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: November 2021

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, 2021 and 2020, 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 F-3 and F-3MEF (File No. 333-232413, File No. 333-232009 and File No. 333-252926), filed with the Securities and Exchange Commission..

Exhibit No.

99.1	Unaudited condensed consolidated financial statements for Enlivex as of September 30, 2021 and December 31, 2020 and for the three and nine-month periods ended September 30, 2021 and 2020.
99.2	Operating and Financial Review and Prospects as of and for the three and nine-month periods ended September 30, 2021 and 2020.

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: November 19, 2021

ENLIVEX THERAPEUTICS LTD.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2021 AND DECEMBER 31, 2020
AND FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2021 AND 2020

ENLIVEX THERAPEUTICS LTD.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2021 AND DECEMBER 31, 2020
AND FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2021 AND 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

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

	September 30, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 22,146	$ 5,673
Short term deposits	-	30,034
Marketable securities	65,484	-
Prepaid expenses and other receivables	1,777	1,164
Restricted cash	82	79
Cash held with respect to CVR Agreement	792	1,171
Total Current Assets	90,281	38,121
Non-Current Assets		
Property and equipment, net	1,673	1,481
Other assets	6,213	756
Total Non-Current Assets	7,886	2,237
TOTAL ASSETS	$ 98,167	$ 40,358
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable trade	$ 1,062	$ 463
Accrued expenses and other liabilities	2,878	2,738
CVR holders	792	1,171
Total Current Liabilities	4,732	4,372
Non-Current Liabilities		
Other long-term Liabilities	5,352	499
Total Non-Current Liabilities	5,352	499
Commitments and Contingent Liabilities		
TOTAL LIABILITIES	10,084	4,871
SHAREHOLDERS' EQUITY		
Ordinary shares of NIS 0.40 ($0.12) par value: Authorized: 45,000,000 shares as of September 30, 2021 and December 31, 2020; Issued and outstanding: 18,330,507 and 14,587,934 as of September 30, 2021 and December 31, 2020;	2,107	1,646
Additional paid in capital	132,104	70,361
Foreign currency translation adjustments	1,101	977
Accumulated deficit	(47,229)	(37,497)
TOTAL SHAREHOLDERS' EQUITY	**88,083**	**35,487**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 98,167	$ 40,358

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,	
	2021	2020	2021	2020
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development expenses	2,679	1,122	7,715	3,642
General and administrative expenses	1,185	837	3,759	2,446
	3,864	1,959	11,474	6,088
Operating loss	(3,864)	(1,959)	(11,474)	(6,088)
Other income/(expense), net	440	(166)	1,742	128
Net (loss)	(3,424)	(2,125)	(9,732)	(5,960)
Other comprehensive income (loss)				
Exchange differences arising from translating financial statements from functional to presentation currency	857	227	124	99
Total other comprehensive income (loss)	857	227	124	99
Total comprehensive (loss)	$ (2,567)	$ (1,898)	$ (9,608)	$ (5,861)
Basic & diluted (loss) per share	$ (0.19)	$ (0.16)	$ (0.54)	$ (0.47)
Weighted average number of shares outstanding	18,312,418	13,463,771	17,705,913	12,770,226

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 adjustments	Accumulated deficit	Total Shareholders' deficit
	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 CHANGES IN SHAREHOLDERS' EQUITY (UNAUDITED)

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

	Ordinary shares		Additional paid-in capital	Currency translation adjustments	Accumulated deficit	Total Shareholders' deficit
	Shares	Amount				
Balance as of December 31, 2019	10,334,126	$ 1,151	$ 37,104	$ (1,300)	$ (25,673)	$ 11,282
Changes during the three months period ended March 31, 2020:						
Issuance of shares and warrants for cash consideration of $26,968 net of $2,501 issuance costs	3,093,750	358	22,098	-	-	22,456
Stock based compensation	-	-	131	-	-	131
Other comprehensive loss	-	-	-	(1,016)	-	(1,016)
Net loss	-	-	-	-	(794)	(794)
Balance as of March 31, 2020 (unaudited)	13,427,876	1,509	59,333	(2,316)	(26,467)	32,059
Changes during the three months period ended June 30, 2020:						
Exercise of options	35,895	4	93	-	-	97
Stock based compensation	-	-	189	-	-	189
Other comprehensive loss	-	-	-	888	-	888
Net loss	-	-	-	-	(3,041)	(3,041)
Balance as of June 30, 2020 (unaudited)	13,463,771	1,513	59,615	(1,428)	(29,508)	30,192
Changes during the three months period ended September 30, 2020:						
Stock based compensation	-	-	205	-	-	205
Other comprehensive loss	-	-	-	227	-	227
Net loss	-	-	-	-	(2,125)	(2,125)
Balance as of September 30, 2020 (unaudited)	13,463,771	$ 1,513	$ 59,820	$ (1,201)	$ (31,633)	$ 28,499

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,	
	2021	**2020**
Cash flows from operating activities		
Net (loss)	$ (9,732)	$ (5,960)
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation	396	186
Non-cash operating lease expenses	194	117
Share-based compensation	1,219	525
Income on marketable securities	(2,212)	-
Changes in operating asset and liability items:		
(Increase) decrease in prepaid expenses and other receivables	(611)	1,648
Increase in accounts payable trade	596	(62)
Increase (decrease) in accrued expenses and other liabilities	(651)	(1,609)
Operating lease liabilities	(150)	(93)
Net cash (used in) provided by operating activities	(10,951)	(5,248)
Cash flows from investing activities		
Purchase of property and equipment	(592)	(538)
Release (investment) in short-term bank deposits	29,666	(16,000)
Purchases of marketable securities	(90,337)	-
Proceeds from sales of marketable securities	28,201	-
Net cash (used in) investing activities	(33,062)	(16,538)
Cash flows from financing activities		
Proceeds from issuance of shares and warrants net of $4,455 and $2,294 issuance expenses, respectively	53,174	22,456
Proceeds from exercise of warrants	7,702	-
Proceeds from exercise of options	109	97
Net cash provided by financing activities	60,985	22,553
Increase in cash and cash equivalents	16,972	767
Cash and cash equivalents - beginning of period	7,012	5,524
Exchange rate differences on cash and cash equivalents	(657)	106
Cash and cash equivalents - end of period	$ 23,327	$ 6,397
Non-cash transactions:		
Warrants issued in settlement of issuance costs to a placement agent	$ 2,095	$ 563
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ -	$ -
Cash received for interest, net	$ 51	$ 204

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

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.

The Company is 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 certain diseases, which include solid tumors, sepsis, COVID-19, and others.

The Allocetra™ concept 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.

Enlivex Therapeutics R&D Ltd. ("Enlivex R&D", formerly known as Enlivex Therapeutics Ltd.) 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, pursuant to which a wholly owned subsidiary of the Parent merged with and into Enlivex R&D, the Parent changed its name to Enlivex Therapeutics Ltd. Enlivex R&D is a wholly owned subsidiary of the Company.

In January 2015, Bioblast Pharma Inc. was incorporated in the State of Delaware as a wholly owned subsidiary of the Parent. On July 1, 2020 Bioblast Pharma Inc changed its name to Enlivex Therapeutics Inc.

The Company's ordinary shares, NIS 0.40 per share ("Ordinary Shares" or "ordinary shares"), are traded under the symbol "ENLV" on both the Nasdaq Capital Market and 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, 2021, had an accumulated deficit of $47,229 thousand.

During the first quarter of 2021 the Company raised a net aggregated amount of $53.2 million in cash from the issuance and sale of 2,848,629 of its ordinary shares and an additional $7.7 million from the exercise of 855,813 warrants and 13,435 options. However, the Company expects to continue to incur losses for at least the next several years and over that period 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 an adequate level of financing needed for its long-term development. The Company's ability to continue to operate in the long term is dependent upon additional financial support.

Based on the Company's current assessment, the Company does not expect any material impact on its liquidity due to the worldwide spread of the SARS-CoV-2 coronavirus. However, the timelines for the Company's clinical development programs may be extended due to direct and indirect impacts of the COVID-19 pandemic or new variants of the virus. For example, there has been a delay in recruiting patients for the Company's randomized, controlled Phase IIb clinical trial of Allocetra™ in patients with severe sepsis due to a lower number of pneumonic septic patients, as a result of the COVID-19 pandemic environment. The Company previously reported that the Company expected to obtain interim results from this Phase IIb clinical trial during 2021 or early 2022 followed by top-line results later in 2022, and also reported that its COVID-19 Phase IIb clinical trial was expected to commence in the third quarter of 2021, with top-line results expected in the second quarter of 2022. Based on current assessment of management, interim results for the sepsis Phase IIb are expected in the first or second quarter of 2022, and top line results for this trial are expected in the fourth quarter of 2022. The COVID-19 Phase IIb clinical trial commenced as expected in the third quarter of 2021, but the current assessment of management is that topline results for this clinical trial will be available in the fourth quarter of 2022 or first quarter of 2023 due to expected lower enrollment of patients in Israel and increased enrollment in European sites. The full extent to which the COVID-19 pandemic, vaccination rates in various countries or new variants of the virus will directly or indirectly impact the Company's business, results of operations, timelines for enrollment of patients in clinical trials and financial condition will depend on future developments that are highly uncertain as of the date of issuance of these unaudited condensed consolidated financial statements. Actual results could differ materially from the Company's estimates.

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 2020 Annual Report on Form 20-F, as filed with the SEC on April 30, 2021. The results of operations for these interim periods are not necessarily indicative of the operating results for any future period. The December 31, 2020 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 New Israeli Shekel ("NIS"), which is the local currency where the Company operates. The financial statements of the Company were translated into U.S. dollars in accordance with ASC 830, "Foreign Currency Matters". Accordingly, assets and liabilities were translated from NIS to U.S. dollars using period-end exchange rates, equity items were translated at the exchange rates as of the dates of the respective equity transactions, and income and expense items were translated at average exchange rates during the period.

Gains or losses resulting from translation adjustments (which result from translating an entity's financial statements into U.S. dollars if its functional currency is other than the U.S. dollar) are reported in other comprehensive income (loss) and are reflected in equity, under "accumulated other comprehensive income (loss)".

Balances denominated in, or linked to foreign currencies are stated on the basis of the exchange rates prevailing at the balance sheet date. For foreign currency transactions included in the statement of income, the exchange rates applicable on the relevant transaction dates are used. Transaction gains or losses arising from changes in the exchange rates used in the translation of such balances are carried to financing income or expenses as applicable.

1 U.S. $ = 3.229 NIS and 3.215 NIS as of September 30, 2021 and December 31, 2020, respectively.

The U.S. $ increased (decreased) against the NIS (0.95%), 0.44%, (0.72%) and (0.43%) in the three and nine months ended September 30, 2021 and 2020, 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.

Recent Accounting Pronouncements

Effective January 1, 2021, the Company adopted ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which removes specific exceptions to the general principles in Topic 740 and simplifies the accounting for income taxes. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements.

Effective January 1, 2021, the Company adopted ASU No. 2020-10, *Codification Improvements*, which amends a variety of topics in the Accounting Standards Codification to improve consistency and clarify guidance. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements.

There have been no other 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, 2020.

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 gain recognized on equity securities for the three and nine months ended September 30, 2021 was $629 and $2,212 thousand of which $610 and $1,952 thousand, respectively, were not realized.

NOTE 3 – CASH, CASH EQUIVALENTS AND RESTRICTED CASH

(in thousands)	September 30, 2021	December 31, 2020
Cash held in banks	$ 1,133	$ 1,173
Bank deposits in U.S.$ (annual average interest rates 0.3% and 0.32%)	21,013	4,500
Total cash and cash equivalents	22,146	5,673
Cash held with respect to CVR Agreement	792	1,171
Short-term restricted cash	82	79
Long-term restricted cash	307	89
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 23,327	$ 7,012

NOTE 4 – SHORT TERM DEPOSITS

(in thousands)	September 30, 2021	December 31, 2020
Bank deposits in U.S.$ (annual average interest rates -and 0.6%)	-	30,034
Total short-term deposits	$ -	$ 30,034

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

(in thousands)	September 30, 2021	December 31, 2020
Cost:		
Laboratory equipment	$ 1,744	$ 1,256
Computers	212	169
Office furniture & equipment	109	102
Leasehold improvements	761	712
	2,826	2,239
Accumulated depreciation:		
Laboratory equipment	851	588
Computers	122	87
Office furniture & equipment	11	5
Leasehold improvements	169	78
	1,153	758
Depreciated cost	$ 1,673	$ 1,481

Depreciation expenses for the three and nine months ended September 30, 2021 and 2020 were $157 and $92 thousand and $396 and $186 thousand, respectively.

NOTE 6 – OTHER ASSETS

(in thousands)	September 30, 2021	December 31, 2020
Restricted cash	$ 307	$ 89
Long-term prepaid expenses	6	8
Right-of-Use assets, net	5,900	659
	$ 6,213	$ 756

NOTE 7 – ACCRUED EXPENSES AND OTHER LIABILITIES

(in thousands)	September 30, 2021	December 31, 2020
Vacation, convalescence and bonus accruals	$ 407	$ 684
Employees and payroll related	464	352
Short term operating lease liabilities	636	203
Accrued expenses and other	1,371	1,499
	$ 2,878	$ 2,738 394

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

NOTE 8 – LEASES

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

(in thousands)	Nine months ended September 30, 2021	2020
The components of lease expense were as follows:		
Operating leases expenses	$ 245	$ 155
Supplemental consolidated cash flow information related to operating leases follows:		
Cash used in operating activities	$ 210	$ 133
Non-cash activity:		
Right of use assets obtained in exchange for new operating lease liabilities	$ 5,444	$ 352

(in thousands)	September 30, 2021	December 31, 2020
Supplemental information related to operating leases, including location of amounts reported in the accompanying consolidated balance sheets, follows:		
Other assets - Right-of-Use assets	$ 6,377	$ 920
Accumulated amortization	477	261
Operating lease Right-of-Use assets, net	$ 5,900	$ 659
Lease liabilities – current - Accounts payable and accrued liabilities	$ 636	$ 203
Lease liabilities – noncurrent - Other long-term liabilities	5,352	499
Total operating lease liabilities	$ 5,988	$ 702
Weighted average remaining lease term in years	9.12	3.64
Weighted average annual discount rate	9.3%	11.9%

Maturities of operating lease liabilities as of September 30, 2021, were as follows:

2021 (after September 30)	$ 231
2022	842
2023	796
2024	680
2025	743
2026 and onwards	3,696
Total undiscounted lease liability	$ 6,988
Less: Imputed interest	$ (1,000)
Present value of lease liabilities	$ 5,988

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

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, 2021, was approximately $8 million. As of September 30, 2021, the Company had not paid any royalties to the IIA.

In January 2021, the Company submitted a new non-dilutive grant application to the IIA for reimbursement by the IIA of certain expenses associated with its clinical development program of prevention of cytokine storms and organ dysfunction associated with sepsis for a period commencing January 1, 2021 and ending December 31, 2021 (the "2021 Sepsis Grant Application"). In May 2021 the IIA approved the 2021 Sepsis Grant Application in the total amount of NIS 3.8 million ($1.16 million).

On July 17, 2021 a single Israeli plaintiff filed a request in the Israeli court of Tel Aviv to approve an Israeli class action lawsuit against the Company. The claim alleges that the Company did not make various documents filed with the Israel Securities Authority's submission system appropriately accessible for people with disabilities, specifically that certain PDF filings were not prepared in accordance with certain provisions of the Israeli law and regulations regarding accessibility of documents to the disabled. The plaintiff filed requests for approval of similar class action lawsuits on the same day against 17 other companies whose securities are traded on the Tel-Aviv Stock Exchange. The Company believes that the plaintiff's claims against the Company are without merit and intends to vigorously defend against them.

NOTE 10 – EQUITY

a. On October 22, 2020, the Company entered into an at the market offering agreement (the "Sales Agreement"), pursuant to which the Company may, from time to time and at the Company's option, issue and sell ordinary shares having an aggregate offering price of up to $25 million through a sales agent, subject to certain terms and conditions. All shares sold pursuant to the Sales Agreement were sold pursuant to the Company's effective shelf registration statement on Form F-3. The Company must pay the sales agent a cash commission of 3% of the gross proceeds of the sale of any shares sold through the sales agent under the Sales Agreement. Between February 5, 2021 and February 9, 2021, the Company received gross proceeds of $6,339,095 from the sale of 284,317 ordinary shares at an average gross price per share of $22.29 under the Sales Agreement. Issuance expenses totaled $192 thousand.

   On February 9, 2021, the Company terminated the prospectus supplement related to the offer and sale of ordinary shares under the Sales Agreement, but the Sales Agreement remains in full force and effect. To that date, the Company had sold an aggregate of 476,983 ordinary shares under the Sales Agreement, having a gross aggregate offering price of $8,557,437 at a gross average price per share of $17.94. Until such time as the Company files with the SEC a new registration statement on Form F-3 and such registration statement becomes effective, the Company may not offer and sell any additional ordinary shares under the Sales Agreement.

b. On February 9, 2021, the Company entered into an amended and restated underwriting agreement (the "Underwriting Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") with respect to the offer, issuance and sale (the "Offering") of an aggregate of 2,296,107 ordinary shares, together with an option granted to Wainwright to purchase up to 344,416 additional ordinary shares. The ordinary shares were offered to the public at a price of $20 per share.

The Offering closed on February 12, 2021, on which date the Company completed the issuance of 2,296,107 ordinary shares to Wainwright at a price, including the underwriting discount but before other associated fees, of $18.60 per ordinary share, as set forth in the Underwriting Agreement.

On February 17, 2021, Wainwright exercised in part its option to purchase additional ordinary shares and purchased 268,205 ordinary shares at a price, including the underwriting discount but before other associated fees, of $18.60 per share, as set forth in the Underwriting Agreement.

In accordance with the Underwriting Agreement, the Company paid Wainwright underwriting discounts and commissions equal to 7% of the gross proceeds received by the Company from the sale of the ordinary shares in the Offering, as well as a management fee equal to 1% of the gross proceeds received by the Company from the sale of the ordinary shares in the Offering. In addition, the Company issued to Wainwright 179,501 warrants to purchase ordinary shares of the Company (the "Underwriter Warrants"). The Underwriter Warrants are exercisable for five years from commencement of the Offering and have an exercise price of $25 per ordinary share, subject to customary adjustments as provided in the Underwriter Warrants. The Company has also paid Wainwright approximately $126,000 for various expenses.

The Underwriter Warrants were valued at $2,095 thousand using a Black-Scholes model with the following assumptions: estimated weighted average volatility 78.4%; weighted average risk-free interest rate of 0.5%; no dividend; and a weighted average contractual life of 5 years.

The net proceeds from the Offering were $47,023 thousand after deducting Wainwright's fees and other expenses relating to the Offering.

c. During February 2021, 855,813 warrants were exercised for an aggregate of 855,813 ordinary shares, which provided the Company with aggregate gross proceeds of $7.7 million.

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	Exercise price per share
Outstanding January 1, 2021	1,407,683	
Issued to placement agent	179,501	$ 25
Forfeited and expired	(27,016)	$ 180
Exercised	(855,813)	$ 9
Outstanding September 30, 2021	704,355	

Comprised as follows:	Number of Warrants	Exercise Price Per Share	Issuance date	Expiration date
	22,750	$ 10	February 26, 2020	February 24, 2025
	455,937	$ 9	March 5, 2020	March 5, 2022
	46,167	$ 10	March 4, 2020	March 4, 2022
	160,727	$ 25	February 12, 2021	February 9, 2026
	18,774	$ 25	February 17, 2021	February 9, 2026
	704,355			

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

NOTE 11 – SHARE-BASED COMPENSATION

a) On May 28, 2021, the Board approved an increase in the number of ordinary shares authorized for issuance to employees, directors and consultants by 1,800,000. As of September 30, 2021, 4,150,704 ordinary shares were authorized for issuance to employees, directors and consultants under the 2019 Equity Incentive Plan, of which 1,604,587 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,			
	2021		2020	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of period	2,177,925	$ 6.54	1,877,713	$ 5.59
Granted	15,000	$ 8.30	-	$ -
Forfeited and expired	(19,395)	$ 72.00	(30,897)	$ 6.13
Exercised	(24,321)	$ 2.76	-	$ -
Outstanding at end of period	2,149,209	$ 6.01	1,846,816	$ 5.44
Exercisable at end of period	1,421,418	$ 4.67	1,107,741	$ 4.96

	Three months ended September 30,			
	2021		2020	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Non-vested at beginning of period	773,116	$ 8.19	779,760	$ 5.85
Granted	15,000	$ 8.30	-	$ -
Vested	(56,075)	$ 7.81	(36,595)	$ 5.28
Forfeited	(4,250)	$ 9.74	(4,090)	$ 5.45
Non-vested at the end of period	727,791	$ 8.21	739,075	$ 5.88

	Nine months ended September 30,			
	2021		2020	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of period	1,884,420	$ 5.52	1,625,042	$ 5.72
Granted	325,500	$ 12.38	320,000	$ 3.89
Forfeited and expired	(22,580)	$ 62.83	(62,331)	$ 6.26
Exercised	(38,131)	$ 2.84	(35,895)	$ 2.69
Outstanding at end of period	2,149,209	$ 6.01	1,846,816	$ 5.44
Exercisable at end of period	1,421,418	$ 4.67	1,107,741	$ 4.96
Non-vested at beginning of period	601,227	$ 5.93	526,351	$ 7.03
Granted	325,500	$ 12.38	320,000	$ 3.89
Vested	(191,501)	$ 8.10	(72,116)	$ 5.22
Forfeited	(7,435)	$ 8.47	(35,160)	$ 6.26
Non-vested at the end of period	727,791	$ 8.21	739,075	$ 5.88

During the three and nine months ended September 30, 2021 and 2020, the Company recognized $336 thousand, $1,114 thousand, $205 thousand and $525 thousand, respectively, of share-based compensation expenses related to stock options. As of September 30, 2021, the total unrecognized estimated compensation cost related to outstanding non-vested stock options was $2,822 thousand which is expected to be recognized over a weighted average period of 3.96 years.

c) Set forth below is data regarding the range of exercise prices and remaining contractual life for all options outstanding at September 30, 2021:

Exercise price	Number of options outstanding	Remaining contractual Life (in years)	Intrinsic Value of Options Outstanding	No. of options exercisable
			(in thousands)	
$ 2.69	649,882	3.76	$ 4,672,653	649,882
$ 3.66	250,000	8.59	1,554,250	118,057
$ 4.68	56,500	8.50	293,800	14,875
$ 6.22	658,590	6.30	2,408,074	511,038
$ 8.19	150,000	8.13	253,500	37,500
$ 8.30	15,000	9.85	23,700	-
$ 9.02	40,500	9.13	34,830	-
$ 10.12	12,126	7.18	-	7,274
$ 12.21	2,421	7.49	-	1,211
$ 21.40	3,190	7.82	-	2,220
$ 12.22	250,000	9.67	-	48,611
$ 14.00	60,500	9.57	-	30,250
$ 90.16	500	0.10	-	500
	2,149,209		$ 9,240,807	1,421,418

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

	Three months ended September 30,			
	2021		2020	
	Number of shares	Weighted average grant date fair value	Number of shares	Weighted average grant date fair value
Nonvested at beginning of period	60,125	$ 14.67	-	$ -
Granted	-	$ -	-	$ -
Vested	-	$ -	-	$ -
Forfeited	(5,000)	$ 14.67	-	$ -
Nonvested at end of period	55,125	$ 13.67	-	$ -

	Nine months ended September 30,			
	2021		2020	
	Number of shares	Weighted average grant date fair value	Number of shares	Weighted average grant date fair value
Nonvested at beginning of period	-	$ -	-	$ -
Granted	62,125	$ 13.7	-	$ -
Vested	-	$ -	-	$ -
Forfeited	(7,000)	$ 14.67	-	$ -
Nonvested at end of period	55,125	$ 13.67	-	$ -

The Company estimates the fair value of restricted stock units based on the closing sales price of the Company's ordinary shares on the date of grant (or the closing bid price, if no sales were reported). During the three and nine months ended September 30, 2021 and 2020, the Company recognized $41 thousand, $105 thousand, $0 and $0, 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, 2021 was $657 thousand, which is expected to be recognized over a weighted average period of 3.4 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)	2021	2020	2021	2020
Research & development	$ 130	$ 207	$ 576	$ 407
General & administrative	247	(2)	643	118
Total	$ 377	$ 205	$ 1,219	$ 525

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2021 (UNAUDITED)

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, 2021 and December 31, 2020:

(in thousands)	September 30, 2021			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 22,146	$ 22,146	$ -	$ -
Short term deposits	-	-		
Marketable securities	65,484	65,484		
Restricted cash	389	389	-	-
Cash held with respect to CVR Agreement	792	792	-	-
Total financial assets	$ 88,811	$ 88,811	$ -	$ -

(in thousands)	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 5,673	$ 5,673	$ -	$ -
Short term deposits	30,034	30,034	-	-
Cash held with respect to CVR Agreement	1,171	1,171	-	-
Restricted cash	168	168	-	-
Total financial assets	$ 37,046	$ 37,046	$ -	$ -

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 the following subsequent event necessitated disclosure:

Following the Company's General Meeting of Shareholders held on November 4, 2021, the Company approved the amendment of the consulting agreement with an entity controlled by the Company's Executive Chairman of the Board (the "Consultant"). Pursuant to this amendment, if the Company consummates a Commercial Transaction or Sale (each as defined in the consulting agreement, as amended), the Consultant will receive 3.33% of the gross proceeds actually received by the Company (the "Fee") during the first five (5) years following the Sale or Commercial Transaction. In the case of a Commercial Transaction, the Fee with respect to such Commercial Transaction shall be paid only once the aggregate consideration actually received by the Company in respect of such Commercial Transaction is equal to or greater than $20 million.

Exhibit 99.2

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, 2020. 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, the novel strain of coronavirus ("COVID-19"), and others.

We believe that the Company's primary innovative immunotherapy, Allocetra™, represents a paradigm shift in macrophage reprogramming, moving from a binary classification of M1 (pro-inflammatory macrophages) or M2 (anti-inflammatory macrophages) status, 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 three main clinical verticals: sepsis; COVID-19; and solid malignant tumors (the "Indications"). The Company believes that negatively-reprogrammed macrophages may be key contributors to disease severity across all of the Indications, and thus effective reprogramming of these previously negative-reprogrammed macrophages into their respective homeostatic states may provide resolution to the diseases underlying these Indications, some of which are considered "unmet medical needs", such as preventing or treating complications associated with sepsis.

Impact of COVID-19

Based on the Company's current assessment, the Company does not expect any material impact on its liquidity due to the worldwide spread of the SARS-CoV-2 coronavirus. However, the timelines for the Company's clinical development programs may be extended due to direct and indirect impacts of the COVID-19 pandemic or new variants of the virus. For example, there has been a delay in recruiting patients for the Company's randomized, controlled Phase IIb clinical trial of AllocetraTM in patients with severe sepsis due to a lower number of pneumonic septic patients, as a result of the COVID-19 pandemic environment. The Company previously reported that the Company expected to obtain interim results from this Phase IIb clinical trial during 2021 or early 2022 followed by top-line results later in 2022, and also reported that its COVID-19 Phase IIb clinical trial was expected to commence in the third quarter of 2021, with top-line results expected in the second quarter of 2022. Based on current assessment of management, interim results for the sepsis Phase IIb are expected in the first or second quarter of 2022, and top line results for this trial are expected in the fourth quarter of 2022. The COVID-19 Phase IIb clinical trial commenced as expected in the third quarter of 2021, but the current assessment of management is that topline results for this clinical trial will be available in the fourth quarter of 2022 or first quarter of 2023 due to expected lower enrollment of patients in Israel and increased enrollment in European sites. The full extent to which the COVID-19 pandemic, vaccination rates in various countries or new variants of the virus will directly or indirectly impact the Company's business, results of operations, timelines for enrollment of patients in clinical trials and financial condition will depend on future developments that are highly uncertain as of the date of issuance of these unaudited condensed consolidated financial statements. Actual results could differ materially from the Company's estimates.

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 and pursuant to the sale of equity and equity-linked securities in both private and registered equity offerings. As of September 30, 2021, we had approximately $88.0 million in cash and cash equivalents, short-term bank deposits, marketable securities and restricted cash. As of September 30, 2021, we had an accumulated deficit of approximately $47.2 million. Although we can provide no assurance, we believe that our existing funds will be sufficient to continue our business and operations as currently conducted through year end 2023. We expect that we will continue to incur operating losses, which may be substantial, over at least the next several years, and we will likely need to obtain additional funds to further develop our research and development programs. Our ability to generate revenue and become profitable depends upon the clinical success of our product candidates, regulatory approvals and our ability to successfully commercialize products.

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, including the costs of consultants and certain other service providers, salaries and related personnel expenses (including stock 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 stock-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. We expect that our general and administrative expenses will increase over time, as we currently expect increases in the number of our executive, accounting and administrative personnel due to our anticipated growth.

On July 12, 2021, we announced that we had initiated the design and construction process for a new wholly owned manufacturing plant in Israel. Construction of the plant began during the third quarter of 2021. Upon completion, this cGMP plant will provide additional manufacturing capacity for Allocetra, and we expect to use the additional manufacturing capacity to support ongoing clinical trials, future clinical trials and initial commercial production of Allocetra that may occur if we receive all applicable regulatory approvals. We expect that our general and administrative expenses will increase as we proceed with this new construction project.

Other income, net

Other income consist of bank fees, exchange rate differences and gains and losses resulting from our investments in marketable equity securities.

Other Comprehensive income (Loss)

Our functional currency is the New Israeli Shekel ("NIS"), while our presentation currency is the U.S. dollar. Gains or losses resulting from the translation from our functional currency to our presentation currency are recognized in other comprehensive income (loss).

Critical Accounting Policies and Estimate

The preparation of financial statements in accordance with United States 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, 2020 as filed with the SEC on April 30, 2021.

Share-Based Compensation and Fair Value of Ordinary Shares

ASC 718 - "Compensation-stock Compensation"- requires companies to estimate the fair value of equity-based payment awards on the date of grant using an Option Pricing Model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods.

We estimate the fair value of our share-based awards using Black-Scholes, which requires the input of assumptions, some of which are highly subjective, including:

- expected volatility of our ordinary shares;
- expected term of the award;
- risk-free interest rate;
- expected dividends; and
- estimated fair value of our ordinary shares on the measurement date.

Prior the consummation of our merger transaction that closed on March 26, 2019 (the "Merger"), there was no active external or internal market for our ordinary shares. Thus, it was not possible to estimate the expected volatility of our share price in estimating fair value of options granted with respect to periods preceding the Merger. Accordingly, we use an average of the historical volatility of our shares and the historical volatility of comparable companies in our industry. The expected term of options granted represents the period of time that options granted are expected to be outstanding, we use management's estimates for the expected term of options due to insufficient readily available historical exercise data.

Results of Operations

Nine and Three-Months Ended September 30, 2021 Compared to Nine and Three-Months Ended September 30, 2020

The table below provides our results of operations for the nine months ended September 30, 2021 and September 30, 2020:

	Nine Months Ended September 30	
	2021	**2020**
	(In thousands, except per share data) (unaudited)	
Research and development expenses	$ 7,715	$ 3,642
General and administrative expenses	3,759	2,446
Operating loss	(11,474)	(6,088)
Other income (expenses), net	1,742	128
Operating income (loss) post-finance expense & other income, net	(9,732)	(5,960)
Taxes on income		
Net income (loss)	(9,732)	(5,960)
Other comprehensive income (loss)	124	99
Total comprehensive income (loss)	$ (9,608)	$ (5,861)
Basic income (loss) per share	$ (0.54)	$ (0.47)
Diluted income (loss) per share	$ (0.54)	$ (0.47)

The table below provides our results of operations for the three months ended September 30, 2021 and September 30, 2020:

	Three Months Ended September 30	
	2021	2020
	(In thousands, except per share data) (unaudited)	
Research and development expenses	$ 2,679	$ 1,122
General and administrative expenses	$ 1,185	837
Operating loss	(3,864)	(1,959)
Other income (expenses), net	440	(166)
Operating income (loss) post-finance expense & other income, net	(3,424)	(2,125)
Taxes on income		
Net income (loss)	(3,424)	(2,125)
Other comprehensive income (loss)	857	227
Total comprehensive income (loss)	$ (2,567)	$ (1,898)
Basic income (loss) per share	$ (0.19)	$ (0.16)
Diluted income (loss) per share	$ (0.19)	$ (0.16)

Research and Development Expenses

For the nine and three months ended September 30, 2021 and 2020, we incurred research and development expenses in the aggregate of $7,715,000, $2,679,000, $3,642,000 and $1,122,000, respectively. The increase of $4,073,000, or 112% for the nine months ended September 30, 2021 as compared to 2020 period was primarily due to a $1,286,000 increase in salaries as a result of hiring additional personnel and certain pay raises, a $1,833,000 increase in expenses for pre-clinical studies, clinical studies and consumption of materials, a $479,000 increase in consultant fees, and a $182,000 increase in stock-based compensation to employees.

The increase of $1,557,000, or 139%, in research and development expenses for the three months ended September 30, 2021 as compared to the third quarter of 2020 was primarily due to a $366,000 increase in salaries, a $941,000 increase expenses for pre-clinical studies, clinical studies and consumption of materials and a $177,000 increase in consultant fees.

General and Administrative Expenses

For the nine and three months ended September 30, 2021 and 2020, we incurred general and administrative expenses in the aggregate of $3,759,000, $1,185,000, $2,446,000 and $837,000, respectively. The increase of $1,313,000, or 54%, in general and administrative expenses for the nine months ended September 30, 2021 as compared to the 2020 period was primarily due to a $203,000 increase in compensation to directors, a $514,000 increase in stock-based compensation, a $237,000 increase in insurance expenses and a $102,000 increase in professional service fees.

The increase of $348,000, or 42%, in general and administrative expenses for the three months ended September 30, 2021 as compared to the third quarter of 2020 was primarily due to a $240,000 increase in stock-based compensation to employees and directors and $80,000 increase in insurance expenses.

Operating Loss

Due to an increase in research and development and general and administrative expenses for the nine and three months ended September 30, 2021, our operating loss was $11,474,000 and $3,864,000, respectively, representing an increase of $5,386,000 and $1,905,000, or 88% and 97%, respectively, as compared to our operating loss for the nine and three months ended September 30, 2020. This increase primarily resulted from increases in research and development salaries, the costs of clinical and pre-clinical studies and material consumption and compensation to directors, as described above.

Other Income (Expenses), Net

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

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

For the nine and three months ended September 30, 2021 and 2020, we recorded net other income (expense) of $1,742,000, $440,000, $128,000 and $(166,000), respectively. The increase in financial income for the nine and three months ended September 30, 2021 as compared to the nine and three months ended September 30, 2020 was primarily due to an increase in income from changes in the fair value of marketable equity securities and from interest earned on our cash and cash equivalents, which was offset by a decrease in income from currency fluctuations on cash and cash equivalents and deposits denominated in currencies other than the NIS.

Net Loss

For the nine and three months ended September 30, 2021, our net loss was $9,732,000 and $3,424,000 respectively, representing an increase of $3,772,000 and $1,299,000, respectively, as compared to our net loss for the comparable prior year periods. This increase primarily resulted from an increase in research and development expenses, including salaries, the costs of clinical studies and material consumption and an increase in compensation to directors, offset by an increase in financial income.

Other Comprehensive Income (Loss)

As a result of an increase of 0.44% and a decrease of 0.95% in the U.S. dollar against the NIS in nine and three months ended September 30, 2021, respectively, as compared to a decrease of 0.43% and a decrease of 0.72% in the comparable prior year period, we recorded income of $124,000 and $857,000 for the nine and three months ended September 30, 2021 from exchange rate differences arising from translating our unaudited condensed consolidated financial statements from functional to presentation currency, as compared to income of $99,000 and $227,000 for the comparable prior year periods, respectively.

Cash Flows

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

For the nine months ended September 30, 2021 and 2020, net cash (used in) operations was $(10,951,000) and $(5,248,000) respectively. The increase in net cash used in operations for 2021 was primarily due to an increase in research and development expenses and general and administrative expenses as a result of increases in salaries, expenses for clinical studies and consumption of materials, directors compensation fees, professional services fees and insurance expenses.

For the nine months ended September 30, 2021 and 2020, net cash used in investing activities was $(33,062,000) and $(16,538,000), respectively. The increase in net cash used in investing activities for 2021 as compared to 2020 resulted primarily from our investments in marketable equity securities, offset by the release of short-term bank deposits.

For the nine months ended September 30, 2021, and 2020, net cash provided by financing activities was $60,985,000 and $22,553,000, respectively. This increase in cash provided by financing activities for 2021 as compared to 2020 resulted primarily from net proceeds of $53,174,000 from our issuance of ordinary shares and warrants in the February 2021 offering (as defined and described below) and proceeds of $7,702,000 from the exercise of warrants.

Liquidity and Capital Resources

During February 2021, we received gross proceeds of approximately $6,339,000 from the sale of 284,317 ordinary shares under an at the market offering agreement (the "Sales Agreement"), dated as of October 22, 2020, by and between the Company and H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which we could elect to sell, through the sales agent party to the Sales Agreement, up to an aggregate of $25 million of our ordinary shares. On February 9, 2021, we terminated the prospectus supplement related to the offering of sales under the Sales Agreement, but the Sales Agreement remains in effect.

On February 9, 2021, we entered into an underwriting agreement with Wainwright with respect to our offer, issuance and sale (the "February 2021 offering") of an aggregate of 2,296,107 ordinary shares, together with an option granted to Wainwright to purchase up to 344,416 additional ordinary shares. The ordinary shares were offered to the public at a price of $20 per share. The February 2021 offering closed on February 12, 2021, on which date the Company completed the issuance of 2,296,107 ordinary shares to Wainwright at a price of $18.60 per share, including underwriting discounts. We paid Wainwright underwriting discounts and commissions equal to 7% of the gross proceeds from the sale of ordinary shares to the public in the February 2021 offering, as well as a management fee equal to 1% of the gross proceeds from the sale of the ordinary shares in the February 2021 offering. In addition, the Company issued to Wainwright 179,501 five-year warrants to purchase ordinary shares at an exercise price of $25 per ordinary share, subject to customary adjustments. The Company also reimbursed Wainwright approximately $126,000 for various expenses.

The net proceeds from the February 2021 offering were approximately $42 million after deducting Wainwright's fees and other estimated expenses relating to the February 2021 offering. On February 17, 2021, Wainwright exercised in part its option to purchase additional ordinary shares, and purchased 268,205 ordinary shares at a price of $18.60 per share, after underwriting discounts. The net proceeds from the purchase of additional ordinary shares by Wainwright were approximately $5.0 million after deducting Wainwright's fees.

During February 2021, 855,813 warrants issued in our two registered direct offerings that occurred in February 2020 and March 2020 were exercised for an aggregate of 855,813 ordinary shares, providing the Company with aggregate gross proceeds of $7.7 million.

We have incurred substantial losses since our inception. As of September 30, 2021, we had an accumulated deficit of approximately $47.2 million and working capital (current assets minus current liabilities) of approximately $85.5 million. We expect to incur losses from operations for the foreseeable future, and we expect to incur increasing research and development expenses, including expenses related to the hiring of personnel, 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. As described above, we have initiated the design and construction process for a new wholly owned manufacturing plant in Israel, for which we expect to incur costs and expenses of approximately $11 million.

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 year-end 2023. 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 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, subcontractors 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.