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: December 2022

Commission file number: 001-36578

ENLIVEX THERAPEUTICS LTD.
(Translation of registrant's name into English)

14 Einstein Street, Nes Ziona, Israel 7403618
(Address of principal executive offices)

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

Form 20-F ☒ Form 40-F ☐

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

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

Financial Statements

The unaudited condensed consolidated financial statements for Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel ("Enlivex"), as of and for the three and nine month periods ended September 30, 2022 and 2021, and the Operating and Financial Review and Prospects of Enlivex for the corresponding periods are furnished as Exhibits 99.1 and Exhibit 99.2, respectively, to this Report on Form 6-K and incorporated by reference into Enlivex's registration statements on Forms S-8, F-3 and F-3MEF (File No. 333-256799, File No. 333-232413, File No. 333-232009, File No. 333-252926 and File No. 333-264561), filed with the Securities and Exchange Commission.

Exhibit No.	
99.1	Unaudited condensed consolidated financial statements for Enlivex as of September 30, 2022 and December 31, 2021 and for the three and nine month periods ended September 30, 2022 and 2021.
99.2	Operating and Financial Review and Prospects as of and for the three and nine month periods ended September 30, 2022 and 2021.

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.

Enlivex Therapeutics Ltd.
(Registrant)

By: /s/ Oren Hershkovitz
Name: Oren Hershkovitz
Title: Chief Executive Officer

Date: December 2, 2022

ENLIVEX THERAPEUTICS LTD.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2022 AND DECEMBER 31, 2021
AND FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2022 AND 2021

ENLIVEX THERAPEUTICS LTD.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2022 AND DECEMBER 31, 2021
AND FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2022 AND 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	September 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 57,655	$ 11,202
Short term deposits	-	10,004
Marketable securities	-	62,924
Prepaid expenses and other receivables	1,463	2,199
Cash held with respect to CVR Agreement	113	113
Total Current Assets	59,231	86,442
Non-Current Assets		
Property and equipment, net	7,515	2,530
Other assets	5,668	6,174
Total Non-Current Assets	13,183	8,704
TOTAL ASSETS	$ 72,414	$ 95,146
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable trade	$ 1,056	$ 878
Accrued expenses and other liabilities	3,360	3,727
CVR holders	113	113
Total Current Liabilities	4,529	4,718
Non-Current Liabilities		
Other long-term Liabilities	4,611	5,389
Total Non-Current Liabilities	4,611	5,389
Commitments and Contingent Liabilities		
TOTAL LIABILITIES	9,140	10,107
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.4 par value: Authorized: 45,000,000 shares as of September 30, 2022 and December 31, 2021; Issued and outstanding: 18,411,728 and 18,331,507 as of September 30 and December 31, 2021;	2,116	2,107
Additional paid in capital	135,893	133,796
Foreign currency translation adjustments	1,101	1,101
Accumulated deficit	(75,836)	(51,965)
TOTAL SHAREHOLDERS' EQUITY	63,274	85,039
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 72,414	$ 95,146

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development expenses	4,201	2,679	12,993	7,715
General and administrative expenses	1,476	1,185	4,959	3,759
	5,677	3,864	17,952	11,474
Operating loss	(5,677)	(3,864)	(17,952)	(11,474)
Other income/(expense), net	(56)	440	(5,919)	1,742
Net (loss)	(5,733)	(3,424)	(23,871)	(9,732)
Other comprehensive income (loss)				
Exchange differences arising from translating financial statements from functional to presentation currency	-	857	-	124
Total other comprehensive income (loss)	-	857	-	124
Total comprehensive (loss)	$ (5,733)	$ (2,567)	$ (23,871)	$ (9,608)
Basic & diluted (loss) per share	$ (0.31)	$ (0.19)	$ (1.30)	$ (0.54)
Weighted average number of shares outstanding	18,391,929	18,312,418	18,379,062	17,705,913

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

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (UNAUDITED)

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

	Ordinary Shares		Additional paid in capital	Currency translation reserve	Accumulated deficit	Total
	Shares	Amount				
Balance as of December 31, 2021	18,331,507	$ 2,107	$ 133,796	$ 1,101	$ (51,965)	$ 85,039
Changes during the three months period ended March 31, 2022:						
Restricted stock units vested	34,295	4	(4)	-	-	-
Exercise of options	7,625	1	49	-	-	50
Stock based compensation	-	-	788	-	-	788
Net loss	-	-	-	-	(8,225)	(8,225)
Balance as of March 31, 2022 (unaudited)	18,373,427	2,112	134,629	1,101	(60,190)	77,652
Changes during the three months period ended June 30, 2022:						
Exercise of options	7,625	1	49	-	-	50
Stock based compensation	-	-	697	-	-	697
Net loss	-	-	-	-	(9,913)	(9,913)
Balance as of June 30, 2022 (unaudited)	18,381,052	2,113	135,375	1,101	(70,103)	68,486
Changes during the three months period ended September 30, 2022:						
Restricted stock units vested	23,051	2	(2)	-	-	-
Exercise of options	7,625	1	49	-	-	50
Stock based compensation	-	-	471	-	-	471
Net loss	-	-	-	-	(5,733)	(5,733)
Balance as of September 30, 2022 (unaudited)	18,411,728	$ 2,116	$ 135,893	$ 1,101	$ (75,836)	$ 63,274

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

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (UNAUDITED)

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

	Ordinary Shares		Additional paid in capital	Currency translation reserve	Accumulated deficit	Total
	Shares	Amount				
Balance as of December 31, 2020	14,587,934	$ 1,646	$ 70,361	$ 977	$ (37,497)	$ 35,487
Changes during the three months period ended March 31, 2021:						
Issuance of shares and warrants for cash consideration of $57,629 net of $4,455 issuance costs	2,848,629	352	52,822	-	-	53,174
Exercise of options	13,435	2	38	-	-	40
Exercise of warrants	855,813	104	7,598	-	-	7,702
Stock based compensation	-	-	190	-	-	190
Other comprehensive loss	-	-	-	(2,788)	-	(2,788)
Net loss	-	-	-	-	(3,200)	(3,200)
Balance as of March 31, 2021 (unaudited)	18,305,811	2,104	131,009	(1,811)	(40,697)	90,605
Changes during the three months period ended June 30, 2021:						
Exercise of options	375	*	2	-	-	2
Stock based compensation	-	-	652	-	-	652
Other comprehensive loss	-	-	-	2,055	-	2,055
Net loss	-	-	-	-	(3,108)	(3,108)
Balance as of June 30, 2021 (unaudited)	18,306,186	2,104	131,663	244	(43,805)	90,206
Changes during the three months period ended September 30, 2021:						
Exercise of options	24,321	3	64			67
Stock based compensation			377			377
Other comprehensive loss				857		857
Net loss	-	-	-	-	(3,424)	(3,424)
Balance as of September 30, 2021 (unaudited)	18,330,507	$ 2,107	$ 132,104	$ 1,101	$ (47,229)	$ 88,083

* Less than $1

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. dollars in thousands

	For the nine months ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net (loss)	$ (23,871)	$ (9,732)
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation	556	396
Non-cash operating lease expenses	625	194
Share-based compensation	1,955	1,219
Loss (income) on marketable securities and short-term bank deposits	1,987	(2,212)
Changes in operating asset and liability items:		
Increase (decrease) in prepaid expenses and other receivables	762	(611)
Increase (decrease) in accounts payable trade	179	596
Increase in accrued expenses and other liabilities	(400)	(651)
Operating lease liabilities	(928)	(150)
Net cash (used in) operating activities	(19,135)	(10,951)
Cash flows from investing activities		
Purchase of property and equipment	(5,541)	(592)
Release (investment) in short-term bank deposits	10,000	29,666
Purchases of marketable securities	(1,608)	(90,337)
Proceeds from sales of marketable securities	62,549	28,201
Net cash provided by (used in) investing activities	65,400	(33,062)
Cash flows from financing activities		
Proceeds from issuance of shares and warrants net of $4,455 issuance expenses	-	53,174
Proceeds from exercise of warrants	-	7,702
Proceeds from exercise of options	150	109
Net cash provided by financing activities	150	60,985
Increase in cash and cash equivalents	46,415	16,972
Cash and cash equivalents - beginning of period	11,636	7,012
Exchange rate differences on cash and cash equivalents	-	(657)
Cash and cash equivalents - end of period	$ 58,051	$ 23,327
Non-cash transactions:		
Warrants issued in settlement of issuance costs to a placement agent	$ -	$ 2,095
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ -	$ -
Cash paid (received) for interest, net	$ (258)	$ 51

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

NOTE 1 – GENERAL

a. Enlivex Therapeutics Ltd. (the "Parent" and, including its consolidated subsidiaries, "we", "us", "our" or the "Company") is a clinical-stage macrophage reprogramming immunotherapy company originally incorporated on January 22, 2012 under the laws of the State of Israel.

Enlivex Therapeutics R&D Ltd. ("Enlivex R&D") was incorporated in September 2005 under the laws of the State of Israel. On March 26, 2019, upon consummation of a merger transaction between the Parent and Enlivex R&D, Enlivex R&D became a wholly owned subsidiary of the Company.

In January 2015, Enlivex Therapeutics Inc. was incorporated in the State of Delaware as a wholly owned subsidiary of the Parent.

On June 21, 2021 Enlivex Therapeutics RDO Ltd. was incorporated in Israel as a wholly owned subsidiary of the Parent.

The Company is a clinical stage macrophage reprogramming immunotherapy company, developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of certain diseases, which include solid tumors, sepsis and others.

Allocetra™ is based on the discoveries of Professor Dror Mevorach, an expert on immune activity, macrophage activation and clearance of dying (apoptotic) cells, in his laboratory in the Hadassah University Hospital located in the State of Israel.

The Company's ordinary shares, NIS 0.40 per share ("Ordinary Shares"), are traded under the symbol "ENLV" on both the Nasdaq Capital Market and on the Tel Aviv Stock Exchange.

b. Financial Resources

The Company devotes substantially all of its efforts toward research and development activities and raising capital to support such activities. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before the Company achieves sustainable revenues and profit from operations.

Research and development activities have required significant capital investment since the Company's inception. The Company expects that its operations will require additional cash investment to pursue the Company's research and development activities, including preclinical studies, formulation development, clinical trials and related drug manufacturing. The Company has not generated any revenues or product sales and has not achieved profitable operations or positive cash flow from operations. The Company has incurred net losses since its inception, and, as of September 30, 2022, had an accumulated deficit of $75,836 thousand.

The Company expects to continue to incur losses for at least the next several years, and the Company will need to raise additional debt or equity financing or enter into partnerships to fund its development. If the Company is not able to achieve its funding requirements, it may be required to reduce discretionary spending, may not be able to continue the development of its product candidates or may be required to delay its development programs, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. There can be no assurances that additional financing will be secured or, if secured, will be on favorable terms. The ability of the Company to transition to profitability in the longer term is dependent on developing products and product revenues to support its expenses.

The Company's management and board of directors (the "Board") are of the opinion that the Company's current financial resources will be sufficient to continue the development of the Company's product candidates for at least twelve months from the filing of these financial statements on Form 6-K. The Company may determine, however, to raise additional capital during such period as the Board deems prudent. The Company's management plans to finance its operations with issuances of the Company's equity securities and, in the longer term, revenues. There are no assurances, however, that the Company will be successful in obtaining the financing necessary for its long-term development. The Company's ability to continue to operate in the long term is dependent upon additional financial support.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These unaudited condensed consolidated financial statements include the accounts of the Company and have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been made.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited annual financial statements and notes thereto included in the Company's 2021 Annual Report on Form 20-F, as filed with the SEC on April 29, 2022. The results of operations for these interim periods are not necessarily indicative of the operating results for any future period. The December 31, 2021 financial information has been derived from the Company's audited financial statements.

Use of Estimates

The preparation of interim financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments and assumptions that affect the reported amounts in the consolidated balance sheets and statements of operations, it also requires that management exercise its judgment in applying the Company's accounting policies. On an ongoing basis, management evaluates its estimates, including estimates related to its stock-based compensation expense and implicit interest rate on new lease liabilities. Significant estimates in these interim financial statements include estimates made for accrued research and development expenses and stock-based compensation expenses.

Functional Currency and Translation to The Reporting Currency

The functional currency of the Company is the U.S. dollar because the U.S. dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future.

Until September 30, 2021, the functional currency of Enlivex R&D was the New Israeli Shekel ("NIS").

Balances related to non-monetary assets and liabilities are based on translated amounts as of the date of the change, and non-monetary assets acquired and liabilities incurred after September 30, 2021 were translated at the approximate exchange rate prevailing at the date of the transaction. Transactions included in the statement of income for the three and nine month periods ended September 30, 2022 were translated at the approximate exchange rate in effect at the time of the applicable transaction. Transactions included in the statement of income for the three and nine month periods ended September 30, 2021 were translated at average exchange rates during the applicable period. Gains or losses resulting from translation adjustments for the three and nine month periods ended September 30, 2021 are reported in other comprehensive income (loss).

One U.S. dollar = 3.543 NIS and 3.11 NIS as of September 30, 2022 and December 31, 2021, respectively.

The U.S. dollar increased (decreased) against the NIS: 1.23%, 13.92%, (0.95%) and 0.44% in the three and nine month periods ended September 30, 2022 and 2021, respectively.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU 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)* ("ASU 2020-06"). ASU 2020-06 simplifies the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity by removing certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. The standard also enhances the consistency of earnings-per-share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings-per-share calculations. ASU 2020-06 became effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2021. The Company evaluated ASU 2020-06 and determined that its adoption did not have an impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

The Company has evaluated other recently issued accounting pronouncements and does not currently believe that any of these pronouncements will have a material impact on its condensed consolidated financial statements and related disclosures.

Significant Accounting Policies

There have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 20-F for the year ended December 31, 2021.

Marketable Securities.

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company invests its excess cash primarily in mutual funds that are classified based on the nature of their underlying securities and their availability for use in current operations. The Company's marketable equity securities are measured at fair value with gains and losses recognized in other income/(expense), net.

Net (loss) income recognized on equity securities for the three and nine month periods ended September 30, 2022 and 2021 was $0, ($1,982), $639 and $2,212 thousand of which $0, $0, $610 and $1,952 thousand, respectively, were not realized.

NOTE 3 – CASH, CASH EQUIVALENTS AND RESTRICTED CASH

(in thousands)	September 30, 2022	December 31, 2021
Cash held in banks	$ 19,103	$ 1,199
Bank deposits in U.S.$ (annual average interest rates 3.02% and 0.1%)	38,552	10,003
Total cash and cash equivalents	57,655	11,202
Cash held with respect to CVR Agreement	113	113
Restricted cash – noncurrent – Other assets	283	321
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 58,051	$ 11,636

NOTE 4 – SHORT TERM DEPOSITS

(in thousands)	September 30, 2022	December 31, 2021
Bank deposits in U.S.$ and NIS (annual average interest rate of 0.6%)	$ -	$ 10,004
Total short-term deposits	$ -	$ 10,004

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

(in thousands)	September 30, 2022	December 31, 2021
Cost:		
Laboratory equipment	$ 2,679	$ 1,891
Computers	276	256
Office furniture & equipment	225	192
Leasehold improvements	6,221	1,521
	9,401	3,860
Accumulated depreciation:		
Laboratory equipment	1,291	960
Computers	187	138
Office furniture & equipment	24	15
Leasehold improvements	384	217
	1,886	1,330
Depreciated cost	$ 7,515	$ 2,530

Depreciation expenses for the three and nine month periods ended September 30, 2022 and 2021 were $192, $556, $157 and $396 thousand, respectively.

NOTE 6 – OTHER ASSETS

(in thousands)	September 30, 2022	December 31, 2021
Restricted cash	$ 283	$ 321
Long-term prepaid expenses	139	164
Right-of-Use assets, net	5,246	5,689
	$ 5,668	$ 6,174

NOTE 7 – ACCRUED EXPENSES AND OTHER LIABILITIES

(in thousands)	September 30, 2022	December 31, 2021
Vacation, convalescence and bonus accruals	$ 507	$ 1,068
Employees and payroll related	561	519
Short term operating lease liabilities	649	617
Accrued expenses and other	1,643	1,523
	3,360	$ 3,727

NOTE 8 – LEASES

The Company is a party to operating leases for its corporate offices, laboratory space and vehicles. The Company's real property operating leases have remaining lease terms of up to 3.25 years, some of which include options to extend the leases for up to five years.

(in thousands)	Nine months ended September 30, 2022	2021
The components of lease expense were as follows:		
Operating leases expenses	$ 773	$ 245
Supplemental consolidated cash flow information related to operating leases follows:		
Cash used in operating activities	$ 624	$ 210
Non-cash activity:		
Right of use assets obtained in exchange for new operating lease liabilities	$ 182	$ 5,444

	September 30, 2022	December 31, 2021
Supplemental information related to operating leases, including location of amounts reported in the accompanying consolidated balance sheets, follows:		
Other assets - Right-of-Use assets	$ 6,459	$ 6,329
Accumulated amortization	1,213	640
Operating lease Right-of-Use assets, net	$ 5,246	$ 5,689
Lease liabilities – current - Accounts payable and accrued liabilities	$ 649	$ 617
Lease liabilities – noncurrent	4,611	5,389
Total operating lease liabilities	$ 5,260	$ 6,006
Weighted average remaining lease term in years	7.85	8.6
Weighted average annual discount rate	3.6%	3.6%

Maturities of operating lease liabilities as of September 30, 2022, were as follows:

2022 (after September 30)	$ 251
2023	816
2024	710
2025	732
2026 and following	3,499
Total undiscounted lease liability	$ 6,008
Less: Imputed interest	$ (748)
Present value of lease liabilities	$ 5,260

NOTE 9 – COMMITMENTS AND CONTINGENT LIABILITIES

The Company is required to pay royalties to the State of Israel (represented by the Israeli Innovation Authority (the "IIA")), computed on the basis of proceeds from the sale or license of products for which development was supported by IIA grants. These royalties are generally 3% - 5% of sales until repayment of 100% of the grants (linked to the dollar) received by the Company plus annual interest at a LIBOR-based rate.

The gross amount of grants received by the Company from the IIA, including accrued interest as of September 30, 2022, was approximately $9.1 million. As of September 30, 2022, the Company had not paid any royalties to the IIA.

In January 2022, the Company submitted a new grant application to the IIA to approve an expenditure of $4.8 million for its clinical development program for the prevention of cytokine storms and organ dysfunction associated with sepsis for a period that commenced January 1, 2022 and ended December 31, 2022, the Company received a grant of approximately $960 thousand for expenses associated with the Company's ongoing sepsis clinical Phase II trial.

NOTE 10 – EQUITY

All Company warrants are classified as a component of shareholders' equity because such warrants are free standing financial instruments that are legally detachable, separately exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of Ordinary Shares upon exercise, requires physical settlement and do not provide any guarantee of value or return.

	Number of Warrants	Weighted average exercise price
Outstanding January 1, 2022	704,355	$ 13.18
Forfeited and expired	(502,104)	$ 9.50
Outstanding and exercisable September 30, 2022	202,251	$ 23.31

Comprised as follows:

Number of Warrants	Exercise Price Per Share	Issuance date	Expiration date
22,750	$ 10	February 26, 2020	February 24, 2025
160,727	$ 25	February 12, 2021	February 9, 2026
18,774	$ 25	February 17, 2021	February 9, 2026
202,251			

NOTE 11 – SHARE-BASED COMPENSATION

a) As of September 30, 2022, 4,150,704 Ordinary Shares were authorized for issuance to employees, directors and consultants under the Company's Global Share Incentive Plan (2019), of which 1,193,656 shares were available for future grant.

b) The following table contains information concerning options granted under the existing equity incentive plans:

	Three months ended September 30,			
	2022		2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of period	2,388,997	$ 5.95	2,177,925	$ 6.54
Granted	-	$ -	15,000	$ 8.30
Forfeited and expired	(3,750)	$ 5.21	(19,395)	$ 72.00
Exercised	(7,625)	$ 6.49	(24,321)	$ 2.76
Outstanding at end of period	2,377,622	$ 5.95	2,149,209	$ 6.01
Exercisable at end of period	1,787,448	$ 5.14	1,421,418	$ 4.67
Non-vested at beginning of period	660,374	$ 7.59	773,116	$ 8.19
Granted	-	$ -	15,000	$ 8.30
Vested	(66,638)	$ 7.55	(56,075)	$ 7.81
Forfeited	(3,562)	$ 5.24	(4,250)	$ 9.74
Non-vested at the end of period	590,174	$ 7.60	727,791	$ 8.21

	Nine months ended September 30,			
	2022		2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of period	2,142,547	$ 6.02	1,884,420	$ 5.52
Granted	264,700	$ 5.48	325,500	$ 12.38
Forfeited and expired	(6,750)	$ 5.27	(22,580)	$ 62.83
Exercised	(22,875)	$ 6.49	(38,131)	$ 2.84
Outstanding at end of period	2,377,622	$ 5.95	2,149,209	$ 6.01
Exercisable at end of period	1,787,448	$ 5.14	1,421,418	$ 4.67
Non vested at beginning of period	529,082	$ 8.69	601,227	$ 5.93
Granted	264,700	$ 5.48	325,500	$ 12.38
Forfeited and expired	(6,562)	$ 5.28	(191,501)	$ 8.10
vested	(197,046)	$ 7.73	(7,435)	$ 8.47
Outstanding at end of period	590,174	$ 7.60	727,791	$ 8.21

During the three and nine month periods ended September 30, 2022 and 2021, the Company recognized $313, $1,385, $336 and $1,114 thousand, respectively, of share-based compensation expenses related to stock options. As of September 30, 2022, the total unrecognized estimated compensation cost related to outstanding non-vested stock options was $1,482 thousand, which is expected to be recognized over a weighted average period of 1.25 years.

c) Set forth below is data regarding the range of exercise prices and remaining contractual life for all options outstanding at September 30, 2022:

Exercise price	Number of options outstanding	Remaining contractual Life (in years)	Intrinsic Value of Options Outstanding	No. of options exercisable
			(in thousands)	
$ 2.69	649,883	2.67	1,014	649,883
$ 3.66	250,000	7.59	147	201,389
$ 4.68	54,750	7.50	-	27,375
$ 5.35	228,200	9.50	-	-
$ 6.22	634,177	4.75	-	634,177
$ 6.49	7,625	0.03	-	-
$ 8.19	150,000	7.13	-	75,000
$ 8.23	20,000	9.13	-	-
$ 8.30	15,000	8.85	-	3,750
$ 9.02	40,500	8.13	-	10,125
$ 10.12	12,126	6.18	-	9,700
$ 12.21	2,421	6.49	-	1,816
$ 12.23	250,000	8.66	-	131,945
$ 14.00	60,500	8.57	-	40,333
$ 21.40	1,940	6.82	-	1,455
$ 90.16	500	2.17	-	500
	2,377,622		$ 1,161	1,787,448

d) The following table contains information concerning restricted stock units granted under the existing equity incentive plans:

	Three months ended September 30,			
	2022		2021	
	Number of shares	Weighted average grant date fair value	Number of shares	Weighted average grant date fair value
Nonvested at beginning of period	181,350	$ 10.02	60,125	$ 14.67
Granted	-	$ -	-	$ -
Vested	(9,352)	$ 8.98	-	$ -
Forfeited	(563)	$ 14.67	(5,000)	$ 14.67
Nonvested at end of period	171,435	$ 9.71	55,125	$ 13.67

	Nine months ended September 30,			
	2022		2021	
	Number of shares	Weighted average grant date fair value	Number of shares	Weighted average grant date fair value
Nonvested at beginning of period	229,331	$ 10.08	-	$ -
Granted	-	$ -	62,125	$ 13.7
Vested	(57,333)	$ 10.19	-	$ -
Forfeited	(563)	$ 14.67	(7,000)	$ 14.67
Nonvested at end of period	171,435	$ 9.71	55,125	$ 13.67

The Company estimates the fair value of restricted stock units based on the closing sales price of the Ordinary Shares on the date of grant (or the closing bid price, if no sales were reported). For the three and nine month periods ended September 30, 2022 and 2021, the Company recognized $158, $570, $41 and $105 thousand, respectively, of share-based compensation expense related to restricted stock units. Total share-based compensation expense related to restricted stock units not yet recognized as of September 30, 2022 was $725 thousand, which is expected to be recognized over a weighted average period of 1.25 years.

e) The following table summarizes share-based compensation expenses related to grants under the existing equity incentive plans included in the statements of operations:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2022	2021	2022	2021
Research & development	$ 208	$ 130	$ 717	$ 576
General & administrative	263	247	1,238	643
Total	$ 471	$ 377	$ 1,955	$ 1,219

NOTE 12 – FAIR VALUE MEASUREMENT

The Company's financial assets and liabilities measured at fair value on a recurring basis consisted of the following types of instruments as of September 30, 2022 and December 31, 2021:

(in thousands)	September 30, 2022			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 57,655	$ 57,655	$ -	$ -
Cash held with respect to CVR Agreement	113	113	-	-
Restricted cash	283	283	-	-
Total financial assets	$ 58,051	$ 58,051	$ -	$ -

(in thousands)	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 11,202	$ 11,202	$ -	$ -
Short term deposits	10,004	10,004	-	-
Cash held with respect to CVR Agreement	113	113	-	-
Marketable securities	62,924	62,924	-	-
Restricted cash	321	321	-	-
Total financial assets	$ 84,564	$ 84,564	$ -	$ -

NOTE 13 – EVENTS SUBSEQUENT TO THE BALANCE SHEET DATE

The Company evaluated all events and transactions that occurred subsequent to the balance sheet date and prior to the date on which these unaudited condensed consolidated financial statements were issued and determined that there were no events that necessitated disclosure.

OPERATING AND FINANCIAL REVIEW AND PROSPECTS

This Operating and Financial Review and Prospects contains forward-looking statements, which may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "would", "could", "intends," "estimates," "suggests," "has the potential to" and other words and phrases of similar meaning, including, without limitation, statements regarding expected cash balances, market opportunities for the results of current clinical studies and preclinical experiments, and the effectiveness of, and market opportunities for, ALLOCETRA™ programs, all of which statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect Enlivex's business and prospects, including the risks that Enlivex may not succeed in generating any revenues or developing any commercial products; that the products in development may fail, may not achieve the expected results or effectiveness and/or may not generate data that would support the approval or marketing of these products for the indications being studied or for other indications; that ongoing studies may not continue to show substantial or any activity; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. The results of clinical trials in humans may produce results that differ significantly from the results of clinical and other trials in animals. The results of early-stage trials may differ significantly from the results of more developed, later-stage trials. The development of any products using the ALLOCETRA™ product line could also be affected by a number of other factors, including unexpected safety, efficacy or manufacturing issues, additional time requirements for data analyses and decision making, the impact of pharmaceutical industry regulation, the impact of competitive products and pricing and the impact of patents and other proprietary rights held by competitors and other third parties. In addition to the risk factors described above, investors should consider the economic, competitive, governmental, technological and other factors discussed in Enlivex's filings with the Securities and Exchange Commission, including in its Annual Report on Form 20-F for the year ended December 31, 2021. The forward-looking statements contained in this Operating and Financial Review and Prospects speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law.

Overview

Enlivex Therapeutics, Ltd., a company organized under the laws of the State of Israel (including its consolidated subsidiaries, "we", "us", "our" or the "Company"), is a clinical-stage macrophage reprogramming immunotherapy company, developing Allocetra™, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of the respective diseases, which include solid tumors, sepsis and others.

We believe the Company's primary innovative immunotherapy, Allocetra™, represents a paradigm shift in macrophage reprogramming, moving from targeting a specific subset of macrophages or a specific pathway effecting macrophages activity, to a fundamental view of macrophage homeostasis. Restoring macrophage homeostasis may induce the immune system to rebalance itself to normal levels of operation, thereby promoting disease resolution.

The Company is focused on two main clinical verticals, sepsis and solid tumors (the "Indications"). The Company believes that negatively-reprogrammed macrophages may be key contributors to disease severity across these two Indications, and thus effective reprogramming of these previously negative-reprogrammed macrophages into their respective homeostatic state may provide diseases resolution for these Indications, some of which are considered "unmet medical needs", such as preventing or treating complications associated with sepsis and certain solid tumors.

Financial Overview

Since inception, we have incurred significant losses in connection with our research and development and have not generated any revenue. We have funded our operations primarily through grants from the Israel Innovation Authority (the "IIA") and the sale of equity and equity linked securities in public and private offerings. As of September 30, 2022, we had approximately $57.6 million in cash and cash equivalents and had an accumulated deficit of approximately $75.8 million, see "—Liquidity and Capital Resources" below.

For the nine months ended September 30, 2022, our cash expenditures included a one-time, non-recurring expense of $4.9 million related to the construction of our new manufacturing facility, which is expected to be completed in the fourth quarter of 2022.

Although we provide no assurance, we believe that our existing funds will be sufficient to continue our business and operations as currently conducted through the third quarter of 2024. We expect that we will continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to further develop our research and development programs.

Costs and Operating Expenses

Our current costs and operating expenses consist of two components: (i) research and development expenses; and (ii) general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of research and development activities at our laboratory in Israel, including drug and laboratory supplies and costs for facilities and equipment, outsourced development expenses, salaries and related personnel expenses (including share based compensation) and fees paid to external service providers and the costs of preclinical studies and clinical trials. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expenses in the near future as we continue to develop our product candidates. Increases or decreases in research and development expenditures are attributable to the number and duration of our preclinical and clinical studies.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates in our pipeline for potential commercialization. Furthermore, although we expect to obtain additional grants from the Israel Innovation Authority, we cannot be certain that we will do so. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidates in preclinical studies for toxicology, safety and efficacy and to conduct additional clinical trials for our product candidates.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of each candidate's commercial potential. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for our product candidates in certain Indications in order to focus our resources on more promising indications for any such product candidate. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

We expect our research and development expenses to increase in the future as we continue the advancement of our clinical product development for the Indications and as we potentially pursue additional indications. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation (including share-based compensation) for employees in executive and operational roles, including accounting, finance, investor relations, information technology and human resources. Our other significant general and administrative expenses include facilities costs, professional fees for outside accounting and legal services, including legal work in connection with patent applications, travel costs and insurance premiums.

Other income (expenses), net

Other income (expenses) consists of bank fees, exchange rate differences and gains and losses resulting from our investments in short term deposits and marketable securities.

Other Comprehensive income (Loss)

Our functional currency is the U.S. dollar because the U.S. dollar is the currency of the primary economic environment in which we operate and expect to continue to operate for the foreseeable future.

The functional currency of our primary operating subsidiary, Enlivex Therapeutics R&D Ltd. ("Enlivex R&D") was the New Israeli Shekel ("NIS") until September 30, 2021. We reassessed Enlivex R&D's functional currency and determined that, as of September 30, 2021, the U.S. dollar became the functional currency of Enlivex R&D. Significant elements supporting such determination included (i) a change in our business strategy resulting from our planned initiation of oncology clinical trials, and (ii) our newly-developed frozen formulation of Allocetra™, which eliminates the constraints of short shelf life and long-term storage of the liquid formulation, enabling us to conduct clinical trials for sepsis and oncology outside of Israel. Additional elements were the fact that our main sources of financing have been the U.S. capital markets and U.S. dollar denominated government grants from the IIA and the fact that all of our budgeting and planning is conducted solely in U.S. dollars. Monetary assets and liabilities denominated in foreign currencies were translated into U.S. dollars using exchange rates in effect at the balance sheet date. Balances related to non-monetary assets and liabilities are based on translated amounts as of the date of the change, and non-monetary assets acquired, and non-monetary liabilities incurred after September 30, 2021 are translated at the approximate exchange rate prevailing at the date of the particular transaction. Transactions included in the statement of income until the date of change were translated at average exchange rates during the applicable period, and transactions after September 30, 2021 were translated at the approximate exchange rate in effect at the time of the particular transaction. Gains or losses resulting from translation adjustments until September 30, 2021 are reported in other comprehensive income (loss).

Critical Accounting Policies and Estimate

The preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

We believe the following accounting policies to be the most critical to the judgments and estimates used in the preparation of our financial statements. For additional detail regarding our significant accounting policies, please see the notes to our audited consolidated financial statements contained in our Annual Report on Form 20-F for the year ended December 31, 2021 as filed with the SEC on April 29, 2022.

Share-Based Compensation

We have issued options to purchase our ordinary shares. Share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense over the requisite service/vesting period. Determining the appropriate fair value model and calculating the fair value of share-based payment awards require the use of highly subjective assumptions, including the expected life of the share-based payment awards and share price volatility.

We estimate the grant date fair value of share options and the related compensation expense, using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate and (4) dividends. In general, the assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment.

Leases:

We determine if an arrangement includes a lease at inception. Right-of-use assets represent our right to use an underlying asset for the lease term; and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the commencement date of the lease, renewal date of the lease or significant remodeling of the lease space based on the present value of the remaining future minimum lease payments. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rate to discount lease payments, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Our leases include options to extend or terminate the lease. In determining the lease term, management uses its judgement to determine whether or not an option would be reasonably certain to be exercised. Management considers all facts and circumstances, including their past practice and any cost that will be incurred to change the asset if an option to extend is not taken, to help determine the lease term. Extension options are only included in the lease term if the lease is reasonably certain to be extended.

Results of Operations

Nine -Months Ended September 30, 2022 Compared to nine-Months Ended September 30, 2021

The table below provides our results of operations for the nine months ended September 30, 2022 and September 30, 2021:

	Nine Months Ended September 30	
	2022	2021
	(In thousands, except per share data) (unaudited)	
Research and development expenses	$ 12,993	$ 7,715
General and administrative expenses	4,959	3,759
Operating loss	(17,952)	(11,474)
Other income (expense), net	(5,919)	1,742
Operating income (loss) post-finance expense & other income, net	(23,871)	(9,732)
Taxes on income	-	-
Net income (loss)	(23,871)	(9,732)
Other comprehensive income (loss)	-	124
Total comprehensive income (loss)	$ (23,871)	$ (9,608)
Basic income (loss) per share	$ (1.30)	$ (0.54)
Diluted income (loss) per share	$ (1.30)	$ (0.54)

Three-Months Ended September 30, 2022 Compared to Three-Months Ended September 30, 2021

The table below provides our results of operations for the three months ended September 30, 2022 and September 30, 2021:

	Three Months Ended September 30	
	2022	2021
	(In thousands, except per share data) (unaudited)	
Research and development expenses	$ 4,201	$ 2,679
General and administrative expenses	1,476	1,185
Operating loss	(5,677)	(3,864)
Other income(expenses), net	(56)	440
Operating income (loss) post-finance expense & other income, net	(5,733)	(3,424)
Taxes on income		
Net income (loss)	(5,733)	(3,424)
Other comprehensive income (loss)	-	857
Total comprehensive income (loss)	$ (5,733)	$ (2,567)
Basic income (loss) per share	$ (0.31)	$ (0.19)
Diluted income (loss) per share	$ (0.31)	$ (0.19)

Research and Development Expenses

For the nine and three months ended September 30, 2022 and 2021, we incurred research and development expenses in the aggregate of $12,993,000, $4,201,000, $7,715,000 and $2,679,000, respectively. The increase of $5,278,000, or 68%, in research and development expenses for the nine months ended September 30, 2022 as compared to the nine months ended September 30 ,2021 was primarily due to (a) a $2,364,000 increase in expenses for clinical studies, pre-clinical studies and an increase in the number of Allocetra™ doses that were manufactured and inventoried, which represented 45% of the increase in research and development expenses for such period, (b) a $1,347,000 increase in salaries as a result of hiring additional R&D personnel, as well as certain pay increases for existing R&D personnel, which represented 26% of the increase in research and development expenses for such period, and (c) a $975,000 increase in lease payments and overhead expenses with respect to the lease of our plant space used for the manufacture of Allocetra™ to support ongoing clinical trials, which represented 19% of the of the increase in research and development expenses for such period.

The increase of $1,522,000, or 56%, in research and development expenses for the three months ended September 30, 2022 as compared to the third quarter of 2021 was primarily due to a $347,000 increase in salaries, a $538,000 increase in pre-clinical studies, clinical studies and consumption of materials, and a $322,000 increase in lease payments and overhead expenses with respect to the lease of our plant space used for the manufacture of Allocetra™ to support ongoing clinical trials

General and Administrative Expenses

For the nine and three months ended September 30, 2022 and 2021, we incurred general and administrative expenses in the aggregate of $4,959,000, $1,476,000, $3,759,000 and $1,185,000 respectively. The increase of $1,200,000, or 32%, in general and administrative expenses for the nine months ended September 30, 2022 as compared to the 2021 period was primarily due to a $369,000 increase in salaries as a result of hiring additional personnel and certain pay raises for existing personnel, a $606,000 increase in non-cash share-based compensation and a $206,000 increase in professional fees, which was partially offset by a $346,000 decrease in compensation to directors.

The increase of $291,000, or 25%, in general and administrative expenses for the three months ended September 30, 2022 as compared to the 2021 period was primarily due to a $90,000 increase in salaries as a result of hiring additional personnel and certain pay raises for existing personnel, a $18,000 increase in professional fees and a $60,000 increase resulting from intellectual property regulatory expenses.

Operating Loss

Due to an increase in research and development and general and administrative expenses for the nine and three month periods ended September 30, 2022 as compared to the applicable 2021 periods, our operating loss was $17,952,000 and $5,677,000 respectively, representing an increase of $6,478,000 and $1,813,000, or 56% and 47%, respectively, as compared to our operating loss of $11,474,000 and $3,864,000 for the nine and three month periods ended September 30, 2021. A $2,364,000 increase in expenses for clinical studies, pre-clinical studies and an increase in the number of Allocetra™ doses that were manufactured and inventoried represented 36% of the increase in the operating loss for the for the nine months ended September 30, 2022. In addition, a $1,716,000 increase in salaries as a result of hiring additional personnel and certain pay increases for existing personnel represented 26.5% of the increase in the operating loss for the respective nine-month periods, and a $733,000 non-cash expenses increase in share based compensation represents 11.3% of the increase in the operating loss for the respective nine-month periods.

Other Income (Expenses), Net

Other income (expenses), net consist of the following:

- Interest earned on our cash and cash equivalents; and
- Expenses or income resulting from fluctuations of the NIS and Euro, in which a portion of our assets and liabilities are denominated, against the U.S. dollar; and
- Gain and losses from marketable equity securities.

For the nine and three months ended September 30, 2022 and 2021, we recorded other (expenses) income net of $(5,919,000), $(56,000), $ 1,742,000 and $440,000, respectively. The increase in other expenses for the nine and three months ended September 30, 2022 as compared to the nine and three months ended September 30, 2021 was primarily due to a loss from changes in the fair value of marketable equity securities and an increase in expenses resulting from currency fluctuations on cash and cash equivalents and deposits denominated in NIS currency.

Net Loss

For the nine and three months ended September 30, 2022, our net loss was $23,871,000 and $5,733,000, respectively, representing an increase of $14,139,000 and $2,309,000, or 145% and 67%, respectively, as compared to our net loss of $9,732,000 and $3,424,000 the comparable prior-year periods, respectively. This increase in loss for the nine months period resulted primarily from a non-operating $6,313,000 expense associated with a change in fair value of marketable securities and currency fluctuations on cash and cash equivalents and deposits denominated in NIS for the nine months ended September 30 2022 as compared to a non-operating gain of $1,652,000 for the nine months ended September 30 2021, together representing $7,965,000, or 56%, of the increase in the loss. In addition, a $2,364,000 increase in expenses for clinical studies, pre-clinical studies and increase in the number of Allocetra™ doses that were manufactured and inventoried represented 17% of the increase in the loss for the respective nine-month periods.

Other Comprehensive Income (Loss)

As of October 1, 2021, the U.S. dollar had become the functional currency of Enlivex R&D; therefore, for the nine and three months ended September 30, 2022, we did not record any other comprehensive income (loss) from exchange rate differences arising from the translation of our unaudited condensed consolidated financial statements from our functional to our presentation currency.

Cash Flows

Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

For the nine months ended September 30, 2022 and 2021, net cash used in operations was $19,135,000 and $10,951,000, respectively. The increase in net cash used in operations for 2022 was primarily due to a $2,364,000 increase in expenses for clinical studies, pre-clinical studies and increase in the number of Allocetra™ doses that were manufactured and inventoried, as well as a $1,716,000 increase in salaries as a result of hiring additional personnel and certain pay increases for existing personnel, and a $1,115,000 increase in lease payments and overhead expenses with respect to the lease of our plant space used for the manufacture of Allocetra™ to support ongoing clinical trials.

For the nine months ended September 30, 2022 and 2021, net cash provided by (used in) investing activities was $65,400,000 and $(33,062,000), respectively. The increase in net cash provided by investing activities for 2022 as compared to 2021 resulted primarily from proceeds from sales of marketable securities of $62,549,000 as compared to a purchase of marketable securities of $62,136,000, net of sales, in the comparable prior year period. In addition, we incurred a non-recurring expense of $4.9 million related to the construction of our new manufacturing facility.

For the nine months ended September 30, 2022 and 2021, net cash provided by financing activities was $150,000 and $60,985,000, respectively. This decrease in cash provided by financing activities for 2022 as compared to 2021 resulted primarily from net proceeds of $53,174,000 from our issuance of ordinary shares and warrants in an offering in February 2021 and proceeds of $7,702,000 from the exercise of warrants in the comparable prior year period.

Liquidity and Capital Resources

We have incurred substantial losses since our inception. As of September 30, 2022, we had an accumulated deficit of approximately $75.8 million and working capital (current assets minus current liabilities) of approximately $54.7 million. We expect to incur losses from operations for the foreseeable future, and we expect to incur increasing research and development expenses, conducting preclinical studies and clinical trials and outsourcing of certain development activities. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff and add infrastructure.

Developing product candidates, conducting clinical trials and commercializing products are expensive, and we will need to raise substantial additional funds to achieve our strategic objectives. We believe that our existing cash resources, due to our 2021 financing activity, as described above, will be sufficient to fund our projected cash requirements approximately through the third quarter of 2024. Nevertheless, we will require significant additional financing in the future to fund our operations, including if and when we progress into additional clinical trials, obtain regulatory approval for any of our product candidates and commercialize the same. We believe that we will need to raise significant additional funds before we have any cash flow from operations, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, development and commercialization arrangements with respect to our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or platforms;
- the receipt of additional government grants;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to our product candidates.

We currently do not have any commitments for future external funding. In the future, we will need to raise additional funds, and we may decide to raise additional funds even before we need such funds if the conditions for raising capital are favorable. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financings, credit facilities or by out-licensing applications of our product candidates. The sale of equity or convertible debt securities may result in dilution to our existing shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also subject us to covenants that restrict our operations. We cannot be certain that additional funding, whether through grants from the Israel Innovation Authority, financings, credit facilities or out-licensing arrangements, will be available to us on acceptable terms, if at all. If sufficient funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our product candidates, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain potential products that we might otherwise seek to develop or commercialize independently.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS mainly against the U.S. dollar, and vice versa, because most of our expenses are denominated in NIS and the U.S. dollar. Our NIS and U.S. dollar expenses consist principally of payments made to employees, sub-contractors and consultants for preclinical studies, clinical trials and other research and development activities. We anticipate that a sizable portion of our expenses will continue to be denominated in the NIS and U.S. dollar. Our financial position, results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates.