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): ☐

On November 10, 2021, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (the "Company"), issued a press release announcing that the Spanish Agency of Medicines and Medical Devices has authorized the expansion of the Company's Phase IIb trial evaluating Allocetra™ in severe and critical COVID-19 patients with acute respiratory distress syndrome to sites in Spain. 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 November 10, 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: November 10, 2021

Spanish Regulator Grants Enlivex Authorization to Expand its Phase IIb Trial Evaluating Allocetra in Severe and Critical COVID-19 Patients into Spain

Nes Ziona, Israel, November 10, 2021 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced that the Spanish Agency of Medicines and Medical Devices (AEMPS) has authorized the expansion of the Company's Phase IIb trial evaluating Allocetra™ in severe and critical COVID-19 patients with acute respiratory distress syndrome (ARDS) to sites in Spain.

The placebo-controlled trial, which is currently enrolling patients at clinical trial sites in Israel, is expected to recruit up to 152 severe or critical COVID-19 patients. It is designed to assess the safety and efficacy of Allocetra™ when administered in addition to standard of care treatment. The trial's two primary endpoints are ventilation-free survival and recovery for each of the two sub-populations of patients in the study (severe and critical). The trial is supported by previously reported positive 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 the 28-day follow-up period, 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.

Oren Hershkovitz, Ph.D., CEO of Enlivex, commented, "We are very pleased to have regulatory clearance to expand our COVID-19 trial to Spain. We believe AEMPS' decision to authorize this expansion, together with their prior decision authorizing the expansion of our sepsis trial, speaks to Allocetra's broadly applicable mechanism of action, the strength of our clinical datasets, and the rigor of our study designs and manufacturing process. The inclusion of several European countries in our ongoing clinical trials is an important component of our regulatory strategy, and one that we plan to continue executing by working with regulatory agencies in additional countries."

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, 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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