
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 2020

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 10, 2020, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (the “Company”), issued a press release announcing the dosing of the first patient in an investigator-initiated multi-center clinical trial of Allocetra™ in COVID-19 patients in severe condition with respiratory failure. 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 10, 2020.](#)

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.

Date: August 10, 2020

Enlivex Therapeutics Ltd.

(Registrant)

By: /s/ Oren HersHKovitz

Name: Oren HersHKovitz

Title: Chief Executive Officer

Enlivex Announces Dosing of First Patient in Clinical Trial of Allocetra in COVID-19 Patients with Severe Illness Respiratory Failure

Nes Ziona, Israel, Aug. 09, 2020 (GLOBE NEWSWIRE) – Enlivex Therapeutics Ltd. (Nasdaq: ENLV), a clinical-stage immunotherapy company, today announced that the first patient has been dosed in an investigator-initiated multi-center clinical trial of Allocetra™ in COVID-19 patients with severe illness and respiratory failures.

The clinical trial has been designed to assess Allocetra™ in combination with standard of care therapy in patients with COVID-19 associated lung dysfunction. Safety, tolerability, cytokine profile and efficacy parameters will be evaluated, with change in PaO₂/FiO₂ ratio number and severity of adverse events and serious adverse events serving as the co-primary study endpoints.

The COVID-19 trial is scheduled to run independently of Enlivex's currently planned Phase IIb clinical trial of Allocetra™ for the treatment of organ failures associated with sepsis. The planned Phase IIb trial will be a controlled, randomized study that is expected to commence in the fourth quarter of 2020.

ABOUT ENLIVEX

Enlivex is a clinical stage immunotherapy company, developing an allogeneic drug pipeline for immune system rebalancing. Immune system rebalancing is critical for the treatment of life-threatening immune and inflammatory conditions which involve hyper-expression of cytokines (Cytokine Release Syndrome) and for which there are no approved treatments (unmet medical needs), as well as solid tumors immune-checkpoint rebalancing. 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.

ENLIVEX CONTACT

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INVESTOR RELATIONS CONTACT

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