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: April 2025

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 April 3, 2025, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel, issued a press release announcing that the first patient has been dosed in an investigator-initiated Phase I trial to evaluate the safety, tolerability and initial efficacy of Allocetra™ for injection into the temporomandibular joint (TMJ) in patients suffering from TMJ 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 April 3, 2025.

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: April 3, 2025

Enlivex Announces the Dosing of the First Patient in a Phase I Trial Evaluating Allocetra in Patients with TMJ Osteoarthritis

- Temporomandibular joint (TMJ) osteoarthritis is a degenerative, debilitating and progressive disease, the second most common musculoskeletal condition affecting five to 12% of the population globally
- TMJ causes pain and stiffness in the jaw, making it difficult to chew
- TMJ osteoarthritis currently has no long-term effective treatments

Ness-Ziona, Israel, April 03, 2025 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company" or "Enlivex"), a clinical-stage macrophage reprogramming immunotherapy company, today announced that the first patient has been dosed in an investigator-initiated Phase I trial to evaluate the safety, tolerability and initial efficacy of Allocetra™ for injection into the temporomandibular joint (TMJ) in patients suffering from TMJ osteoarthritis.

The study will be conducted by the Rheumatology Unit at Sheba Medical Center in collaboration with the Department of Oral and Maxillofacial Surgery at Sheba Medical Center. Notably, Sheba Medical Center was recently ranked among the top 10 hospitals in the world by *Newsweek*.

Dr. Einat Galamidi, CMO of Enlivex, commented, "This study will provide a preliminary evaluation of the safety and potential effect of Allocetra™ for the treatment of TMJ osteoarthritis, which affects a joint that is critical for daily function. We are pleased to report that the injection of Alloctera™ into the first patient's TMJ was successfully completed with no complications."

The trial currently plans to recruit six patients who have insufficiently responded to conventional therapies for TMJ osteoarthritis. The trial's primary safety endpoint will measure the frequency and severity of adverse events and serious adverse events, and efficacy endpoints will assess changes from baseline in TMJ pain, joint functionality, and other disease parameters for up to 12 months following administration of Allocetra™.

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, 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 TEMPOROMANDIBULAR JOINT (TMJ) OSTEOARTHRITIS

TMJ disorders are the second most common musculoskeletal condition affecting five to 12% of the population globally, with an annual health cost estimated at $4 billion[1]. Osteoarthritis of the TMJ is the most common form of arthritis in the TMJ, causing pain and stiffness in the jaw. It may become difficult to chew. TMJ osteoarthritis is a degenerative disease of the joint, which culminates in the progressive destruction of all soft and hard tissue components of the TMJ. For patients who present in early adulthood with severe clinical symptoms and catastrophic radiographic changes, there are significant implications for management, including the potential need for early total joint replacement. There are currently no effective long-term treatments for this disease[2].

1 Bianchi et al., Sci Rep 2020
2 Delpachitra et al., British Journal of Oral and Maxillofacial Surgery 60 (2022)

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, expected clinical trial results, 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.

ENLIVEX CONTACT

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