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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 2022 (Report No. 4)

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

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

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

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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, 2022, 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, 2022, 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. 333-257651) and [Form S-8](#) (File No. 333-239517), filed with the SEC, to be a part thereof from the date on which this Form 6-K is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

## EXHIBIT INDEX

**Exhibit No.**

99.1	<a href="#">PolyPid Ltd.'s Unaudited Interim Condensed Financial Statements as of June 30, 2022.</a>
99.2	<a href="#">PolyPid Ltd.'s Management's Discussion and Analysis of Financial Condition and Results of Operation for the Six Months Ended June 30, 2022.</a>
101	The following financial information from the Registrant's Unaudited Interim Condensed Financial Statements as of June 30, 2022, 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 10, 2022

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, 2022

UNAUDITED

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**INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS**

U.S. dollars in thousands

	June 30, 2022	December 31, 2021
	<u>Unaudited</u>	<u>Audited</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 11,640	\$ 9,819
Restricted cash	576	397
Short-term deposits	12,139	22,384
Prepaid expenses and other current assets	661	2,211
<u>Total current assets</u>	<u>25,016</u>	<u>34,811</u>
<b>LONG-TERM ASSETS:</b>		
Property and equipment, net	9,183	8,761
Other long-term assets	618	663
<u>Total long-term assets</u>	<u>9,801</u>	<u>9,424</u>
<u>Total assets</u>	<u>\$ 34,817</u>	<u>\$ 44,235</u>

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, 2022	December 31, 2021
	<u>Unaudited</u>	<u>Audited</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of long-term debt	\$ 2,168	\$ -
Trade payables	2,430	4,136
Accrued expenses and other current liabilities	4,106	3,940
<u>Total current liabilities</u>	<u>8,704</u>	<u>8,076</u>
<b>LONG-TERM LIABILITIES:</b>		
Long-term debt	6,919	-
Other liabilities	84	199
<u>Total long-term liabilities</u>	<u>7,003</u>	<u>199</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Ordinary shares with no par value - Authorized: 47,800,000 shares at June 30, 2022 (unaudited) and December 31, 2021 (audited); Issued and outstanding: 19,551,173 and 18,756,570 shares at June 30, 2022 (unaudited) and December 31, 2021 (audited), respectively	-	-
Additional paid-in capital	217,716	210,847
Accumulated deficit	(198,606)	(174,887)
<u>Total shareholders' equity</u>	<u>19,110</u>	<u>35,960</u>
<u>Total liabilities and shareholders' equity</u>	<u>\$ 34,817</u>	<u>\$ 44,235</u>

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,	
	2022	2021	2022	2021
<i>Operating expenses:</i>				
Research and development, net	\$ 17,095	\$ 13,460	\$ 8,398	\$ 7,442
Marketing and business development	1,698	1,391	923	739
General and administrative	4,723	4,576	2,243	2,449
Operating loss	23,516	19,427	11,564	10,630
Financial expense (income), net	203	(263)	281	(153)
Loss	\$ 23,719	\$ 19,164	\$ 11,845	\$ 10,477
Basic and diluted loss per Ordinary share	\$ 1.23	\$ 1.03	\$ 0.61	\$ 0.56
Weighted average number of Ordinary shares used in computing basic and diluted loss per share	19,222,423	18,685,906	19,505,246	18,747,967

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)

<b>Three Months Ended June 30, 2022</b>	<b>Number of Ordinary shares</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders' equity</b>
Balances as of March 31, 2022	19,470,757	\$ 215,606	\$ (186,761)	\$ 28,845
Share-based compensation	-	1,266	-	1,266
Issuance of 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)	<u>19,551,173</u>	<u>\$ 217,716</u>	<u>\$ (198,606)</u>	<u>\$ 19,110</u>

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

<b>Three Months Ended June 30, 2021</b>	<b>Number of Ordinary shares</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders' equity</b>
Balances as of March 31, 2021	18,745,142	\$ 207,120	\$ (140,973)	\$ 66,147
Share-based compensation	-	1,153	-	1,153
Exercise of options	11,428	62	-	62
Loss	-	-	(10,477)	(10,477)
Balances as of June 30, 2021 (unaudited)	<u>18,756,570</u>	<u>\$ 208,335</u>	<u>\$ (151,450)</u>	<u>\$ 56,885</u>

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)

<b>Six Months Ended June 30, 2022</b>	<b>Number of Ordinary shares</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders' equity</b>
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)	<u>19,551,173</u>	<u>\$ 217,716</u>	<u>\$ (198,606)</u>	<u>\$ 19,110</u>

(1) Net of issuance cost of \$162.

<b>Six Months Ended June 30, 2021</b>	<b>Number of Ordinary shares</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders' equity</b>
Balances as of January 1, 2021	18,494,739	\$ 205,063	\$ (132,286)	\$ 72,777
Share-based compensation	-	2,238	-	2,238
Exercise of warrants	184,473	632	-	632
Exercise of options	77,358	402	-	402
Loss	-	-	(19,164)	(19,164)
Balances as of June 30, 2021 (unaudited)	<u>18,756,570</u>	<u>\$ 208,335</u>	<u>\$ (151,450)</u>	<u>\$ 56,885</u>

<b>Year Ended December 31, 2021</b>	<b>Number of Ordinary shares</b>	<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total shareholders' equity</b>
Balances as of January 1, 2021	18,494,739	\$ 205,063	\$ (132,286)	\$ 72,777
Share-based compensation	-	4,750	-	4,750
Exercise of warrants	184,473	632	-	632
Exercise of options	77,358	402	-	402
Loss	-	-	(42,601)	(42,601)
Balances as of December 31, 2021 (audited)	<u>18,756,570</u>	<u>\$ 210,847</u>	<u>\$ (174,887)</u>	<u>\$ 35,960</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,	
	2022	2021
	<u>Unaudited</u>	
<b><u>Cash flows from operating activities:</u></b>		
Loss	\$ (23,719)	\$ (19,164)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property and equipment	805	547
Non-cash financial expenses, net	146	-
Share-based compensation expenses	2,539	2,238
<b><u>Changes in assets and liabilities:</u></b>		
Prepaid expenses and other assets	1,584	1,387
Trade payables	(1,748)	782
Accrued expenses and other liabilities	51	659
Net cash used in operating activities	<u>(20,342)</u>	<u>(13,551)</u>
<b><u>Cash flows from investing activities:</u></b>		
Short-term and long-term deposits, net	10,245	16,819
Purchase of property and equipment	(1,185)	(391)
Pre-payments for equipment	-	(787)
Net cash provided by investing activities	<u>9,060</u>	<u>15,641</u>
<b><u>Cash flows from financing activities:</u></b>		
Proceeds from issuance of Ordinary shares, net	3,754	-
Proceeds from long-term debt, net	9,331	-
Payments due to long-term debt	(406)	-
Proceeds from issuance of warrants	468	-
Proceeds from exercise of options	108	402
Proceeds from exercise of warrants	-	632
Net cash provided by financing activities	<u>13,255</u>	<u>1,034</u>
<b>Increase in cash, cash equivalents and restricted cash</b>	<b>1,973</b>	<b>3,124</b>
Cash, cash equivalents and restricted cash at the beginning of the period	<u>10,456</u>	<u>4,908</u>
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 12,429</u>	<u>\$ 8,032</u>
<b><u>Non-cash activities:</u></b>		
Property and equipment acquired by credit	<u>\$ 42</u>	<u>\$ -</u>
<b><u>Supplemental disclosures of cash flows:</u></b>		
Interest paid	<u>\$ 77</u>	<u>\$ -</u>
<b><u>Supplemental disclosures of cash flow information:</u></b>		
Cash and cash equivalents	\$ 11,640	\$ 7,448
Restricted cash	<u>789</u>	<u>584</u>
	<u>\$ 12,429</u>	<u>\$ 8,032</u>

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)**

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**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 (“APIs”) 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 in bone and soft tissue. Through June 30, 2022, 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 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. The Company’s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing; (ii) completion of all required clinical studies; (iii) the success of its research and development; activities; (iv) manufacturing of all required clinical and commercial production batches; (v) marketing approval by the relevant regulatory authorities; and (vi) market acceptance of the Company’s product candidates.

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all, or will succeed in achieving the clinical, scientific and commercial milestones as detailed above.

As of June 30, 2022, the Company’s cash, cash equivalents and short-term deposits amounted to a total of \$23,779. During the six-month period ended June 30, 2022, the Company incurred a loss of \$23,719 and had negative cash flows from operating activities of \$20,342. In addition, the Company had an accumulated deficit of \$198,606 as of June 30, 2022.

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.

Based on the abovementioned, as of the approval date of these interim condensed 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.

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except share and per share data)**

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**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, 2021, filed with the Securities and Exchange Commission (the "SEC") on February 28, 2022.

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, 2021. 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, 2021.

## 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 US 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.

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except share and per share data)**

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**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)**

## c. Fair value of financial instruments: (Cont.)

The carrying amounts of cash and cash equivalents, restricted cash, short-term deposits, long-term deposits, prepaid expenses and 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.

The fair value measurement of the Financial Commitment Asset (see Note 4) is measured using unobservable inputs that require a high level of judgment to determine fair value, and thus is classified as a Level 3 financial instrument. The Company estimates the fair value of the abovementioned instrument using the Monte-Carlo simulation and the Black-Scholes option pricing model.

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 adoption dates discussed below reflect this election.

In December 2019, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2019-12, Income Taxes (Topic 740): “Simplifying the Accounting for Income Taxes” (ASU 2019-12), which simplifies the accounting for income taxes. The guidance is effective for interim and annual periods beginning after December 15, 2021, with early adoption permitted. The Company has adopted ASU 2019-12 as of January 1, 2022. The impact of adoption of this standard on the Company’s consolidated financial statements was immaterial.

In August 2020, the FASB issued ASU No. 2020-06, “Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity” (“ASU 2020-06”), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it simplifies the diluted earnings per share calculation in certain areas. The Company adopted ASU 2020-06 on January 1, 2022. The adoption of the standard did not result in a material impact to the Company’s consolidated financial statements.

**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:

In February 2016, the FASB issued ASU No. 2016-02, "Leases", which would require lessees to recognize assets and liabilities on the balance sheet for most leases, whether operating or financing, while continuing to recognize the expenses on their income statements in a manner similar to current practice. Under this guidance, the Company would also be required to provide enhanced disclosures. The guidance requires that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The guidance will be effective for the Company beginning January 1, 2022, and interim periods in fiscal years beginning January 1, 2023.

A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. The standard provides a number of optional practical expedients in transition. The Company elected to use the effective date as the date of initial application and to adopt the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs.

The Company expects adoption of the standard to have a material impact on its consolidated balance sheets which will result in the recognition of right-to-use ("ROU") assets and lease liabilities of approximately \$3,388 as of January 1, 2022. The most significant impact from recognition of ROU assets and lease liabilities relates to office premises.

**NOTE 3:- COMMITMENTS AND CONTINGENT LIABILITIES**

- a. In connection with its research and development programs, through June 30, 2022, 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, 2022, no royalties have been paid or accrued.
- b. The Company's facilities are leased under operating lease agreements for periods ending no later than 2027. The Company has bank guarantees in connection with the facilities lease agreements in the total amount of \$214. Accordingly, cash in the same amount was restricted in bank deposits. The Company also leases motor vehicles under various operating leases, the latest of which expires in 2025. Future minimum lease payments under non-cancelable operating leases as of June 30, 2022, are as follows (unaudited):

2022	\$	854
2023		1,273
2024		515
2025		456
2026 and thereafter		<u>665</u>
<b>Total</b>	<b>\$</b>	<b><u>3,763</u></b>

As of June 30, 2022, the Company made advance payments on account of car leases in the amount of \$84 (unaudited). Lease expenses for the six-month ended June 30, 2022, were \$699 (unaudited).

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except share and per share data)**

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**NOTE 4:- LINE OF CREDIT ARRANGEMENT**

On April 5, 2022, the Company entered into a secured line of credit agreement for up to \$15,000 with Kreos Capital VI (Expert Fund) LP ("Kreos") (the "Credit Line"). The Credit Line is comprised of three tranches in the amount of \$10,000, \$2,500 and \$2,500, respectively, in which the first tranche in the amount of \$10,000 (the "First Tranche") was drawn on April 26, 2022. In addition, in accordance with the Credit Line agreement, the Company will issue to Kreos warrants to purchase the Company's Ordinary shares equal to 8% of the amount of each tranche, when and if borrowed, with an exercise price of \$5.14 per share. The expiration date for each warrant issued will be seven years from the issuance date. Accordingly, as a result of the First Tranche withdrawal, the Company issued to Kreos a warrant in the total amount of \$800. The total number of shares issuable upon exercise is equal to the total amount divided by the exercise price.

The Credit Line is denominated in USD and bears interest at an annual rate equal to 9.25%. The interest paid due to the Credit Line for the six-month period ended June 30, 2022, amounted to \$77.

On each drawdown date, the Company shall pay to Kreos on the drawdown date the last month payment for each tranche. For the First Tranche the amount the Company paid was \$317.

On May 19, 2022, the second tranche milestone was met following the independent data safety monitoring board review of interim analysis of SHEILD I, which recommended to end the trial at the lower end of the patient recruitment target as agreed in the Credit Line agreement (the "Second Tranche"). As of June 30, 2022, the Company has yet to draw the Second Tranche (for further information see Note 7).

Drawdown of the third and final tranche of \$2,500 will be available subject to obtaining positive top-line results from the SHIELD I trial of the Company or if other conditions are met as agreed in the Credit Line agreement (the "Third Tranche"). Drawdown of the Third Tranche can be made by December 31, 2022.

The Company has concluded that the Credit Line Arrangement include several legally detachable and separately exercisable freestanding financial instruments: The first tranche term loan, the warrants, and the right to receive additional loan tranches (the "Financial Commitment Asset" or "FCA").

The Company has concluded that the warrants should be classified as equity since the warrants are not an ASC No. 480 liability, are indexed to the Company's own share and meet all the equity classification conditions pursuant to ASC No. 815-40. The Company has also concluded that the FCA is not indexed to the Company's own share and should be measured at fair value, with changes in fair value recognized in earnings. In addition, the First Tranche term loan was accounted for using the effective interest method.

The Company allocated the proceeds received under the Credit Line between the warrants and the First Tranche term loan using the relative fair value method. The proceeds allocation resulted in \$9,532 (unaudited) allocated to the First Tranche and \$468 (unaudited) allocated to the warrants, net of issuance costs.

During the six-month period ended on June 30, 2022, the Company recognized \$223 of interest expenses related to the First Tranche, which were included as part of financial expenses in the Company's statements of operation.



**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 (CONT.)**

the FCA was measured at its fair value (hierarchy level 3) and presented under prepaid expenses and other current assets in the interim condensed consolidated balance sheets.

The fair value of the underlying asset for the FCA calculation was calculated based on the Monte-Carlo option pricing model using the following inputs:

	<u>June 30,</u> <u>2022</u>	<u>April 26,</u> <u>2022</u>
Expected volatility (%)	65	72
Risk-free interest rate (%)	1.72	1.21

The fair value of the FCA was calculated based on the Black-Scholes option pricing model using the following inputs:

	<u>June 30,</u> <u>2022</u>	<u>April 26,</u> <u>2022</u>
Dividend yield (%)	-	-
Expected volatility (%)	60.8-60.96	60.96-61.11
Risk-free interest rate (%)	3.03-3.04	2.88
Expected term (in years)	6.52-6.73	6.52-6.73

The following table sets forth the changes in the FCA's fair value (unaudited):

Balance as of January 1, 2022	\$	-
Issuance of a FCA		17
Changes to the fair value accounted for as financial income		121
Balance as of June 30, 2022	\$	<u>138</u>

**NOTE 5:- SHAREHOLDERS' EQUITY**

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

	<u>June 30,</u> <u>2022</u>		<u>December 31,</u> <u>2021</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>47,800,000</u>	<u>19,551,173</u>	<u>47,800,000</u>	<u>18,756,570</u>

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. During the six-month period ended June 30, 2022, the Company sold 768,622 Ordinary Shares under the ATM for a total amount of \$3,754, net of issuance cost in the amount of \$162.

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

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

**NOTE 5:- SHAREHOLDERS' EQUITY (CONT.)**

## c. Share option plan:

Through June 30, 2022, 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, 2022, 397,030 of the Company's options were available for future grants.

On May 9, 2022, the Board of Directors approved to increase the Company's options pool by additional one million options from 3,672,094 to 4,672,094.

A summary of the status of options to employees under the Company's option plan as of and for the six-month period ended June 30, 2022, 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	2,726,911	\$ 6.25	\$ 2,323	6.44
Granted	1,088,220	5.55		
Exercised	(25,981)	4.15	\$ 14	
Forfeited and expired	(172,644)	6.93		
<b>Outstanding at end of period</b>	<b><u>3,616,506</u></b>	<b>\$ 6.02</b>	<b>\$ 1,555</b>	<b>6.84</b>
Exercisable options	<u>1,797,434</u>	5.53	\$ 1,555	4.32
Vested and expected to vest	<u>3,616,506</u>	\$ 6.02	\$ 1,555	6.84

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, 2022:

Dividend yield (%)	0
Expected volatility (%)	70.45-87.55
Risk-free interest rate (%)	1.81-3.00
Expected term (in years)	1.2-6.2

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

## NOTE 5:- SHAREHOLDERS' EQUITY (CONT.)

## c. Share option plan: (Cont.)

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

	Six Months Ended June 30,	
	2022	2021
	Unaudited	
Research and development	\$ 1,193	\$ 1,013
Marketing and business development	199	162
General and administrative	1,147	1,063
	<u>\$ 2,539</u>	<u>\$ 2,238</u>

As of June 30, 2022, there were unrecognized compensation costs of \$9,738, which are expected to be recognized over a weighted average period of approximately 2.9 years.

On May 3, 2022, the annual and extraordinary general meeting of shareholders of the Company approved a new grant of 76,120 options to the then current Chief Executive Officer of the Company, Mr. Amir Weisberg. In addition, it was approved to accelerate the vesting of 12,906 options from an outstanding grant, in which in both cases the vesting of all options will occur on June 30, 2022. As a result, the Company recognized a total share-based compensation expense in the amount of \$76.

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

Outstanding options granted to non-employees as of June 30, 2022, were as follows (unaudited):

Grant date	Options outstanding as of June 30, 2022	Average Exercise price per share (\$)	Options exercisable as of June 30, 2022	Exercisable through
October 2013	5,719	\$ 5.06	5,719	October 2023
September 2014	5,719	\$ 5.06	5,719	September 2024
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	\$ 7.70	17,925	November 2027
August 2019	71,700	\$ 8.18	71,700	August 2029
June 2020	64,530	\$ 6.62	42,918	June 2030
April 2021	62,741	\$ 9.57	62,741	April 2031
August 2021	15,000	\$ 8.13	-	August 2031
December 2021	10,000	\$ 6.80	-	December 2031
May 2022	65,625	\$ 5.00	-	May 2032
	<u>529,826</u>		<u>417,589</u>	

No options were exercised by non-employees during the six-month period ended June 30, 2022.

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

## NOTE 5:- SHAREHOLDERS' EQUITY (CONT.)

## e. Warrants:

Further to the discussed in Note 4, as of April 26, 2022, the Company measured the fair value of the warrants to purchase Ordinary shares (a Level 3 valuation) using the Black-Scholes option pricing model.

As of April 26, 2022, the relative fair value of the Warrant to purchase Ordinary shares issued to Kreos was \$468, which was calculated using the following assumptions:

Share price (\$)	4.96
Exercise price (\$)	5.14
Expected volatility (%)	60.81
Adjustment to risk-free interest rate (%)	2.84
Dividend yield (%)	-
Risk-free interest rate (%)	2.88
Expected life (in years)	6.94

As of June 30, 2022, all warrants exercisable into Ordinary Shares as of June 30, 2022, were as follows (unaudited):

Grant date	Warrants outstanding as of June 30, 2022	Average Exercise price per share (\$)	Warrants exercisable as of June 30, 2022	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	\$ 5.14	155,794	April 2029
	<u>374,315</u>		<u>374,315</u>	

## NOTE 6:- 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,	
	2022	2021	2022	2021
	<u>Unaudited</u>			
<i>Numerator:</i>				
Allocation of loss attributable to Ordinary shareholders	<u>23,719</u>	<u>19,164</u>	<u>11,845</u>	<u>10,477</u>
<i>Denominator:</i>				
Weighted average Ordinary shares outstanding	<u>19,222,423</u>	<u>18,685,906</u>	<u>19,505,246</u>	<u>18,747,967</u>
Basic and diluted loss per share	<u>\$ 1.23</u>	<u>\$ 1.03</u>	<u>\$ 0.61</u>	<u>\$ 0.56</u>

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except share and per share data)****NOTE 6:- 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:

	<b>Three and Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>Unaudited</b>	
Ordinary Share options	4,146,332	2,637,154
Warrants	374,315	218,521
	<u>4,520,647</u>	<u>2,855,675</u>

**NOTE 7:- SUBSEQUENT EVENTS**

- a. Further to the discussed in Notes 4 and 5e, on July 19, 2022, the Company withdrew the Second Tranche (additional \$2,500), and accordingly issued to Kreos a warrant in the total amount of \$200, with an exercise price of \$5.14 per share.
- b. On August 2, 2022, the Company entered into a license, distribution and supply agreement (the "License Agreement") with Mercury Pharma Group Limited, under the trade name Advanz Pharma Holdings ("Advanz"), pursuant to which the Company granted the exclusive right to Advanz to market, advertise, promote, distribute, offer for sale, sell and import our product D-PLEX<sub>100</sub>, for the prevention of (i) post abdominal surgery incisional infection; and/or (ii) post cardiac surgery sternal infection, in the European Economic Area and the United Kingdom. The term of the license is until the later of December 31, 2035, or 10 years after the first commercial sale of the Product. The license is also terminable by either party under certain limited circumstances.

Under the terms of the License Agreement, the Company is entitled to receive an upfront payment immediately upon signing and additional development-related milestones for a total of up to €23 million (approximately \$23,500) as follows: upfront payment of €2.5 million (approximately \$2,600), up to €12.25 million (approximately \$12,500) contingent upon positive top-line results of the Company's SHIELD I Phase 3 study and additional development-related milestones of up to €8.25 million (approximately \$8,400). Upon commercialization, the Company will receive up to €87 million (approximately \$89,000) in sales-related milestones. In addition, the Company will also supply D-PLEX<sub>100</sub> to Advanz for a transfer price and will be entitled to royalties on net sales in double-digit percentages of up to mid-twenties.

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

**As of June 30, 2022 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 phase 3 SHIELD I clinical trial;
  - our ability to raise capital through the issuance of securities;
  - our ability to advance the development 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 as well as the behavior of hospitals and health insurance providers, which cover the cost of our product to the patients;
  - 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 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;
- 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, 2021, or our Annual Report, which was filed with the Securities and Exchange Commission, or the SEC, on February 28, 2022, 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, 2022, 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 six months ended June 30, 2021, and 2022 were \$19.4 million and \$23.5 million, respectively. As of June 30, 2022, we had an accumulated deficit of \$198.6 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 that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue clinical development of D-PLEX<sub>100</sub>, including our Phase 3 clinical trials for the prevention of surgical site infections, or SSIs, in abdominal (soft tissue) surgeries and in cardiac sternal (bone) surgeries;
- file new drug applications seeking regulatory approval for D-PLEX<sub>100</sub> 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<sub>100</sub> 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.

On June 30, 2020, we closed our initial public offering, or IPO, whereby we sold 4,312,500 Ordinary Shares to the public (inclusive of 562,500 Ordinary Shares pursuant to the full exercise of an overallotment option granted to the underwriters). The aggregate net proceeds received by us from the IPO were \$62.8 million, net of underwriting discounts and other offering costs. Prior to our IPO, we financed our operations primarily through private placements of equity securities and convertible debt, as well as grants from the Israeli Innovation Authority, or the IIA, and the European Commission's Seventh Framework Program for Research.

## Results of Operations

### Comparison of the Six Months Ended June 30, 2021 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2022:

	Six Months Ended	
	June 30,	
	2021	2022
	(in thousands)	
Research and development, net	\$ 13,460	\$ 17,095
Marketing and business development	1,391	1,698
General and administrative	4,576	4,723
Operating loss	19,427	23,516
Financial expense (income), net	(263)	203
Loss	\$ 19,164	\$ 23,719

### Research and Development, Net

Research and development, net expenses increased by \$3.6 million for the six months ended June 30, 2022, compared to the six months ended June 30, 2021. This increase was primarily related to an increase of \$2.8 million in costs related to the on-going SHIELD I and SHIELD II Phase 3 clinical trials in abdominal (soft tissue) surgery, an increase of \$0.4 million in our manufacturing facility expenses, an increase of \$0.4 million in personnel costs, an increase of \$0.2 million in non-cash share-based compensation, and an increase of \$0.1 million in research and development costs related to D-PLEX<sub>100</sub> and OncoPLEX. These increases were offset by an increase of \$0.3 million in IIA grants recognized in the period.



### *Marketing and Business Development*

Marketing and business development expenses increased by \$0.3 million for the six months ended June 30, 2022, compared to the six months ended June 30, 2021. This increase was primarily related to an increase of \$0.2 million in pre-commercialization activities for the product candidate D-PLEX<sub>100</sub> and an increase of \$0.1 million in personnel costs.

### *General and Administrative*

General and administrative expenses increased by \$0.1 million for the six months ended June 30, 2022, compared to the six months ended June 30, 2021. This increase was primarily related to an increase of \$0.1 million in legal, professional and other costs associated with the Company's status as a publicly traded company.

### *Financial Expense (Income), Net*

Financial expense (income), net changed by \$0.5 million for the six months ended June 30, 2022, compared to the six months ended June 30, 2021. This change was driven by financial expenses related to the line of credit (described below) and financial expenses related to hedging transactions, offset by financial income from bank deposits.

### *Loss*

Loss increased by \$4.6 million for the six months ended June 30, 2022, compared to the six months ended June 30, 2021. This increase was primarily related to the increase in research and development, net expenses of \$3.6 million, an increase in general and administrative expenses of \$0.1 million, an increase of \$0.3 million in marketing and business development costs and an increase of \$0.5 million in financial expense (income), net.

## **Qualitative and Quantitative Disclosures about Market Risk**

### ***Foreign Currency Exchange Risk***

We operate primarily in Israel, and approximately 46% 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 2.2% and 4.2%, respectively, during the six months ended June 30, 2022.

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, 2022. To date, rising interest rates and inflation have not had a material impact, but we continue to monitor these closely.

## **Jumpstart Our Business Startups Act Transition Period**

Section 107 of the Jumpstart Our Business Startups Act, or the JOBS 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 of 1933, as amended, or 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.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act, as implemented under the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, which took place in June 2020, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our Ordinary Shares that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

## **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 IPO, we funded our operations primarily through the sale of equity securities and convertible debt. On June 30, 2020, we closed our IPO, whereby we sold 4,312,500 Ordinary Shares to the public (inclusive of 562,500 Ordinary Shares pursuant to the full exercise of an overallotment option granted to the underwriters). The aggregate net proceeds received by us from the IPO were \$62.8 million, net of underwriting discounts and other offering costs.

On April 5, 2022, we entered into a secured loan agreement, or the line of credit, for up to \$15 million with Kreos Capital VI (Expert Fund) LP, or Kreos. The line of credit 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 agreement. The second tranche of \$2.5 million was available after we met the second tranche milestone in May 2022. Drawdown of the third and final tranche of \$2.5 million will be available subject to obtaining positive top-line results from the SHIELD I trial or if other conditions are met. Drawdown of the third tranche can be made by December 31, 2022.

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

The line of credit 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, and the third tranche, if drawn, 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 and intellectual property, and we paid a customary fee to Kreos for the establishment of the loan.

As part of the line of credit, we will issue to Kreos a 7-year warrant to purchase our ordinary shares equal to 8% of the amount of each tranche, if borrowed, with an exercise price of \$5.14 per 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 connection to the amounts withdrawn, we issued to Kreos a warrant in the total amount of \$1.0 million to acquire 194,742 Ordinary Shares.

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) promulgated under the Securities Act, for an aggregate offering price of up to \$45 million. During the six months period ended on June 30, 2022, the Company sold 768,622 Ordinary Shares under the ATM for a total amount of \$3.9 million, with issuance costs in the amount of \$0.2 million.

As of June 30, 2022, we had \$23.8 million in cash, cash equivalents and short-term deposits.

As of June 30, 2022, our main commitments and contingencies are our ongoing line of credit, which is expected to affect our liquidity over the next three and half years, and our lease obligations. See note 3 of our unaudited condensed consolidated financial statements for the six months ended June 30, 2022, included elsewhere in this Report on Form 6-K for a description of our commitments and contingencies liabilities.

In addition to the foregoing, based on our current assessment, we do not expect any material impact on our long-term liquidity due to the COVID-19 pandemic. However, we will continue to assess the effect of the pandemic to our operations.

### **Cash Flows**

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

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2021</b>	<b>2022</b>
	<b>(in thousands)</b>	
Net cash used in operating activities	\$ (13,551)	\$ (20,342)
Net cash provided by investing activities	15,641	9,060
Net cash provided by financing activities	1,034	13,255
Net increase in cash, cash equivalents and restricted cash	<u>\$ 3,124</u>	<u>\$ 1,973</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 and share-based compensation.

Net cash used in operating activities was \$20.3 million for the six months ended June 30, 2022, as compared to \$13.6 million for the six months ended June 30, 2021. This increase was primarily related to increased research and development costs and associated general and administrative expenses, as we continued SHIELD I and SHIELD II Phase 3 clinical trials in abdominal (soft tissue) surgery.

### *Investing Activities*

Net cash provided by 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 provided by investing activities was \$9.1 million for the six months ended June 30, 2022, as compared to net cash provided in investing activities of \$15.6 million for the six months ended June 30, 2021. This change in net cash provided in investing activities primarily related to the release of short-term and long-term deposits, partially offset by purchases of laboratory equipment and leasehold improvements to our manufacturing facility.

### *Financing Activities*

Net cash provided by financing activities was \$13.3 million for the six months ended June 30, 2022, as compared to \$1.0 million for the six months ended June 30, 2021. The increase in net cash provided by financing activities is primarily related to the net proceeds from the line of credit and proceeds from ATM.

In July 2021, we entered into the Sales Agreement with the Agent, pursuant to which we may offer and sell, from time to time, our Ordinary Shares, through the ATM, for an aggregate offering price of up to \$45.0 million. In that regard, we registered up to \$200 million of our Ordinary Shares on a Registration Statement on Form F-3 (File No. 333-257651), or the F-3. The \$45 million of our Ordinary Shares that may be offered, issued and sold under the Sales Agreement prospectus is included in the \$200 million 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 \$45,000,000 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, and if no shares are sold under the Sales Agreement, the full \$45,000,000 of securities may be sold in other offerings pursuant to the F-3, subject to any applicable limits that may then apply based on our market capitalization. During the six month period ended on June 30, 2022, we sold 768,622 Ordinary shares under the ATM for a total amount of \$3.9 million, with issuance costs in the amount of \$0.2 million.

### **Current Outlook**

On August 2, 2022, we entered into a License, Distribution and Supply Agreement, or the License Agreement, with Mercury Pharma Group Limited, under the trade name Advanz Pharma Holdings, or Advanz, pursuant to which we granted the exclusive right to Advanz to market, advertise, promote, distribute, offer for sale, sell and import our product D-PLEX<sub>100</sub>, or the Product, for the prevention of (i) post abdominal surgery incisional infection and/or (ii) post cardiac surgery sternal infection, in the European Economic Area and the United Kingdom, or the Territory. The term of the license is until the later of December 31, 2035, or 10 years after the first commercial sale of the Product. The license is also terminable by either party under certain limited circumstances.

Under the terms of the License Agreement, we are entitled to receive an upfront payment immediately upon signing and additional development-related milestones for a total of up to €23 million (approximately \$23.5 million) as follows: upfront payment of €2.5 million (approximately \$2.6 million), up to €12.25 million (approximately \$12.5 million) contingent upon positive top-line results of our SHIELD I Phase 3 study and additional development-related milestones of up to €8.25 million (approximately \$8.4 million). Upon commercialization, we will receive up to €87 million (approximately \$89 million) in sales-related milestones. In addition, we will also supply D-PLEX<sub>100</sub> to Advanz for a transfer price and will be entitled to royalties on net sales in double-digit percentages of up to mid-twenties.

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 several years. We expect our expenses to increase 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 the second quarter of 2023. We anticipate that these funds, will be sufficient to complete and report results from our SHIELD I clinical trial. We anticipate that we will need to raise additional capital in order to complete the SHIELD II clinical trial, to resume enrolment in our Phase 3 trial of D-PLEX<sub>100</sub> for the prevention of post-cardiac sternal (bone) SSIs, as well as continue to invest in the research and development of OncoPLEX and any other future product candidates. We anticipate that we will need to raise additional capital in order to commercialize D-PLEX<sub>100</sub>, if approved, in any indication. 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 \$19.1 million as of June 30, 2022, 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 trials;
- the costs, timing and outcome of regulatory review of D-PLEX<sub>100</sub> and any future product candidates;
- the costs and timing of establishing and validating manufacturing processes and facilities for development and commercialization of D-PLEX<sub>100</sub> 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 several 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 offering, debt financings, including additional tranches under the line of credit, 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.

### **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.

### **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 several years. From inception through June 30, 2022, we incurred \$124.6 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 our expenses to increase 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 “B - Liquidity and Capital Resources — Current Outlook” above.

The COVID-19 pandemic has impacted companies in Israel and around the world, and as its trajectory remains highly uncertain, we cannot predict the duration and severity of the pandemic. Further, we cannot predict impacts, trends and uncertainties involving the pandemic’s effects on our clinical development programs, economic activity, the size of our labor force, our third-party partners, our investments in marketable securities, and the extent to which our revenue, income, profitability, liquidity, or capital resources may be materially and adversely affected. See also “Item 3.D. – Risk Factors– Improvement in standard of care infection prevention and control measures being undertaken in hospitals globally as a result of the COVID-19 pandemic may have decreased the rate of surgical site infections, which may adversely impact the ability of our clinical trials to demonstrate an improvement over the standard of care and may ultimately reduce our commercial opportunity even if our trials are successful” and “Item 3.D. – Risk Factors– Our business and operations have been and are likely to further continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic” in our Annual Report.

### **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.

#### **Line of Credit**

The Company has concluded that the line of credit includes several legally detachable and separately exercisable freestanding financial instruments: The first tranche term loan, the warrants, and the right to receive additional loan tranches (the “Financial Commitment Asset” or “FCA”).

The Company has concluded that the warrants should be classified as equity since the warrants are not an ASC No. 480 liability, are indexed to the Company’s own share and meet all the equity classification conditions pursuant to ASC No. 815-40. The Company has also concluded that the FCA is not indexed to the Company’s own share and should be measured at fair value, with changes in fair value recognized in earnings. In addition, the first tranche term loan was accounted for using the effective interest method.

The Company allocated the proceeds received under the line of credit between the warrants and the first tranche term loan using the relative fair value method.