
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: August 2022

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 August 3, 2022, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (the “Company”), issued a press release announcing that the Company received a Notice of Allowance for its U.S. patent application covering methods of treating sepsis with Allocetra™. 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 August 3, 2022.](#)

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 Herskovitz
Name: Oren Herskovitz
Title: Chief Executive Officer

Date: August 3, 2022



Enlivex Receives Notice of Allowance for U.S. Patent Application Covering Methods of Treating Sepsis with Allocetra™

Nes-Ziona, Israel, Aug 3, 2022 (GLOBE NEWSWIRE) – Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the “Company”), a clinical-stage macrophage reprogramming immunotherapy company targeting diseased macrophages in patients with sepsis and solid tumors, today announced that the U.S. Patent and Trademark Office has issued a Notice of Allowance for patent application number 16/594,463. Once issued, the resulting patent will provide Enlivex with added intellectual property (IP) protection into at least 2036 with additional claims covering methods of treating sepsis with Allocetra™, on top of previously granted patents. The Company expects that this new patent will be issued in the United States in the fourth quarter of 2022.

“Receiving this Notice of Allowance is an important corporate achievement that we believe positions us to optimize Allocetra’s™ commercial potential in sepsis,” said Oren HersHKovitz, Ph.D., Chief Executive Officer of Enlivex. “The resulting patent will provide an additional layer of protection for this program, which targets a multi-billion-dollar market that is not well served by current therapies. In addition, we continue to work diligently to further expand our IP portfolio with patents covering Allocetra’s™ use in other indications.”

Enlivex’s sepsis program includes an ongoing placebo-controlled, randomized, dose-finding, multi-center Phase II trial, which includes four cohorts receiving varying doses of Allocetra™ or placebo, all in addition to standard-of-care therapy. The trial’s two primary endpoints are safety (number and severity of adverse events and severe adverse events) and efficacy (change from baseline in sequential organ failure (SOFA) score), which will be assessed throughout a 28-day follow-up period. Additionally, the trial’s secondary endpoint is 28-day all-cause mortality. Interim results from the trial are expected in the first quarter of 2023. Top-line data are expected in the third quarter of 2023.

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 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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