,000	$ 6.80	4,975	December 2031
May 2022	65,625	$ 1.37	65,625	May 2032
November 2022	5,000	$ 1.05	1,650	November 2032
February 2023	16,000	$ 0.81	-	February 2033
May 2023	170,628	$ 0.60	-	May 2033
	710,016		508,732	

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' EQUITY (CONT.)

f. Warrants:

As of June 30, 2023, all warrants are exercisable into Ordinary shares, in which the outstanding issued warrants as of June 30, 2023, were as follows (unaudited):

Grant date	Warrants outstanding as of June 30, 2023	Average Exercise price per share ($)	Warrants exercisable as of June 30, 2023	Exercisable through
August 2019	200,596	$ 15.95	200,596	August 2023
September 2020	17,925	$ 16.00	17,925	September 2024
April 2022	155,794	$ *) 0.42	155,794	April 2029
July 2022	38,948	$ *) 0.42	38,948	July 2029
	413,263		413,263	

*) Following the modification mentioned in Note 4.

NOTE 7:- BASIC AND DILUTED LOSS PER SHARE

The following table sets forth the computation of the Company's basic and diluted net loss per Ordinary share:

	Six Months Ended June 30,		Three Months Ended June 30,	
	2023	2022	2023	2022
	Unaudited			
Numerator:				
Allocation of loss attributable to ordinary shareholders	11,905	23,719	5,837	11,845
Denominator:				
Weighted average Ordinary shares outstanding	32,910,446	19,222,423	44,383,474	19,505,246
Basic and diluted loss per share	$ 0.36	$ 1.23	$ 0.13	$ 0.61

The potential Ordinary shares that were excluded from the computation of diluted loss per share attributable to ordinary shareholders for the periods presented because including them would have been anti-dilutive are as follows:

	Three and Six Months Ended June 30,	
	2023	2022
	Unaudited	
Ordinary share options	2,078,310	4,146,332
Warrants	413,263	374,315
	2,491,573	4,520,647

Exhibit 99.2

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

As of June 30, 2023, and for the Six Months then Ended

Cautionary Statement Regarding Forward-Looking Statements

Certain information included herein may be deemed to be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our dependence on enrollment of patients in our clinical trial in order to continue development of our product candidates;
- the outcomes of our anticipated interim analysis in our phase 3 SHIELD II clinical trial;
- the outcomes of our phase 3 SHIELD II clinical trial;
- our ability to raise capital through the issuance of securities;
- our ability to advance the development of our product candidates, including the anticipated starting and ending dates of our anticipated clinical trials;
- our assessment of the potential of our product candidates to treat certain indications;
- our ability to successfully receive approvals from the U.S. Food and Drug Administration, or FDA, the European Medicines Agency or other applicable regulatory bodies, including approval to conduct clinical trials, the scope of those trials and the prospects for regulatory approval of, or other regulatory action with respect to, our product candidates, including the regulatory pathway to be designated to our product candidates;
- the regulatory environment and changes in the health policies and regimes in the countries in which we operate, including the impact of any changes in regulation and legislation that could affect the pharmaceutical industry;
- our ability to commercialize our existing product candidates and future sales of our existing product candidates or any other future potential product candidates;

- our ability to meet our expectations regarding the commercial supply of our product candidates;
- the overall global economic environment, including the potential impact of the COVID-19 pandemic on the markets in which the Company operates;
- the impact of competition and new technologies;
- general market, political and economic conditions in the countries in which we operate;
- projected capital expenditures and liquidity;
- our ability to regain and effectively comply with the listing requirements, including the minimum bid requirement, of Nasdaq Stock Market LLC;
- changes in our strategy; and
- litigation.

The foregoing list is intended to identify only certain of the principal factors that could cause actual results to differ. For a more detailed description of the risks and uncertainties affecting our company, reference is made to our Annual Report on Form 20-F for the year ended December 31, 2022, or our Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on March 31, 2023, and the other risk factors discussed from time to time by our company in reports filed or furnished to the SEC.

Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Unless otherwise indicated, all references to “Company,” “we,” “our” and “PolyPid” refer to PolyPid Ltd., its wholly owned subsidiaries, PolyPid Inc., a Delaware corporation, and PolyPid Pharma SRL, a company organized and existing under the laws of Romania. References to “U.S. dollars” and “$” are to currency of the United States of America, and references to “shekel,” “Israeli shekel” and “NIS” are to New Israeli Shekels. References to “Ordinary Shares” are to our Ordinary Shares, no par value. We report our financial statements in accordance with generally accepted accounting principles in the United States.

A. Operating Results.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included in our Annual Report, as well as our unaudited condensed consolidated financial statements and the related notes thereto for the six months ended June 30, 2023, included elsewhere in this Report on Form 6-K. The discussion below contains forward-looking statements that are based upon our current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from these expectations due to inaccurate assumptions and known or unknown risks and uncertainties.

Overview

Since our inception in 2008, we have incurred significant operating losses. Our operating loss for the six months ended June 30, 2022 and 2023 were $23.5 million and $11.6 million, respectively. As of June 30, 2023, we had an accumulated deficit of $226.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We anticipate we will continue to incur expenses in connection with our ongoing activities, as we:

- continue clinical development of D-PLEX$_{100}$, including our SHIELD II Phase 3 clinical trial for the prevention of SSIs in open abdominal surgeries;
- file New Drug Applications, or NDAs, seeking regulatory approval for D-PLEX$_{100}$ pursuant to the FDA's Section 505(b)(2) regulatory pathway in the United States and the hybrid application pathway in the European Union;
- continue to invest in the preclinical research and development of OncoPLEX and any other future product candidates;
- continue to invest in our manufacturing facility and complete commercial process validation for the facility;
- establish commercial infrastructure to support the marketing, sale and distribution of D-PLEX$_{100}$ if it receives regulatory approval;
- hire field and office-based employees to prepare for and launch any approved product;
- hire additional research and development and general and administrative personnel to support our operations;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a public company.

We do not have any product candidates approved for sale and have not generated any revenue from product sales.

During October 2022, we announced a cost reduction plan, including a 20% reduction in headcount across all departments.

Results of Operations

Comparison of the Six months Ended June 30, 2022 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2023:

	Six months Ended June 30,	
	2022	**2023**
	(in thousands)	
Research and development, net	$ 17,095	$ 7,754
Marketing and business development	1,698	742
General and administrative	4,723	3,112
Operating loss	23,516	11,608
Financial expense, net	203	262
Loss before income tax	$ 23,719	$ 11,870
Income tax expense	-	35
Net loss	$ 23,719	$ 11,905

Research and Development, Net

Research and development, net decreased by $9.3 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. This decrease was primarily related to a decrease of $7.2 million in costs related to the completion of the SHIELD I trial, a decrease of $1.0 million in personnel costs due to the cost reduction plan we announced during October 2022, a decrease of $0.7 million in research and development costs related to D-PLEX$_{100}$ and OncoPLEX, a decrease of $0.7 million in our manufacturing facility expenses, and a decrease of $0.2 million in non-cash share-based compensation. These decreases were offset by an increase of $0.5 million in Israel Innovation Authority grants recognized in the six months ended June 30, 2022.

Marketing and business development

Marketing and business development decreased by $1.0 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. This decrease was primarily related to a decrease of $0.7 million in pre-commercialization activities for the product candidate D-PLEX$_{100}$, and a decrease of $0.3 million in personnel costs.

General and Administrative

General and administrative decreased by $1.6 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. This decrease was primarily related to a decrease of $0.9 million in directors' and officers' insurance premiums, a decrease of $0.3 million in personnel costs and a decrease of $0.4 million in non-cash share-based compensation.

Financial Expense, Net

Financial expense, net changed by $0.1 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022.

Net loss

Net loss decreased by $11.8 million for the six months ended June 30, 2023, compared to the six months ended June 30, 2022. This decrease was primarily related to the decrease in research and development, net of $9.3 million, a decrease in general and administrative of $1.6 million, and a decrease in marketing and business development costs of $1.0 million offset by an increase in financial expense of $0.1 million.

Qualitative and Quantitative Disclosures about Market Risk

Foreign Currency Exchange Risk

We operate primarily in Israel, and approximately 50% of our expenses are denominated in NIS. We are therefore exposed to market risk, which represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We are subject to fluctuations in foreign currency rates in connection with these arrangements. Changes of 5% and 10% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately 1.2% and 2.3%, respectively, during the six months ended June 30, 2023.

We currently partially hedge our foreign currency exchange rate risk to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

Interest Rate Risk

At present, our investments consist primarily of cash and cash equivalents and short-term deposits. We may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any.

Inflation-Related Risks

Inflation generally affects us by increasing our NIS-denominated expenses, including salaries and benefits, as well as facility rental costs and payment to local suppliers. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the six months ended June 30, 2023, but we continue to monitor these closely.

JOBS Act Transition Period

Section 107 of the Jumpstart Our Business Startups Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult.

B. Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred operating losses and negative cash flows from our operations. Prior to our initial public offering, or IPO, we funded our operations primarily through the sale of equity securities and convertible debt.

On April 5, 2022, we entered into a Loan Agreement, or the Loan Agreement, for up to $15 million with Kreos Capital VI (Expert Fund) LP, or Kreos. The Loan Agreement is comprised of three tranches in the amount of $10.0 million, $2.5 million, and $2.5 million, respectively. Drawdown of the first tranche was available upon the execution of the Loan Agreement. The second tranche of $2.5 million was available after we met the second tranche milestone in May 2022. The third and final tranche of $2,500,000 will not be drawn since the third tranche milestone has not been met.

The first tranche in the amount of $10 million was drawn on April 26, 2022. The issuance costs due to the Loan Agreement amounted to $0.2 million and the second tranche in the amount of $2.5 million was drawn on July 19, 2022.

The Loan Agreement provides for interest-only repayments of the first tranche until December 31, 2022, followed by 36 equal monthly repayments of principal and interest. For the second tranche, which was drawn in July 2022 we will make repayments of interest only until August 31, 2023, followed by 33 equal monthly repayments of principal and interest. The senior secured loan initially bears interest at a rate of 9.25%. The loan is prepayable in full, at any time at our option. The loan is secured by our owned equipment, intellectual property and all shares we hold in PolyPid Inc. and PolyPid Pharma SRL, and we paid a customary fee to Kreos for the establishment of the loan. Additionally, PolyPid Inc. entered into a guaranty agreement with Kreos, all as security for monies borrowed by us under the Loan Agreement. On March 29, 2023, we entered into an amendment to the Loan Agreement. Pursuant to this amendment, 70% of the remaining principal and interest repayments will be delayed and repaid on a monthly equal basis from August 2024 to May 2026. The amended secured loan now bears interest at a rate of 10.00%, and we will pay a restructuring fee to Kreos consisting of 1.00% on close of the amendment and an incremental 3.00% at maturity. In return for this additional deferral of repayment, Kreos has the right to receive a potential claw back payment on account of the then outstanding principal amount. This claw back mechanism will be triggered by additional incoming funds from future partnership agreement or additional financing. If triggered, the minimum claw back to be paid is $1.5 million but will not exceed $3 million. Further, the outstanding warrants Kreos received (as described below) were repriced to have an exercise price of $0.42 per each warrant share.

As part of the line of credit, we issued to Kreos 194,742 warrants. Such warrants are 7-year warrants to purchase our Ordinary Shares equal to 8% of the amount of each borrowed tranche, with an exercise price of $5.14 per share. Pursuant to the March 2023 amendment, the outstanding warrants Kreos received were repriced to have an exercise price of $0.42 per each warrant share. The Loan Agreement contains customary affirmative and restrictive covenants and representations and warranties. The expiration date for each warrant issued will be seven years from the issuance date.

In July 2021, we entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or the Agent, pursuant to which we may offer and sell, from time to time, our Ordinary Shares, through the Agent in an at the market offering, or the ATM, as defined in Rule 415(a)(4) under the Securities Act, for an aggregate offering price of up to $45 million. On May 19, 2023, the aggregate offering price was reduced to $8,706,775 due to applicable securities law restrictions resulting from a decrease in the value of the public float of our Ordinary Shares. During the six months ended June 30, 2023, we sold 1,949,029 Ordinary Shares under the ATM for a total amount of $2.3 million, with issuance costs in the amount of $0.1 million.

In March 2023, we completed a public offering, pursuant to which we sold 14,660,000 Ordinary Shares at a public offering price of $0.42 per share, for total gross proceeds of $6.2 million, or the Offering. In addition, we granted to the underwriter a 30-day option to purchase up to an additional 15% of the Ordinary Shares offered in the Offering at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option in full at the closing of the Offering. The securities were offered by us pursuant to a "shelf" registration statement on Form F-3. Concurrently with the Offering, we entered into a private placement with some of our existing shareholders, pursuant to which we issued pre-funded warrants, or the Pre-Funded Warrants, to acquire an aggregate of up to 10,357,139 Ordinary Shares for total gross proceeds of $4.4 million. The exercise price per Pre-Funded Warrant is $0.0001 per Ordinary Share. On May 11, 2023, the Pre-Funded Warrants were fully exercised on a cashless basis into 10,354,532 Ordinary Shares.

As of June 30, 2023, we had $15.1 million in cash, cash equivalents and short-term deposits.

Cash Flows

The following table provides information regarding our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2022	**2023**
	(in thousands)	
Net cash used in operating activities	$ (20,342)	$ (8,281)
Net cash provided by (used in) investing activities	9,060	(7,863)
Net cash provided by financing activities	13,255	10,976
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,973	$ (5,168)

Operating Activities

Net cash used in operating activities related primarily to our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net loss for non-cash items mainly included depreciation, remeasurement of pre-funded warrants and share-based compensation.

Net cash used in operating activities was $8.3 million for the six months ended June 30, 2023, as compared to $20.3 million for the six months ended June 30, 2022. This decrease was primarily related to the completion of SHIELD I Phase 3 clinical trials in abdominal (soft tissue) surgery.

Investing Activities

Net cash provided by/used in investing activities related primarily to the purchase and release of short-term and long-term deposits and the acquisition of laboratory equipment, office equipment and furniture and leasehold improvements.

Net cash used in investing activities was $7.9 million for the six months ended June 30, 2023, as compared to net cash provided by investing activities of $9.1 million for the six months ended June 30, 2022. This change in net cash used in investing activities primarily related to the purchase of short-term deposits in the 2023 period.

Financing Activities

Net cash provided by financing activities was $11.0 million for the six months ended June 30, 2023, as compared to $13.3 million for the six months ended June 30, 2022. The decrease in net cash provided by financing activities is primarily related to the net proceeds from the loan provided by Kreos and offset by the net proceeds from the March 2023 Offering and private placement.

We have registered up to $200,000,000 of our Ordinary Shares on a Registration Statement on Form F-3 (File No. 333-257651), or the F-3. The Ordinary Shares that may be offered, issued and sold under the Sales Agreement prospectus, as supplemented, are included in the $200,000,000 of securities that may be offered, issued and sold by us under the F-3. Upon termination of the Sales Agreement, any portion of the amount included in the Sales Agreement prospectus of the F-3 that is not sold pursuant to the Sales Agreement will be available for sale in other offerings pursuant to the F-3.

Current Outlook

To date, we have not generated any revenues from the commercial sale of our product candidates, and we do not expect to generate revenue for at least the next few years. We expect to continue to incur expenses in connection with our ongoing activities, particularly as we continue to conduct clinical trials and seek marketing approval for our product candidates, and as we continue the research and development of our other existing and future product candidates. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

We expect that our existing cash and cash equivalents and short-term deposits will enable us to fund our operating expenses and capital expenditure requirements into late first quarter of 2024. We anticipate that we will need to raise additional capital in order to complete our clinical and regulatory program for D-PLEX$_{100}$ towards potential NDA submission, including the SHIELD II clinical trial, as well as continue to invest in the research and development of OncoPLEX and any other future product candidates. If we are unable to raise additional capital when desired, our business, operating results, and financial condition would be adversely affected, and there is substantial doubt about our ability to continue as a going concern. We have a shareholders' equity of $8.3 million as of June 30, 2023, and negative operating cash flows in recent years. We expect to continue incurring losses and negative cash flows from operations until our products reach commercial profitability. Our plans to reduce the going concern risk include the continued commercialization of our products, maintaining cost efficiency and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing clinical trial;
- the costs, timing and outcome of regulatory review of D-PLEX$_{100}$ and any future product candidates;
- the costs and timing of establishing and validating manufacturing processes and facilities for development and commercialization of D-PLEX$_{100}$ and any future product candidates, if approved, including our manufacturing facility;

- the number and development requirements of any future product candidates that we may pursue;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payors, including government programs and managed care organizations, and competition;

- our ability to establish and maintain collaborations with biopharmaceutical companies on favorable terms, if at all;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and

- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting clinical trials and preclinical studies is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for few years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, including pursuant to the ATM, debt financings, grants, collaborations, strategic alliances and licensing arrangements. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

5.C Research and development, patents and licenses, etc.

A comprehensive discussion of our research and development, patents and licenses, etc., is included in “Item 5. Operating and Financial Review and Prospects - Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in our Annual Report.

5.D Trend Information

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for at least the next few years. From inception through June 30, 2023, we incurred $143.2 million in research and development expenses, net to advance the development of our clinical-stage product candidates, as well as other preclinical research and development programs. We expect to continue to incur expenses in connection with our ongoing activities, particularly as we continue to conduct clinical trials and seek marketing approval for our product candidates, and as we continue the research and development of our other existing and future product candidates. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. For a description of additional factors that may affect our future performance, please see “Item 5. Operating and Financial Review and Prospects— B. Liquidity and Capital Resources— Current Outlook.”

5.E Critical Accounting Estimates

The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, obligations, income and expenses during the reporting periods. In addition to our accounting estimate used in line of credit discussed below, for a comprehensive discussion of our critical accounting estimates please see “Item 5. Operating and Financial Review and Prospects - Management’s Discussion and Analysis of Financial Condition and Results of Operations – E. Critical Accounting Estimates” section in our Annual Report.