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: May 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 May 31, 2022, Enlivex Therapeutics Ltd., a company organized under the laws of the State of Israel (the "Company"), issued a press release announcing new preclinical data from an ovarian cancer study conducted in collaboration with Yale Cancer Center. 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 May 31, 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 Hershkovitz
Name: Oren Hershkovitz
Title: Chief Executive Officer

Date: May 31, 2022

Enlivex Announces New Preclinical Data in Ovarian Cancer Showing a Substantial Survival Benefit when Allocetra is Combined with PD-1 Checkpoint Inhibition at the American Society of Clinical Oncology (ASCO) Annual Meeting

- *Stand-alone therapy with PD1 checkpoint inhibitors has shown limited efficacy against ovarian cancer, with response rates in prior clincical trials ranging from 7-15%. This contributes to poor patient outcomes, as ovarian cancer is currently the fifth leading cause of cancer death among women.*

- *Murine ovarian cancer study results:*

    - *Substantial survival effect of the combination therapy (Allocetra™ + anti-PD1 immune checkpoint inhibitor), with up to 50% survival probability vs. 0% in the untreated group, and a highly significant 83% increase in survival duration*

    - *Comparable and strong effect in survival duration with stand-alone anti-PD1 and stand-alone Allocetra™ treatments (42% and 58% increase, respectively), and no significant effect on survival probability.*

    - *Study conducted in collaboration with Yale Cancer Center*

- *These results, together with prior preclinical data in mesothelioma cancer, demonstrate Allocetra's broadly applicable immunotherapeutic effects and its potential to deliver survival benefits across multiple solid cancers when combined with various immune checkpoint inhibitors.*

Nes-Ziona, Israel, May 31, 2022 (GLOBE NEWSWIRE) – Enlivex Therapeutics Ltd. (Nasdaq: ENLV, the "Company"), a clinical-stage macrophage reprogramming immunotherapy company, today announced new preclinical data from an ovarian cancer study conducted in collaboration with Yale Cancer Center. The study showed substantial and statistically significant improvements in survival benefit, survival duration and tumor burden reduction when Allocetra™ was combined with an anti-PD1 checkpoint inhibitor. The data will be featured in an upcoming poster presentation at the ASCO Annual Meeting, which is taking place both virtually and in-person at the McCormick Place convention center in Chicago, Illinois (United States) from June 3 – 7, 2022.

The upcoming ASCO poster will also highlight a prior preclinical study in mesothelioma cancer that showed a substantial survival benefit when Allocetra™ was combined with a commercially approved anti-CTLA4 checkpoint inhibitor. Previously reported preclinical data in peritoneal cancer that show a substantial survival benefit when Allocetra™ is combined with chimeric antigen receptor (CAR) T-cell therapy will also be presented.

Marcus Bosenberg, MD, PhD, Professor of Dermatology, Pathology, and Immunobiology and Director of the Center for Precision Cancer Modeling at Yale Cancer Center, commented: "I am highly encouraged by these preclinical findings, which clearly demonstrate Allocetra's potential to address a long-standing unmet need. The immunosuppressive microenvironments of ovarian tumors have limited the clinical benefits of checkpoint inhibition in this indication. Allocetra™ may reverse immunosuppressive tumor microenvironments and may ultimately improve patient outcomes by synergistically enhancing checkpoint inhibitor efficacy in clinical trials."

Prof. Dror Mevorach, MD, Chief Scientific Officer of Enlivex, added: "In these latest murine studies, we once again saw Allocetra™ synergistically combine with a checkpoint inhibitor to deliver a statistically significant survival benefit in a difficult-to-treat solid tumor model. We are now working to translate these promising findings to the clinic and expect to initiate two solid tumor trials evaluating Allocetra-based combinations by year-end. Through these studies, we aim to clinically demonstrate the broad applicability of Allocetra's proposed mechanism of action to enable the expansion of its potential therapeutic impact."

Ovarian Cancer, Checkpoint Inhibitors, and Macrophage-Solid Tumor Dynamics

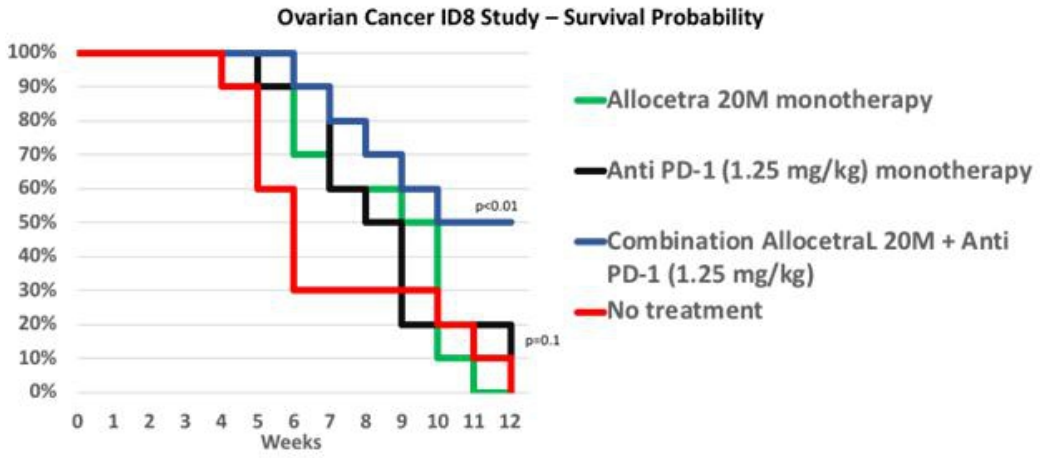
Ovarian cancer is currently the fifth leading cause of cancer death among women. Stand-alone therapy with PD1 checkpoint inhibitors, which are designed to treat cancer by activating immune cells that can identify and destroy tumors, has thus far shown limited efficacy in this indication. Prior clinical trials in ovarian cancer evaluating anti-PD1 monotherapy have shown response rates of only 7% – 15%.

The limited response rates of checkpoint inhibitors in ovarian and other solid cancers is linked to tumor defense mechanisms that facilitate the recruitment of macrophages which become "pro-tumor" tumor associated macrophages (TAMs) rather than "anti-tumor" macrophages. Pro-tumor TAMs typically form a physical layer on top of solid tumors and induce an immunosuppressive tumor microenvironment (TME). This in-turn promotes tumor growth and metastasis and makes it very difficult for immune cells or any anti-cancer drug to efficiently attack cancerous cells. Allocetra™ is a cell therapy in development that is targeted towards TAMs. Its proposed mechanism of action is to change the balance of macrophage populations so that they skew towards anti-tumor macrophages and away from pro-tumor macrophages. This is expected to enhance the efficacy of checkpoint inhibitors and other immunotherapeutic agents.

The Ovarian Cancer Model

To expand upon its previous preclinical findings in mesothelioma and test the potential effects of cell-therapy-induced macrophage reprogramming in a second difficult-to-treat solid tumor model, Enlivex collaborated with the Yale Cancer Center to run preclinical studies in which groups of mice were implanted with ID8 ovarian cancer cells. The difference between the groups was the treatment given, which started on day 7 after the cancer's initial growth period.

Results from the preclinical ovarian cancer study further support Allocetra's potential to significantly improve survival outcomes by facilitating macrophage reprogramming in the solid tumor microenvironment. Twelve weeks after the initial treatment, untreated mice (vehicle) showed a survival rate of 0%, and a median survival duration of 6 weeks. Survival duration was increased with stand-alone treatment with either an anti-PD1 inhibitor or Allocetra™. The magnitude of the increases were similar between these two monotherapy groups (42% and 58% increase, respectively), with no significant effect on overall survival probability observed between the monotherapy groups. Notably, combining Allocetra™ with anti-PD1 therapy led to a synergistic anti-cancer effect, with survival rates of up to 50% (5/10) and an 83% increase in median survival duration observed in the combination therapy groups. The attached figure shows the Kaplan-Meier survival probability curve for each group of the study, and the table below provides the treatment data.



	No treatment	Anti PD-1 (1.25 mg/kg) monotherapy	Allocetra 20M monotherapy	Combination AllocetraL 20M + Anti PD-1 (1.25 mg/kg)
Median survival duration (weeks)	6	8.5	9.5	11
% Survival duration increase vs untreated	--	42%	58%	83%
Overall survival percent	0%	10% (not statistically significant)	0%	50% (statistically significant)

As previously reported, Enlivex plans to initiate a Phase Ib trial evaluating Allocetra™ in combination with chemotherapy in solid peritoneal tumors in Q3 2022, and a Phase I/II trial evaluating Allocetra™ in combination with an immune checkpoint inhibitor in late 2022.

The title of the upcoming ASCO poster is “In-vivo reprogramming macrophages and dendritic cells with Allocetra-OTS: Successful mono- and combination-antitumor therapy.” The poster will be presented during the ASCO Annual Meeting’s “Developmental Therapeutics – Immunotherapy” poster session, which is taking place on June 5, 2022, from 8:00 AM - 11:00 AM CDT (9:00 AM - 12:00 PM ET). A copy of the poster’s corresponding abstract is currently available on the ASCO Annual Meeting Website.

ABOUT THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Founded in 1964, the American Society of Clinical Oncology is the world’s leading professional organization for physicians and oncology professionals caring for people with cancer.

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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