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: September 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 September 22, 2021, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel, issued a press release announcing the initiation of dosing in its multi-center, placebo-controlled, randomized, blinded, Phase IIb clinical trial evaluating Allocetra™ in severe and critical COVID-19 patients with acute respiratory distress syndrome (ARDS). 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 September 22, 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: September 22, 2021

Enlivex Doses First Patient in Placebo-Controlled Phase IIb Clinical Trial Evaluating Allocetra in Severe and Critical COVID-19 Patients with ARDS

Top-line data from the randomized, multi-center trial are expected in Q2-2022

Nes-Ziona, Israel, September 22, 2021 (GLOBE NEWSWIRE) – Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company targeting diseased macrophages in patients with sepsis, COVID-19 and solid tumors, today announced the initiation of dosing in its multi-center, placebo-controlled, randomized, blinded, Phase IIb clinical trial evaluating Allocetra™ in severe and critical COVID-19 patients with acute respiratory distress syndrome (ARDS).

The Phase IIb trial is expected to recruit up to 152 severe or critical COVID-19 patients (76 Allocetra™ plus standard-of-care, 76 placebo plus standard-of-care) in clinical centers in Israel and certain European countries, and is designed to assess the safety and efficacy of Allocetra™ when administered in addition to standard-of-care treatment. The co-primary endpoints of the trial are ventilation-free survival and recovery for each of its two patient sub-populations (severe and critical). In addition, the trial will assess several secondary endpoints, including evaluation of long-COVID-19 symptoms. Top-line data from the trial are expected in the second quarter of 2022.

"We believe that recent variant-driven surges in COVID-19 cases around the world have emphasized the need for novel treatments that can address the most serious forms of the disease," said Dr. Oren Hershkovitz, Chief Executive Officer of Enlivex. "They also reinforce our belief that even with vaccines available, COVID-19 will migrate from a pandemic to an endemic, with multiple variants continuing to circulate throughout the population. Through Allocetra's continued development, we hope to provide physicians with an effective treatment option that can improve survival and decrease the length of hospitalization for patients in severe or critical condition. The initiation of dosing in our Phase IIb trial represents an important step towards this goal. The study was already approved by several Ethics Committees from leading Israeli hospitals, and we are committed to accelerate the patient's recruitment by opening many sites both in Israel and specific EU countries as fast as possible".

Prof. Dror Mevorach, Chief Scientific Officer of Enlivex, added, "We believe Allocetra™ has a broadly applicable mechanism of action for reprogramming macrophages and that was demonstrated through the promising results in prior clinical trials in severe and critical COVID-19 patients. We aim to build on these data through the progression of this placebo-controlled Phase IIb study and look forward to its continued advancement."

Enlivex previously reported positive top-line results from Phase Ib and Phase II investigator-initiated clinical trials of Allocetra™ in COVID-19 patients in severe and critical condition. Aggregate data from the two trials demonstrated that Allocetra™ was safe and well tolerated. Moreover, at the end of these trials' 28-day follow-up periods, a 0% (0/21) mortality rate was observed and 90.5% (19/21) of patients recovered from their respective severe/critical condition and were discharged from the hospital after an average of 5.6 days following Allocetra™ administration.

ABOUT ALLOCETRA™

Allocetra™ is being developed as a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. 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 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. 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, the expected timing of clinical trials' results for, and market opportunities for, ALLOCETRA™ programs, as well as potential changes in the severity level of the COVID-19 pandemic (including due to new variants of the virus) and the effect of such changes on pace of patient recruitment into clinical trials, manufacturing delays, and changes in market opportunities. 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 be delayed and/or 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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