
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 2020

Commission File Number 000-30902

COMPUGEN LTD.

(Translation of registrant's name into English)

**26 Harokmim Street
Holon 5885849, Israel**

(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 Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Compugen Ltd.

On September 8, 2020, Compugen Ltd. (the “**Company**”) issued a press release, a copy of which is filed as Exhibit 99.1 to this Report on Form 6-K and is incorporated by reference herein.

The information contained in the first, second and sixth paragraphs and the section titled “Forward-Looking Statements” in the press release is hereby incorporated by reference into the Company’s Registration Statement on Form F-3, File No. 333-240183.

Exhibits

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
<u>99.1</u>	<u>Press Release dated September 8, 2020.</u>

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.

COMPUGEN LTD.

Date: September 8, 2020

By: /s/ Eran Ben Dor
Eran Ben Dor
General Counsel



FOR IMMEDIATE RELEASE

Compugen Doses First Patient in Phase 1/2 Triple Combination Study of COM701 with Bristol Myers Squibb's Opdivo® and Anti-TIGIT Antibody

Study accelerates evaluation of Compugen's DNAM axis hypothesis and biomarker strategy

HOLON, ISRAEL – September 8, 2020 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today announced that the first patient has been dosed in the Phase 1/2 study evaluating the triple combination of COM701, Compugen's first-in-class anti-PVRIG antibody, with Bristol Myers Squibb's PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab), and their investigational anti-TIGIT antibody, BMS-986207.

The triple combination study is designed to evaluate the simultaneous blockade of three immune checkpoint pathways, PVRIG, TIGIT and PD-1, and will accelerate the clinical evaluation of Compugen's DNAM axis hypothesis and biomarker strategy in patients with advanced solid tumors, including those who are refractory or unresponsive to standard-of-care immune checkpoint inhibitors. Compugen's DNAM axis hypothesis suggests that PVRIG and TIGIT are two parallel and complementary inhibitory pathways in the axis and that blocking both PVRIG and TIGIT may be required in certain tumor types in order to generate or enhance an anti-tumor immune response.

"Dosing the first patient in this triple combination study propels our clinical development plan for COM701 forward, continuing our rapid execution in investigating what we believe is a foundational axis in immuno-oncology," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "The science we have elucidated behind this axis, combined with the preliminary antitumor activity observed in our Phase 1 COM701 study, suggest that our highly differentiated clinical path of targeting PVRIG simultaneously with TIGIT and PD-1 blockers has the potential to expand cancer immunotherapy treatment options to new patient populations."

Dr. Cohen-Dayag added, “We are thrilled to have Bristol Myers Squibb as our partner in this study and are very pleased with their continued support and commitment to our collaboration.”

Henry Adewoye, M.D., Senior Vice President and Chief Medical Officer, said, “While immunotherapies have been transformative in oncology, the majority of cancer patients do not respond to immunotherapy or relapse with currently available treatments. Our expectation is that inhibiting PVRIG and TIGIT, two distinct inhibitory checkpoints in the DNAM axis, together with PD-1, has the potential to translate to clinical benefit for patients by increasing response rates and durability of responses, thereby expanding the reach of this important class of drugs. We are highly encouraged by the durable partial responses observed in the monotherapy and dual combination dose escalation arms of our study evaluating COM701 and thus look forward to the results of this ongoing trial.”

The open-label Phase 1/2 trial is designed to evaluate the safety, tolerability and preliminary antitumor activity of COM701 in combination with Opdivo® and BMS-986207 during dose escalation as well as preliminary antitumor activity in tumor types selected for expansion in a biomarker-driven approach (to initially include ovarian cancer, endometrial cancer and a biomarker-driven arm of tumor types with high expression of PVRL2). An investigation of the contribution of the component parts of the triplet will be enabled in the context of the ovarian expansion cohort. Dose levels for Opdivo® and BMS-986207 combinations have already been determined through prior testing by Bristol Myers Squibb, allowing for dose escalation of COM701 with fixed doses of Opdivo® and BMS-986207. The study will initially enroll approximately 100 patients.

About COM701

COM701 is a humanized antibody that binds with high affinity to PVRIG, a novel immune checkpoint discovered computationally by Compugen, and blocks the interaction with its ligand, PVRL2. TIGIT, an immune checkpoint discovered computationally by Compugen in 2009, and PVRIG constitute parallel immune checkpoint pathways that counteract DNAM, a costimulatory receptor on T cells and NK cells. Preclinical data suggest that the blockade of PVRIG induces a robust anti-tumor immune response and demonstrates synergistic activity when used in combination with inhibitors of TIGIT and/or PD-1. Currently, COM701 is being evaluated in a Phase 1 clinical study. Data from the ongoing study have shown that COM701 is well-tolerated and demonstrated preliminary signals of anti-tumor activity in a heavily pretreated patient population.

About Compugen

Compugen is a clinical-stage therapeutic discovery and development company utilizing its broadly applicable, predictive computational discovery platforms to identify novel drug targets and develop therapeutics in the field of cancer immunotherapy. The Company's lead product candidate, COM701, a first-in-class anti-PVRIG antibody, for the treatment of solid tumors, is undergoing a Phase 1 clinical study. In addition, COM902, Compugen's antibody targeting TIGIT, is in a Phase 1 clinical study. The Company's therapeutic pipeline also includes early stage immuno-oncology programs focused largely on myeloid targets. The Company is headquartered in Israel, with offices in South San Francisco, CA. Compugen's shares are listed on the Nasdaq and the Tel Aviv Stock Exchange under the ticker symbol CGEN. For additional information, please visit Compugen's corporate website at www.cgen.com.

Forward-Looking Statement

This press release contains “forward-looking statements” within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended, and the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs, expectations and assumptions of Compugen. Forward-looking statements can be identified by the use of terminology such as “will,” “may,” “expects,” “anticipates,” “believes,” “potential,” “plan,” “goal,” “estimate,” “likely,” “should,” “confident,” and “intends,” and similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include, but are not limited to, statements that suggest that Compugen’s highly differentiated clinical path of targeting PVRIG simultaneously with TIGIT and PD-1 blockers has the potential to expand cancer immunotherapy treatment options to new patient populations, statements regarding Compugen’s expectation that inhibiting PVRIG and TIGIT, two distinct inhibitory checkpoints in the DNAM axis, together with PD-1, has the potential to translate to a clinical benefit for patients by increasing response rates and durability of responses, thereby expanding the reach of this important class of drugs and statements about the plans for the open-label Phase 1/2 trial, including the cancer types and that the study will initially enroll approximately 100 patients. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of Compugen to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Among these risks: Compugen’s operations could be affected by the outbreak and spread of COVID-19, clinical development involves a lengthy and expensive process, with an uncertain outcome and Compugen may encounter substantial delays or even an inability to begin clinical trials for any specific product, or may not be able to conduct or complete its trials on the timelines it expects; Compugen relies, and expects to continue to rely, on third parties to conduct its clinical trials and if these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines (including as a result of the effect of the COVID-19), Compugen may experience significant delays in the conduct of its clinical trials; Compugen’s approach to the discovery of therapeutic products is based on its proprietary computational target discovery infrastructure, which is unproven clinically; Compugen does not know whether it will be able to discover and develop additional potential product candidates or products of commercial value; Compugen’s business model is substantially dependent on entering into collaboration agreements with third parties; and Compugen may not be successful in generating adequate revenues or commercializing aspects of its business model. These risks and other risks are more fully discussed in the “Risk Factors” section of Compugen’s most recent Annual Report on Form 20-F as filed with the Securities and Exchange Commission (SEC) as well as other documents that may be subsequently filed by Compugen from time to time with the SEC. In addition, any forward-looking statements represent Compugen’s views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Compugen does not assume any obligation to update any forward-looking statements unless required by law.

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