
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 2024 (Report No. 3)

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 "Company"): (i) Unaudited Interim Condensed Consolidated Financial Statements as of June 30, 2024, 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, 2024, which is attached hereto as Exhibit 99.2.

The contents of this Form 6-K are incorporated by reference into the Company's registration statements on Form F-3 (File No. [333-276826](#) and File No. [333-280658](#)) and Form S-8 (File No. [333-239517](#), File No. [333-271060](#), File No. [333-277703](#) and File No. [333-280662](#)) 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and Exchange Commission to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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, 2024.
99.2	PolyPid Ltd.'s Management's Discussion and Analysis of Financial Condition and Results of Operation for the Six Months Ended June 30, 2024.
101	The following financial information from the Registrant's Unaudited Interim Condensed Financial Statements as of June 30, 2024, 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 (Deficit); (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 14, 2024

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

**POLYPID LTD.
AND ITS SUBSIDIARIES**

**INTERIM CONDENSED CONSOLIDATED
FINANCIAL STATEMENTS**

AS OF JUNE 30, 2024

U.S. DOLLARS IN THOUSANDS

UNAUDITED

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INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30, 2024	December 31, 2023
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,076	\$ 5,309
Restricted deposits	163	300
Short-term deposits	6,271	-
Prepaid expenses and other current assets	268	458
Total current assets	9,778	6,067
LONG-TERM ASSETS:		
Property and equipment, net	6,813	7,621
Operating lease right-of-use assets	2,679	1,597
Other long-term assets	257	87
Total long-term assets	9,749	9,305
Total assets	\$ 19,527	\$ 15,372

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, 2024	December 31, 2023
	<u>Unaudited</u>	<u>Audited</u>
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current maturities of long-term debt	\$ 5,437	\$ 4,003
Accrued expenses and other current liabilities	2,984	1,971
Trade payables	992	772
Current maturities of operating lease liabilities	873	540
<u>Total current liabilities</u>	<u>10,286</u>	<u>7,286</u>
LONG-TERM LIABILITIES:		
Long-term debt	3,127	6,379
Deferred revenues	2,548	2,548
Long-term operating lease liabilities	1,594	857
Other liabilities	371	398
<u>Total long-term liabilities</u>	<u>7,640</u>	<u>10,182</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY (DEFICIT):		
Ordinary shares with no par value - Authorized: 107,800,000 shares at June 30, 2024 (unaudited) and December 31, 2023; Issued and outstanding: 4,797,252 and 1,653,559 shares at June 30, 2024 (unaudited) and December 31, 2023, respectively	-	-
Additional paid-in capital	252,652	236,213
Accumulated deficit	(251,051)	(238,309)
<u>Total shareholders' equity (deficit)</u>	<u>1,601</u>	<u>(2,096)</u>
<u>Total liabilities and shareholders' equity</u>	<u>19,527</u>	<u>15,372</u>

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2024	2023	2024	2023
<i>Operating expenses:</i>				
Research and development, net	\$ 9,810	\$ 7,754	\$ 4,760	\$ 3,960
Marketing and business development	501	742	265	357
General and administrative	2,111	3,112	1,096	1,503
Operating loss	12,422	11,608	6,121	5,820
Financial expense, net	311	262	171	7
Loss before income tax	12,733	11,870	6,292	5,827
Income tax expenses	9	35	2	10
Net loss	\$ 12,742	\$ 11,905	\$ 6,294	\$ 5,837
Basic and diluted loss per ordinary share *)	\$ 2.62	\$ 10.85	\$ 1.25	\$ 3.95
Weighted average number of ordinary shares used in computing basic and diluted loss per share *)	4,858,158	1,097,015	5,024,871	1,479,449

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split effected on September 18, 2023 (see Note 1b).

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

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

Three Months Ended June 30, 2024	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of March 31, 2024	4,797,252	\$ 251,902	\$ (244,757)	\$ 7,145
Share-based compensation	-	750	-	750
Net loss	-	-	(6,294)	(6,294)
Balances as of June 30, 2024 (unaudited)	<u>4,797,252</u>	<u>\$ 252,652</u>	<u>\$ (251,051)</u>	<u>\$ 1,601</u>
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	1,297,682	\$ 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	345,151	-	-	-
Net loss	-	-	(5,837)	(5,837)
Balances as of June 30, 2023 (unaudited)	<u>1,642,833</u>	<u>\$ 234,696</u>	<u>\$ (226,349)</u>	<u>\$ 8,347</u>

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split effected on September 18, 2023 (see Note 1b).

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

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

Six Months Ended June 30, 2024	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balances as of January 1, 2024	1,653,559	\$ 236,213	\$ (238,309)	\$ (2,096)
Share-based compensation	-	1,440	-	1,440
Issuance of Ordinary shares, warrants and pre-funded warrants, net (1)	3,143,693	14,999	-	14,999
Net loss	-	-	(12,742)	(12,742)
Balances as of June 30, 2024 (unaudited)	<u>4,797,252</u>	<u>\$ 252,652</u>	<u>\$ (251,051)</u>	<u>\$ 1,601</u>

(1) Net of issuance cost of \$1,217.

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	669,605	\$ 220,273	\$ (214,444)	\$ 5,829
Share-based compensation	-	1,970	-	1,970
Issuance of Ordinary shares, net (2)	626,934	8,627	-	8,627
Issuance of pre-funded warrants, net (3)	-	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	345,151	-	-	-
Exercise of options	1,143	9	-	9
Net loss	-	-	(11,905)	(11,905)
Balances as of June 30, 2023 (unaudited)	<u>1,642,833</u>	<u>\$ 234,696</u>	<u>\$ (226,349)</u>	<u>\$ 8,347</u>

(2) Net of issuance cost of \$734.

(3) Net of issuance cost of \$362.

*) Prior period results have been retroactively adjusted to reflect the 1-for-30 reverse share split effected on September 18, 2023 (see Note 1b).

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

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

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

Year Ended December 31, 2023	Number of ordinary shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity (deficit)
Balances as of January 1, 2023	669,605	\$ 220,273	\$ (214,444)	\$ 5,829
Share-based compensation	-	3,391	-	3,391
Issuance of Ordinary shares, net (1)	637,660	8,723	-	8,723
Issuance of pre-funded warrants, net (2)	-	3,987	-	3,987
Modification of warrants	-	31	-	31
Reclassification of pre-funded warrants into liabilities	-	(2,106)	-	(2,106)
Reclassification of pre-funded warrants into equity	-	1,905	-	1,905
Cashless exercise of pre-funded warrants	345,151	-	-	-
Exercise of options	1,143	9	-	9
Net loss	-	-	(23,865)	(23,865)
Balances as of December 31, 2023	<u>1,653,559</u>	<u>\$ 236,213</u>	<u>\$ (238,309)</u>	<u>\$ (2,096)</u>

(1) Net of issuance costs of \$757.

(2) Net of issuance costs of \$362.

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,	
	2024	2023
	<u>Unaudited</u>	
<u>Cash flows from operating activities:</u>		
Net loss	\$ (12,742)	\$ (11,905)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation of property and equipment	827	913
Non-cash financial expenses, net	676	813
Remeasurement of warrants classified as a liability	-	(201)
Share-based compensation expenses	1,440	1,970
<i>Changes in assets and liabilities:</i>		
Prepaid expenses and other assets	188	950
Operating lease right-of-use-assets	400	539
Operating lease liabilities	(412)	(561)
Trade payables	220	(238)
Accrued expenses and other liabilities	909	(561)
Net cash used in operating activities	<u>(8,494)</u>	<u>(8,281)</u>
<u>Cash flows from investing activities:</u>		
Investment in bank deposits	(14,691)	(17,600)
Proceeds from bank deposits	8,500	9,932
Purchase of property and equipment	(19)	(195)
Net cash used in investing activities	<u>(6,210)</u>	<u>(7,863)</u>
<u>Cash flows from financing activities:</u>		
Proceeds from issuance of Ordinary shares, warrants and pre-funded warrants, net	15,076	12,614
Payments due to long-term debt	(2,574)	(1,522)
Payment of fees due to modification of debt	-	(125)
Proceeds from exercise of options	-	9
Net cash provided by financing activities	<u>12,502</u>	<u>10,976</u>
Decrease in cash, cash equivalents and restricted deposits	(2,202)	(5,168)
Cash, cash equivalents and restricted deposits at the beginning of the period	<u>5,686</u>	<u>9,142</u>
Cash, cash equivalents and restricted deposits at the end of the period	<u>\$ 3,484</u>	<u>\$ 3,974</u>

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,	
	2024	2023
	Unaudited	
Non-cash activities:		
Modification of warrants	\$ -	\$ 31
Credit line derivative	\$ -	\$ 127
Issuance costs	\$ 77	\$ -
Right-of-use asset recognized with corresponding lease liability	\$ 1,482	\$ -
Supplemental disclosures of cash flows:		
Interest paid	\$ 471	\$ 492
Supplemental disclosures of cash flow information:		
Cash and cash equivalents	\$ 3,076	\$ 3,396
Restricted deposits	163	503
Restricted deposits included in other long-term assets	245	75
Cash, cash equivalents and restricted deposits at the end of the period	\$ 3,484	\$ 3,974

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**U.S. dollars in thousands (except share and per share data)****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-PLEX₁₀₀, which incorporates an antibiotic for the prevention of surgical site infections (“SSIs”) in bone and soft tissue. Through June 30, 2024, 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. On September 18, 2023, the Company’s board of directors approved 1-for-30 reverse share split. No fractional shares were issued, and no cash or other consideration was paid as a result of the reverse share split. Instead, the Company issued one additional whole share of the post-reverse share split Ordinary share to any shareholder who otherwise would have received a fractional share as a result of the reverse share split. The amount of authorized Ordinary shares was not affected. All issued and outstanding share and per share amounts included in the accompanying consolidated financial statements have been adjusted to reflect this reverse share split for all periods presented.
- c. 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-PLEX₁₀₀ (“SHIELD”) I Phase 3 trial. SHIELD I did not achieve its primary endpoint. That said, in a pre-specified subgroup analysis requested by the United States Food and Drug Administration (“FDA”) of a total of 423 subjects with large incisions (>20 centimeters), the local administration of D-PLEX₁₀₀ resulted in a significant reduction of 54 percent in the primary endpoint, compared to SoC alone (p=0.0032). The FDA acknowledged that the SHIELD I results may provide supportive evidence on this population and recommended that the Company conduct an additional study to support a potential NDA submission. The FDA stated that the ongoing SHIELD II study could potentially serve as such a study. The Company resumed recruitment into the SHIELD II trial in June 2023.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 1:- GENERAL (CONT.)

- d. 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, 2024, the Company's cash, cash equivalents and short-term deposits amounted to a total of \$9,347. During the six-month period ended June 30, 2024, the Company incurred a loss of \$12,742 and had negative cash flows from operating activities of \$8,494. In addition, the Company had an accumulated deficit of \$251,051 as of June 30, 2024.

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, 2023, filed with the Securities and Exchange Commission on March 6, 2024.

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.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**U.S. dollars in thousands (except share and per share data)****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

a. Basis of presentation and summary of significant accounting policies: (Cont.)

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, 2023 (the "2023 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, 2023.

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 deposits, short-term deposits, long-term debt, 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.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

- e. Recently issued accounting pronouncements, not yet adopted:

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures”, which requires public entities to disclose information about their reportable segments’ significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in Accounting Standards Codification (“ASC”) 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

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 2024 and 2027.

On January 14, 2024, the Company entered into a new lease agreement for one of its premises, with the lease term extending through July 2027.

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 comprise 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, 2024:

Weighted average remaining lease term (years)	2.97
Weighted average discount rates	10.40%

For the six months ended June 30, 2024, the total operating lease cost and cash payments for operating leases were as follows:

Operating lease cost	\$ 526
Cash payments for operating leases	\$ 419

Minimum lease payments over the remaining lease periods as of June 30, 2024, are as follows:

The remainder of 2024	\$ 481
2025	958
2026	919
2027	455
	<hr/>
Total undiscounted lease payments	2,813
Less - imputed interest	(346)
	<hr/>
Present value of lease liabilities	<u>\$ 2,467</u>

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 4:- LINE OF CREDIT ARRANGEMENT

Further to the discussion in Note 7 in the 2023 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”).

On January 9, 2024, the Company repaid \$1,494 due to the included claw back mechanism in the Credit Line.

During the six-month periods ended on June 30, 2024 and 2023, the Company recognized \$756 and \$813 of interest expenses related to the Credit Line, respectively, which were included as part of financial expenses in the Company’s statements of operations.

NOTE 5:- COMMITMENTS AND CONTINGENT LIABILITIES

In connection with its research and development programs, through June 30, 2024, 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 Secured Overnight Financing Rate.

For the six-month period ended June 30, 2024, no new participation payments were received.

Through June 30, 2024, no royalties have been paid or accrued.

NOTE 6:- SHAREHOLDERS’ EQUITY (DEFICIT)

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

	<u>June 30, 2024</u>		<u>December 31, 2023</u>	
	<u>Unaudited</u>		<u>Audited</u>	
	<u>Authorized</u>	<u>Issued and outstanding</u>	<u>Authorized</u>	<u>Issued and outstanding</u>
	<u>Number of shares</u>			
Ordinary shares	<u>107,800,000</u>	<u>4,797,252</u>	<u>107,800,000</u>	<u>1,653,559</u>

b. Financing rounds:

On March 29, 2023, the Company entered into a private placement of unregistered pre-funded warrants to purchase up to 345,238 Ordinary shares (the “PFW”), at a price of \$12.60 per PFW with certain of the Company’s existing shareholders. The PFWs have an exercise price of \$0.003 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 561,967 Ordinary shares (inclusive of 73,300 Ordinary shares pursuant to the full exercise of an over-allotment option granted to the underwriters), at a public offering price of \$12.60 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 \$665.

Following the Public Offering, the Company did not have a sufficient number of authorized Ordinary shares to cover 167,115 PFWs, and as a result, in accordance with ASC 815, these PFWs, which amounted to \$2,106, were classified as a liability at fair value.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIT) (CONT.)

b. Financing rounds: (Cont.)

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 345,151 Ordinary shares on a cashless basis.

On January 4, 2024, the Company entered into a definitive securities purchase agreement for a private placement financing, led by leading U.S. life sciences-focused investors and certain existing investors. Under the securities purchase agreement, the investors purchased 3,143,693 of the Company's Ordinary shares at a purchase price of \$4.81 per share, pre-funded warrants to purchase up to 227,619 Ordinary shares at an exercise price of \$0.0001 per share and warrants to purchase up to 3,371,312 Ordinary shares at an exercise price of \$5.50 per share. The warrants expire upon the earlier of two years from the date of issuance and 10 trading days following the Company's announcement of the positive recommendation by Data Safety Monitoring Board regarding the Company's unblinded interim analysis in its SHIELD II Phase 3 trial of D-PLEX₁₀₀ resulting in the stopping of the trial due to positive efficacy. The proceeds to the Company amounted to \$14,999, net of issuance cost. Exercise of the warrants in full would result in an additional \$18,542 in proceeds to the Company. The closing of the offering occurred on January 9, 2024.

In accordance with ASC 480 and ASC 815, the pre-funded warrants and the warrants were qualified for equity accounting. The fair value for warrant to purchase an ordinary share is \$4.52.

The Black-Scholes option pricing model assumptions used to value the warrants at the grant date are presented in the following table:

Dividend yield (%)	0
Expected volatility (%)	117.40-134.00
Risk-free interest rate (%)	4.36-5.08
Expected term (in years)	0.68-2.00

c. Share option plan:

The Company's board of directors authorizes option grants through its 2012 Share Option Plan to officers, directors, advisors, management and other key employees. The options granted generally have a four-year vesting period and expire ten years after the date of grant. Options granted under the Company's option plan that are canceled or forfeited before expiration become available for future grant.

On May 6, 2024, the Company's board of directors approved to increase the Company's options pool by an additional 2,000,000 options from 312,403 to 2,312,403.

As of June 30, 2024, 867,124 of the Company's options were available for future grants.

During the first quarter of 2023, the Company decreased the exercise price of 67,385 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 \$23.07 (the "Repricing"). Following the Repricing, the Company accounted for an incremental value in the total amount of \$562, of 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.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIT) (CONT.)

c. Share option plan: (Cont.)

On May 5, 2023, the Company's board of directors also approved a similar exercise price decrease of 17,417 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 and non-employees, including Directors, under the Company's 2012 Share Option Plan as of and for the six-month period ended June 30, 2024, and changes during the period then ended is presented below (unaudited):

	<u>Number of options</u>	<u>Weighted average exercise price</u>	<u>Aggregate intrinsic value</u>	<u>Weighted average remaining contractual life (years)</u>
Outstanding at beginning of period	254,436	\$ 22.41	\$ -	8.24
Granted	1,199,975	\$ 4.64		
Forfeited and expired	<u>(14,706)</u>	\$ 51.53		
Outstanding at end of period	<u>1,439,705</u>	\$ 7.30	\$ -	9.52
Exercisable options	<u>73,501</u>	\$ 38.73	\$ -	5.30
Vested and expected to vest	<u>1,439,705</u>	\$ 7.30	\$ -	9.44

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, 2024:

Dividend yield (%)	0
Expected volatility (%)	97.10-98.39
Risk-free interest rate (%)	4.43-5.06
Expected term (in years)	0.5-6.1

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

	<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>
	<u>Unaudited</u>	
Research and development	\$ 849	\$ 1,022
Marketing and business development	144	191
General and administrative	<u>447</u>	<u>757</u>
	<u>\$ 1,440</u>	<u>\$ 1,970</u>

As of June 30, 2024, there were unrecognized compensation costs of \$6,305, which are expected to be recognized over a weighted average period of approximately 3.07 years.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 6:- SHAREHOLDERS' EQUITY (DEFICIT) (CONT.)

c. Share option plan: (Cont.)

On May 6, 2024, the Board of directors granted a total of 280,000 milestone-based options to the Company's officers (collectively, the "Milestone-Based Options"). The milestone condition was set as either the interim analysis outcome of early stopping of the Company's SHIELD II Phase 3 trial of D-PLEX₁₀₀ for efficacy or top-line results (primary endpoint) with overall alpha level of up to (and including) 5%.

The average exercise price for Milestone-Based Options is \$4.64.

As of June 30, 2024, the milestone condition is not probable of being achieved; therefore, no compensation costs were recognized.

d. Warrants and pre-funded warrants:

As of June 30, 2024, all warrants are exercisable into Ordinary shares, in which the outstanding issued warrants as of June 30, 2024, were as follows (unaudited):

<u>Grant date</u>	<u>Warrants outstanding as of June 30, 2024</u>	<u>Average Exercise price per share (\$)</u>	<u>Warrants exercisable as of June 30, 2024</u>	<u>Exercisable through</u>
September 2020	597	\$ 480.00	597	September 2024
April 2022	5,193	\$ 12.60	5,193	April 2029
July 2022	1,298	\$ 12.60	1,298	April 2029
January 2024	3,371,312	\$ 5.50	3,371,312	January 2026 *)
January 2024	227,619	\$ 0.0001	227,619	No maturity date *)
	<u>3,606,019</u>		<u>3,606,019</u>	

No Warrants were exercised during the six-month period ended June 30, 2024.

*) See note 6b.

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:

	<u>Six Months Ended June 30,</u>		<u>Three Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
	<u>Unaudited</u>			
<i>Numerator:</i>				
Allocation of loss attributable to ordinary shareholders	<u>\$ 12,742</u>	<u>\$ 11,905</u>	<u>\$ 6,294</u>	<u>\$ 5,837</u>
<i>Denominator:</i>				
Weighted average Ordinary shares outstanding	<u>4,858,158</u>	<u>1,097,015</u>	<u>5,024,871</u>	<u>1,479,449</u>
Basic and diluted loss per share	<u>\$ 2.62</u>	<u>\$ 10.85</u>	<u>\$ 1.25</u>	<u>\$ 3.95</u>

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

NOTE 7:- BASIC AND DILUTED LOSS PER SHARE (CONT.)

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,	
	2024	2023
	Unaudited	
Ordinary share options	73,501	69,277
Warrants	3,606,019	13,775
	<u>3,679,520</u>	<u>83,052</u>

NOTE 8:- SUBSEQUENT EVENTS

- On July 2, 2024, the shareholders meeting approved a grant of 198,000 options to the Company's Chief Executive Officer and 132,600 milestone-based options. The exercise price for both grants was set at \$4.64.
- On August 1, 2024, the Company entered into a definitive securities purchase agreement for a private placement financing. Under the securities purchase agreement, the investors have agreed to purchase 2,235,457 of the Company's Ordinary shares, or pre-funded warrants in lieu thereof, at a purchase price of \$3.61 per share and warrants to purchase up to 1,676,588 Ordinary shares at an exercise price of \$3.61 per share. The warrants expire upon the earlier of two years from the date of issuance and 10 trading days following the Company's announcement of the recommendation by Data Safety Monitoring Board regarding the Company's unblinded interim analysis in its SHIELD II Phase 3 trial of D-PLEX₁₀₀ resulting in either the stopping of the trial due to positive efficacy, or continuation to planned patient recruitment (up to 630 subjects). The closing of the offering occurred on August 6, 2024. The net proceeds to the Company amounted to approximately \$7,500. Exercise of the warrants in full would result in an additional \$6,052 in proceeds to the Company.
- Further to the discussed in Note 4, on August 1, 2024, the Company entered into a second amendment (the "Second Amendment") to the Credit Line. Pursuant to the Second Amendment, 60% of the remaining principal and interest repayments under the Credit Line will be delayed and repaid on a monthly equal basis from April 1, 2025. The amended secured loan now bears interest at a rate of 12.00%, and the Company will pay a restructuring fee to Kreos of \$125. 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 agreements or additional financing. The claw back to be paid will not exceed \$4,500, out of which \$1,500 was already paid.

As part of the Second Amendment, the Company issued to Kreos a warrant to purchase 40,000 Ordinary shares of the Company at an exercise price of \$3.61 per share. The expiration date of the warrant issued is seven years from the issuance date.

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

As of June 30, 2024, 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 trials in order to continue development of our product candidates;
 - the outcomes of our anticipated interim analysis in our 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;
 - the potential impact of the COVID-19 pandemic on the territories 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;
 - 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, 2023, or our Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on March 6, 2024, 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.

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, 2024, 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 losses for the six months ended June 30, 2023 and 2024 were \$11.6 million and \$12.4 million, respectively. As of June 30, 2024, we had an accumulated deficit of \$251.1 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-PLEX₁₀₀, including our SHIELD II Phase 3 clinical trial for the prevention of SSIs in patients undergoing abdominal colorectal surgery with large incisions;
- file New Drug Applications, or NDAs, seeking regulatory approval for D-PLEX₁₀₀ 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-PLEX₁₀₀ 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.

Results of Operations

Comparison of the Six months Ended June 30, 2023 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2024:

	Six months Ended June 30,	
	2023	2024
	(in thousands)	
Research and development, net	\$ 7,754	\$ 9,810
Marketing and business development	742	501
General and administrative	3,112	2,111
Operating loss	11,608	12,422
Financial expense, net	262	311
Loss before income tax	\$ 11,870	\$ 12,733
Income tax expense	35	9
Net loss	<u>\$ 11,905</u>	<u>\$ 12,742</u>

Research and Development, Net

Research and development, net increased by \$2.1 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. This increase was primarily related to an increase of \$2.7 million in costs related to the ongoing SHIELD II trial and an increase of \$0.1 million in our manufacturing facility expenses. These increases were offset by a decrease of \$0.4 million in research and development costs related to D-PLEX₁₀₀ and OncoPLEX, a decrease of \$0.1 million in personnel costs and a decrease of \$0.2 million in non-cash share-based compensation.

Marketing and business development

Marketing and business development decreased by \$0.2 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. This decrease was primarily related to a decrease of \$0.1 million in pre-commercialization activities for the product candidate D-PLEX₁₀₀, and a decrease of \$0.1 million in personnel costs and non-cash share-based compensation.

General and Administrative

General and administrative decreased by \$1.0 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. This decrease was primarily related to a decrease of \$0.2 million in directors' and officers' insurance premiums, a decrease of \$0.3 million in personnel costs and a decrease of \$0.3 million in non-cash share-based compensation and a decrease of \$0.2 million in professional services costs.

Financial Expense, Net

Financial expense, net generally remained unchanged for the six months ended June 30, 2024, compared to the six months ended June 30, 2023.

Net loss

Net loss increased by \$0.8 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. This increase was primarily related to the increase in research and development, net of \$2.1 million, offset by a decrease in general and administrative of \$1.0 million and a decrease in marketing and business development costs of \$0.2 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 2.4%, respectively, during the six months ended June 30, 2024.

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, 2024, 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.

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.

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 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 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 third and final tranche of \$2.5 million will not be drawn since the third tranche milestone has not been met.

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, 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. 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 and August 1, 2024, we entered into amendments to the Loan Agreement. Pursuant to the most recent amendment, 60% of the remaining principal and interest repayments will be delayed and repaid on a monthly equal basis from April 2025. The amended secured loan now bears interest at a rate of 12.00%, and we will pay a restructuring fee to Kreos of \$125,000. 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. The claw back will not exceed \$4.5 million. As of June 30, 2024, the Company has paid \$1.5 million of the claw back.

As part of the recent amendment, we issued to Kreos a warrant to purchase 40,000 ordinary shares of the Company at an exercise price of \$3.61 per share. Following the execution of the recent amendment, Kreos holds warrants to purchase a total of 46,491 ordinary shares of the Company, as follows: (i) 6,491 shares at an exercise price of \$12.60 per share; and (ii) 40,000 shares at an exercise price of \$3.61 per share. The expiration date for each warrant issued is seven years from the respective issuance date.

In March 2023, we completed an offering, or the March 2023 Offering, pursuant to which we sold 488,667 Ordinary Shares at a public offering price of \$12.60 per share, for total gross proceeds of \$6.2 million. 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” under the F-3. Concurrently with the March 2023 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 345,238 Ordinary Shares for total gross proceeds of \$4.4 million. The exercise price per Pre-Funded Warrant is \$0.003 per Ordinary Share. Exercise of the Pre-Funded Warrants was subject to an increase in our authorized share capital. We held an annual and extraordinary general meeting of shareholders on May 5, 2023 under which we obtained shareholders’ approval to increase the number of our authorized share capital. On May 11, 2023, all of the Pre-Funded Warrants were exercised into 345,151 Ordinary shares on a cashless basis.

On January 4, 2024, we entered into a definitive securities purchase agreement, or the January Securities Purchase Agreement, for a private placement financing. Pursuant to the January Securities Purchase Agreement, on January 9, 2024, certain investors purchased 3,143,693 of our Ordinary Shares at a purchase price of \$4.81 per share, pre-funded warrants to purchase up to 227,619 Ordinary Shares at an exercise price of \$0.0001 and warrants to purchase up to 3,371,312 Ordinary Shares at an exercise price of \$5.50 per share. The pre-funded warrants do not expire and the warrants expire upon the earlier of two years from the date of issuance and 10 trading days following the Company’s announcement of the positive recommendation by Data Safety Monitoring Board regarding the Company’s unblinded interim analysis in the SHIELD II Phase 3 trial of D-PLEX₁₀₀ resulting in the stopping of the trial due to positive efficacy. The offering resulted in net proceeds of approximately \$15.0 million. Exercise of the warrants in full would result in an additional \$18.5 million in gross proceeds. We intend to use the net proceeds from the sale of the securities for our ongoing SHIELD II phase 3 clinical trial for the prevention of SSI in patients undergoing abdominal colorectal surgery with large incisions, working capital and general corporate purposes.

On August 1, 2024, we entered into a definitive securities purchase agreement, or the August Securities Purchase Agreement, for a private placement financing, or the August 2024 Private Placement. Pursuant to the August Securities Purchase Agreement, on August 6, 2024, certain investors purchased 2,006,226 of our Ordinary Shares at a purchase price of \$3.61 per share, pre-funded warrants to purchase up to 229,231 Ordinary Shares at an exercise price of \$0.0001 and warrants to purchase up to 1,676,588 Ordinary Shares at an exercise price of \$3.61 per share. The pre-funded warrants do not expire and the warrants expire upon the earlier of two years from the date of issuance and 10 trading days following our announcement of the recommendation by Data Safety Monitoring Board regarding our unblinded interim analysis in its SHIELD II Phase 3 trial of D-PLEX₁₀₀ resulting in either the stopping of the trial due to positive efficacy, or continuation to planned patient recruitment (up to 630 subjects). The offering resulted in net proceeds of approximately \$7.5 million. Exercise of the warrants in full would result in an additional \$6.1 million in gross proceeds. We intend to use the net proceeds from the sale of the securities for our ongoing SHIELD II phase 3 clinical trial for the prevention of surgical site infections in patients undergoing abdominal colorectal surgery, working capital and general corporate purposes.

As of June 30, 2024, we had \$9.3 million in cash and 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,	
	2023	2024
	(in thousands)	
Net cash used in operating activities	\$ (8,281)	\$ (8,494)
Net cash provided by (used in) investing activities	(7,863)	(6,210)
Net cash provided by financing activities	10,976	12,502
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (5,168)</u>	<u>\$ (2,202)</u>

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 \$8.5 million for the six months ended June 30, 2024, as compared to \$8.3 million for the six months ended June 30, 2023. This increase was primarily related to the ongoing SHIELD II Phase 3 clinical trials in abdominal colorectal surgery with large incisions.

Investing Activities

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

Net cash used in investing activities was \$6.2 million for the six months ended June 30, 2024, as compared to net cash used in investing activities of \$7.9 million for the six months ended June 30, 2023. This change in net cash used in investing activities primarily related to change in short-term deposits, net.

Net cash provided by financing activities was \$12.5 million for the six months ended June 30, 2024, as compared to \$11.0 million for the six months ended June 30, 2023. The increase in net cash provided by financing activities is primarily related to the net proceeds from the January 2024 Private Placement offset by the repayments of the loan provided by Kreos.

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 first quarter of 2025. We anticipate that we will need to raise additional capital in order to complete our clinical and regulatory program for D-PLEX₁₀₀ 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 had a shareholders' equity of \$1.6 million as of June 30, 2024, and negative operating cash flows in recent years. As of August 11, 2024, however, our shareholders' equity is approximately \$7 million following the completion of the August 2024 Private Placement. 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-PLEX₁₀₀ and any future product candidates;
- the costs and timing of establishing and validating manufacturing processes and facilities for development and commercialization of D-PLEX₁₀₀ 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, 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.

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.

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, 2024, we incurred \$161.4 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.”

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.