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: October 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): ☐

On October 4, 2021, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (the "Company"), issued a press release announcing the peer-reviewed publication of clinical data from the Company's Phase Ib sepsis trial in *Frontiers in Immunology,* a leading journal in its field publishing rigorously peer-reviewed research articles. A copy of such press release is furnished as Exhibit 99.1 to this Report on Form 6-K and incorporated herein by reference.

Exhibit No.

99.1	Press Release issued by Enlivex Therapeutics Ltd. on October 4, 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: October 4, 2021

Enlivex Announces the Peer-Reviewed Publication in *Frontiers in Immunology* of Clinical Data from Phase Ib Trial Evaluating Allocetra in Patients with Sepsis

Data published in Frontiers in Immunology show a robust safety profile and substantial improvements in state of organ failure, duration of ICU stay, and mortality in 10 Allocetra-treated severe sepsis patients vs. matched historical controls

Nes-Ziona, Israel, October 4, 2021 (GLOBE NEWSWIRE) – Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced the peer-reviewed publication of clinical data from the Company's Phase Ib sepsis trial in *Frontiers in Immunology,* a leading journal in its field publishing rigorously peer-reviewed research articles. The paper, entitled "Apoptotic Cells for Therapeutic Use in Cytokine Storm Associated With Sepsis – A Phase Ib Clinical Trial" was published in collaboration with researchers at Hadassah-Hebrew University Medical Center and The Wohl Institute for Translational Medicine.

Data presented in the paper compared 10 patients admitted to the intensive care unit (ICU) with sepsis who were treated with Allocetra™ plus standard-of-care with 37 matched controls with sepsis who received only standard-of-care treatment at the same hospital from 2014-2019. Control patients were matched by age, gender, severity of the septic condition reflected by Sequential Organ Failure Assessment (SOFA) score, and infection source. The clinical trial was conducted at Hadassah Medical Center, which is one of the largest and most prestigious hospitals in Israel.

"We believe that this peer-reviewed publication provides important external validation for Allocetra™ and its broadly applicable mechanism of action (MOA) in bacterial systemic infections ," said Prof. Dror Mevorach, M.D., Chief Scientific Officer of Enlivex and lead author of the study. "Compared to matched controls, patients with severe sepsis treated with Allocetra™ experienced substantial improvements in state of organ failure, duration of ICU stay, and mortality. Exploratory analyses suggest that these improvements were due to Allocetra's ability to resolve heterogenous cytokine storms by reprogramming macrophages through the modulation of multiple immune pathways. We believe this immunotherapeutic MOA positions Allocetra™ to address critical unmet needs not only in sepsis, which currently has no specific pharmacologic treatments, but also in other conditions linked to non-homeostatic macrophages such as cancer and acute respiratory distress syndrome associated with COVID-19."

Key data and conclusions from the paper include:

- Allocetra-treated patients (N=10) had a mortality rate of 0% at the end of the study's 28-day follow-up period compared to a mortality rate of 27% in matched historical controls (N=37).
- Allocetra-treated patients exhibited rapid resolution of organ dysfunction and had significantly shorter ICU stays compared to matched controls ($p < 0.0001$).
- All patients had elevated pro- and anti-inflammatory cytokines, chemokines, and additional immune modulators that steadily decreased following Allocetra™ treatment.
- No serious related adverse events or definite treatment-related adverse events were reported with Allocetra™ treatment.

Allocetra™ is currently being evaluated in patients with pneumonia-associated sepsis in a randomized, placebo-controlled Phase IIb trial and in COVID-19 patients with acute respiratory distress syndrome in a separate randomized, placebo-controlled Phase IIb trial. Top-line data from both trials are expected in the second quarter of 2022.

ABOUT THE PHASE Ib SEPSIS STUDY

The aim of this study was to determine the safety, tolerability and efficacy of Allocetra™ in subjects admitted to the ICU with sepsis. Allocetra™ (140 x 10^6 cells/kg) was administered in either a single dose to 6 patients at day 1 or in two doses to 4 additional patients at days 1 and 3. Patients were followed for 28 days. The study subjects were also compared to historical controls hospitalized in the ICU, matched by age, gender, SOFA score, and infection source.

ABOUT ALLOCETRA™

Allocetra™ is being developed as a universal, off-the-shelf cell therapy designed to reprogram macrophages. Diseases such as solid cancers, sepsis, COVID-19 and many others reprogram macrophages out of their homeostatic state. These non-homeostatic macrophages contribute significantly to the severity of the respective diseases. By restoring macrophage homeostasis, Allocetra™ has the potential to provide a novel immunotherapeutic mechanism of action for life-threatening clinical indications that are defined as "unmet medical needs", as a stand-alone therapy or in combination with leading therapeutic agents.

ABOUT ENLIVEX

Enlivex is a clinical stage 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. For more information, visit http://www.enlivex.com.

Safe Harbor Statement: This press release 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 of similar meaning, including statements regarding expected cash balances, market opportunities for the results of current clinical studies and preclinical experiments, the effectiveness of, and market opportunities for, ALLOCETRA™ programs. All such forward-looking 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 the Company's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission. The forward-looking statements contained in this press release 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.

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