
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 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 September 9, 2025, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (“Enlivex”), issued a press release announcing the issuance of an Israeli patent that will provide Enlivex with added intellectual property protection in Israel through at least 2040 with claims covering methods of using Allocetra™ to treat subjects with 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 September 9, 2025.
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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 9, 2025



Enlivex Announces Issuance of New Patent Application Covering the Use of Allocetra in Patients with Osteoarthritis

Nes-Ziona, Israel, September 8, 2025 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the “Company”), a clinical-stage macrophage reprogramming immunotherapy company, today announced the issuance of an Israeli patent, numbered 290470, titled, “THERAPEUTIC APOPTOTIC CELLS FOR TREATMENT OF OSTEOARTHRITIS”. The patent will provide Enlivex with added intellectual property protection in Israel through at least 2040 with claims covering methods of using Allocetra™ to treat subjects with osteoarthritis.

Enlivex recently reported positive three-month topline data from the Phase IIa stage of ENX-CL-05-001, a multi-center, two-stage Phase I/II double-blind, randomized, placebo-controlled clinical trial evaluating Allocetra™ in patients with moderate-to-severe knee osteoarthritis.

In the overall modified intention-to-treat (mITT) population, improvements across all efficacy and secondary endpoints, including 24% reduction in knee pain and 26% improvement in knee function, were observed in the Allocetra™ treatment arm vs placebo; moreover, 72% reduction in knee pain and 109% improvement in knee function were observed for age-related primary osteoarthritis patients compared with placebo – a substantial, clinically meaningful and statistically significant effect in commonly used Phase III primary endpoints for knee osteoarthritis clinical trials.

Oren HersHKovitz, Ph.D, CEO of Enlivex, commented, “We are very pleased to receive another patent issuance for the use of Allocetra™ as a potential treatment in patients with osteoarthritis. We believe that this issuance provides high assurance that we will be able to obtain similar patents in all major jurisdictions as part of our IP portfolio rollout.”

ABOUT KNEE OSTEOARTHRITIS²

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 According to the OMERACT-OARSI criteria (Outcome Measures in Arthritis Clinical Trials-Osteoarthritis Research Society International)

² 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 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.

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