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 2024

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 ☐

On November 12, 2024, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel ("Enlivex"), issued a press release announcing the enrollment and dosing of the first 10 patients in the randomized Phase II stage of Enlivex's multi-country Phase I/II Allocetra™ trial in patients with moderate to severe knee osteoarthritis. 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 12, 2024.

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 12, 2024

Enlivex Announces the Enrollment and Dosing of the First 10 Patient in the Randomized Phase II Stage of its Allocetra Trial in Patients with Moderate to Severe Knee Osteoarthritis

Nes-Ziona, Israel, Nov. 11, 2024 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced the enrollment and dosing of the first 10 patients in the randomized Phase II stage of the Company's multi-country Phase I/II Allocetra™ trial in patients with moderate to severe knee osteoarthritis. The initiation of patient dosing follows the recently announced recommendation by the independent Data and Safety Monitoring Board to proceed with the randomized Phase II stage at the highest tested dose, as well as the Danish Medicines Agency's authorization to initiate this next trial stage.

The multi-center Phase I/II clinical trial consists of two stages. The first stage, which was successfully completed, was a Phase I safety run-in, open-label dose escalation phase to characterize the safety and tolerability of Allocetra™ injections to the target knee in order to identify the dose and injection regimen for the subsequent Phase II stage. The Phase II stage is a double-blind, randomized, placebo-controlled stage. In addition to evaluating safety, the blinded randomized stage is statistically powered to assess the efficacy of Allocetra™ injections into the knee. The trial's key efficacy end points will evaluate joint-pain and joint-function in comparison to placebo at three months, six months and 12 months after treatment.

Einat Galamidi, MD, Medical Vice President of Enlivex, commented, "We are highly committed to executing our clinical programs in accordance with our projected timelines. The first 10 patients in the double-blind, randomized, placebo-controlled Phase II stage of the study successfully started their course of intra-articular knee injections. No safety concerns were recorded following the initial dosing. Osteoarthritis is the most prevalent form of arthritis and is a leading cause of adult chronic pain and long-term disability. Currently there are no commercially available drugs proven to arrest or reverse progression of this disease, and we are hopeful that the novel mechanism of action of AllocetraTM will change the way we treat these patients."

ABOUT KNEE OSTEOARTHRITIS[1]

Osteoarthritis is by far the most common form of arthritis, affecting more than 32.5 million Americans and more than 300 million individuals worldwide. About half of knees with ACL injuries develop osteoarthritis within 5 to 15 years. 78 million Americans are projected to have osteoarthritis by the year 2040. Symptomatic knee osteoarthritis is particularly prevalent and disabling, with 40% of men and 47% of women developing knee osteoarthritis in their lifetimes. Osteoarthritis accounts for over one million hospitalizations annually in the United States, primarily for total joint replacement. The burden of osteoarthritis is enormous, and the need for treatments that reduce pain and attendant disability for persons with osteoarthritis is critical. There are currently no medications approved by either the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) that have been demonstrated to arrest, slow or reverse progression of structural damage in the joint.

[1] Source: The Arthritis Foundation; Disease modification in osteoarthritis; pathways to drug approval, Katz et. Al., Osteoarthritis and Cartilage Open (2) (2020)

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 and life debilitating conditions. For more information, visit https://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 timelines for completing current clinical studies, market opportunities for the results of current clinical studies and preclinical experiments, and the effectiveness of, and market opportunities for, ALLOCETRATM 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 ALLOCETRATM 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.

ENLIVEX CONTACT

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