
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: March 2021

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 March 1, 2021, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel, issued a press release announcing a new research collaboration with Mount Sinai Health System for the development of clinical strategies for Allocetra™ with checkpoint inhibitors. 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 March 1, 2021.](#)

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: March 1, 2021



Enlivex and Mount Sinai Health System Announce Research Collaboration for the Development of Allocetra in Combination with Immune Checkpoint Inhibitors

-- Collaboration aims to evaluate the potential of Allocetra™ in combination with immune-checkpoint inhibitors in solid cancer patients that do not respond to stand-alone checkpoint inhibitor therapies --

Nes Ziona, Israel, March 1, 2021 (GLOBE NEWSWIRE) -- Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company targeting diseased macrophages in patients with sepsis, COVID-19 and solid tumors, and Mount Sinai Health System, one of the world's leading academic health systems, today announced a new research collaboration for the development of clinical strategies for Allocetra™ with checkpoint inhibitors. Allocetra™ is a macrophage-reprogramming immunotherapy product candidate currently in clinical development by Enlivex for the potential treatment of life-threatening immune-mediated diseases.

Under the strategic collaboration agreement, the parties have agreed to develop and execute a pre-clinical program to investigate the potential synergies between Allocetra™ and commercially approved checkpoint inhibitor therapies for select solid cancers.

Carlos Cordon-Cardo, M.D., Ph.D., Irene Heinz Given and John LaPorte Given Professor and Chair of the Lillian and Henry M. Stratton-Hans Popper Department of Pathology, Molecular and Cell-Based Medicine at the Icahn School of Medicine at Mount Sinai, commented, "We are impressed with the data supporting the immunotherapeutic effects of Allocetra™ in preclinical cancer models. The scientific rationale supporting Allocetra™-checkpoint inhibitor combination therapies is intriguing, as preclinical studies suggest Allocetra™ may reverse the immunosuppressive tumor microenvironments that often hamper checkpoint inhibitors by reprogramming anti-tumor macrophages to their homeostatic state. We look forward to the further development of Allocetra-checkpoint inhibitor combination therapies through this newly formed collaboration."

A pioneer of the oncologic molecular pathology discipline, Dr. Cordon-Cardo has helped establish a deeper understanding of the mechanisms of human cancers and new targets for cancer diagnosis and therapeutics, enhancing the vision of personalized medicine. Dr. Cordon-Cardo is one of the "Highly Cited Authors" by the Institute of Scientific Information, one of the "Highly Influential Biomedical Researchers" (one of the top 400 over 15,153,100 author identifiers) by the European Society for Clinical Investigation; and one of the top "List of 500 Most Highly Cited Researchers Worldwide," Google Scholar, Citations 101,185; h-index 158; i10-index 521 (Google Scholar-2020). Dr. Cordon-Cardo is the recipient of numerous honors and awards, including "Roll of Honour" of the International Union Against Cancer; Gold Medal of the Swedish Society of Physicians; Distinguished Alumnus Award, Weill-Cornell Graduate School of Medical Science, Cornell University; Fellow, Royal Society of Medicine.

Dror Mevorach, M.D., Chief Medical Officer of Enlivex, commented, "We are excited to collaborate with the distinguished research and clinical teams at Mount Sinai. Allocetra™ may have a rebalancing effect on the typically immunosuppressive tumor microenvironment, potentially by facilitating the conversion of pro-tumor macrophage populations to anti-tumor populations. Together, we plan to investigate the potential of Allocetra™ to synergistically combine with commercially available checkpoint inhibitors for the treatment of solid tumors."

Oren Hershkovitz, Ph.D., CEO of Enlivex, stated, "The researchers and clinicians at Mount Sinai are world-class and ideal partners as we work toward the realization of Allocetra's potential. We are pleased with the decision of Mount Sinai to formulate a strategic collaboration with Enlivex for the development of Allocetra™ as a potentially key component of combination therapies for solid tumors."

Allocetra™ is currently in clinical development for acute life-threatening immune-mediated diseases such as sepsis and COVID-19. Enlivex recently reported positive top-line results in 21 patients from Phase Ib and Phase II investigator-initiated trials in COVID-19 patients in severe/critical condition. The Company has also previously reported positive results from a Phase Ib investigator-initiated trial in 10 sepsis patients and plans to initiate a controlled, randomized, Phase IIb study in sepsis during the first quarter of 2021.

ABOUT THE MOUNT SINAI HEALTH SYSTEM

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of premiere education, translational research and discovery, and collaborative clinical leadership ensuring that it delivers the highest quality care—from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians are in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit <https://www.mountsinai.org> or find Mount Sinai on Facebook, Twitter and YouTube.

ABOUT ALLOCETRA™

Allocetra™ is a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Diseases such as solid cancers, sepsis, COVID-19 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 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.

MOUNT SINAI HEALTH SYSTEM CONTACT

Tracy Diamond
Mount Sinai Press Office
tracy.diamond@mssm.edu

ENLIVEX CONTACT

Shachar Shlosberger, CFO
Enlivex Therapeutics, Ltd.
shachar@enlivexpharm.com

INVESTOR RELATIONS CONTACT

Eric Ribner
LifeSci Advisors
eric@lifesciadvisors.com
