
**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 June 2021

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 June 8, 2021, Compugen Ltd. (the “**Company**”) issued a press release announcing updated data from the Company’s Phase 1 Study of COM701, First-in-Class Anti-PVRIG, as presented at the ASCO 2021 Annual Meeting, a copy of which is furnished as Exhibit 99.1 to this Form 6-K and incorporated by reference herein.

The information contained in the first and fifth paragraphs, including the sections titled “COM701 and Opdivo® combination arm dose escalation;” “COM701 monotherapy arm;” “Demonstrated durable antitumor activity in extensively pretreated population;” and “Preliminary biomarker results demonstrate immune activation with COM701 treatment;” and the section titled “Forward-Looking Statement” in the Press Release attached as Exhibit 99.1 is hereby incorporated by reference into the Company’s Registration Statement on Form F-3, File No. 333-240183.

Exhibits

Exhibit Number	Description of Exhibit
99.1	Press Release Dated June 8, 2021 - "Compugen Announces Updated Data from Phase 1 Study of COM701, First-in-Class Anti-PVRIG, at the ASCO 2021 Annual Meeting."

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: June 8, 2021

By: /s/ Eran Ben Dor

Eran Ben Dor
General Counsel



FOR IMMEDIATE RELEASE

**Compugen Announces Updated Data from Phase 1 Study of
COM701, First- in-Class Anti- PVRIG, at the ASCO 2021
Annual Meeting**

*Data show ongoing durable responses beyond one year in monotherapy and in
combination with Opdivo® in heavily pre-treated patients including one patient with
prior progression on Opdivo®*

*Preliminary biomarker data reveal immune activation evidenced by a trend of increased
proliferation of peripheral CD8 + effector memory T cells, NK-T cells, and increased
serum IFN γ*

*Anti-tumor activity also observed in PD-L1 low, PVR12 positive patients, suggesting
COM701 treatment may drive anti tumor immunity even in non-inflamed tumors*

HOLON, ISRAEL – June 8, 2021 – [Compugen Ltd.](#) (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, presented updated data from its Phase 1 dose escalation and expansion study of COM701 as a monotherapy, and in a dose escalation combination study with Opdivo® (nivolumab) in an oral presentation at the ASCO 2021 Annual Meeting, being held virtually on June 4-8, 2021. COM701 is a first-in-class investigational therapeutic antibody targeting PVRIG, a novel immune checkpoint discovered computationally by Compugen.

“These new data from our COM701 clinical program are meaningful for two key reasons,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “First, durability data show multiple patients on treatment beyond one year, strengthening our confidence that PVRIG blockade through COM701 may provide meaningful clinical benefit in tumor types typically unresponsive to immune checkpoint inhibitors, including in patients with prior progression on these treatments. Our ongoing confirmed complete response from the combination arm is particularly noteworthy given it was achieved in a patient with anal squamous cell carcinoma with prior progression on Opdivo® and is on study treatment now out to 22 months. We believe these results support our hypothesis that dual blockade of PVRIG and PD-1 may be key to driving immune responses in certain patient populations.”

Dr. Cohen-Dayag continued, “Second, preliminary biomarker data provide important insights into the mechanism of COM701 immune activation. A trend of increased peripheral immune cell proliferation of CD8+ effector memory T cells and NK-T cells was observed in the monotherapy and combination arms. In addition, increased levels of the key antitumor cytokine IFN γ , observed with increasing doses of COM701, suggest that the demonstrated immune activity is derived from the combination regimen and not the effect of Opdivo® alone. Furthermore, our biomarker data suggest that COM701 as monotherapy, and in combination with Opdivo®, has the potential to drive durable clinical activity in patients with PD-L1 low, PVR12 positive tumors. Specifically, data obtained from an archival biopsy of a primary peritoneal cancer patient support this, showing that COM701 monotherapy has the potential to drive tumor shrinkage and increased peripheral proliferation of immune cell subsets and IFN γ secretion in a patient with an immune desert, non-inflamed tumor microenvironment. Together, these clinical and preliminary biomarker results provide an important foundation of data that are supportive of our DNAM axis hypothesis, which we are evaluating comprehensively in the clinic across monotherapy, dual and triple combination studies.”

Daniel Vaena M.D., Director of Experimental Therapeutics Program at West Cancer Center Research Institute (Memphis, TN), said, “Although these results are very preliminary, they suggest that targeting PVR12 may extend the benefit of immunotherapy to patient populations and tumor types which are typically unresponsive to existing immunotherapy agents. Achieving durable responses in patients with progression on immune checkpoint inhibitors is encouraging and speaks to the potential of this novel immune checkpoint inhibitor to improve clinical outcomes for patients with significant unmet medical need”

Data highlights with a cut-off of April 15 2021 from the presentation titled, "COM701 with or without nivolumab: Results of an ongoing Phase 1 study of safety, tolerability and preliminary antitumor activity in patients with advanced solid malignancies", presented by Daniel Vaena, M.D., West Cancer Center Research Institute, include:

COM701 and Opdivo® combination arm dose escalation:

- In 15 evaluable patients, COM701 in combination with Opdivo® was well-tolerated with no reported dose-limiting toxicities up to the fifth and final dose cohort of COM701 20 mg/kg and Opdivo® 480 mg, both IV Q4 weeks.
- The disease control rate (DCR) was 66.7% (N=10) with best responses of complete response (CR) 6.7% (N=1), partial response (PR) 6.7% (N=1) and stable disease (SD) 53.3% (N=8).
- Previously reported patient with anal squamous cell carcinoma with confirmed CR remains on treatment at 96 weeks (22 months). This patient had three prior lines of therapy and enrolled within one month after progression on Opdivo® monotherapy.
- Previously reported patient with renal cell carcinoma with best response of SD remains on treatment at 75 weeks.
- A patient with microsatellite stable (MSS)-colorectal cancer with durable confirmed partial response previously reported at AACR 2020 remained on study treatment for 44 weeks.

COM701 monotherapy arm:

- Overall 36 patients enrolled. 16 patients, all comers in dose escalation and 20 patients in dose expansion; four patients of each: endometrial cancer, NSCLC, ovarian cancer, breast cancer and colorectal cancer (MSS).
- The disease control rate (DCR) was 47.2% (N=17) with best responses of partial response (PR) 2.7% (N=1) and stable disease (SD) 44.4% (N=16).
- Previously reported patient with primary peritoneal cancer (platinum resistant, MSS) with confirmed PR remains on study treatment at 79 weeks (18 months). Patient had three prior lines of standard-of-care treatment.
 - Archival pre-treatment biopsy data revealed the patient was PD-L1 negative, with PVRL2 expression on tumor and endothelial cells, with an immune desert phenotype (i.e, no immune cells detected prior to treatment).
 - Peripheral blood assessment showed immune activation as measured by immune cell proliferation and IFN γ induction prior to tumor shrinkage.

Demonstrated durable antitumor activity in extensively pretreated population:

- Durable responses to treatment (CR, PR or SD \geq 6 months) in 10/51 (19%) patients.
 - Best responses of CR, PR, or SD were observed in 11/21 (52%) patients with prior treatment refractory disease.
 - Best response of CR, PR or SD were observed in 13/18 (72%) patients with prior treatment with immune checkpoint inhibitors.
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Preliminary biomarker results demonstrate immune activation with COM701 treatment:

- Peripheral pharmacodynamic changes were measured via immune cell proliferation and cytokine levels in peripheral blood before and on treatment.
- After one treatment cycle, patients treated with COM701 monotherapy showed a trend of increased proliferation of effector memory CD8+ T cells (average change 87%), an immune cell population that expresses high level of PVRIG and are critical in driving anti-tumor immunity. Similar results were observed in the combination arm.
- Proliferation of NK-T cells, an immune cell population that expresses high level of PVRIG and plays a role in antitumor activity, increased significantly one day after COM701 monotherapy treatment, with a similar trend observed in the combination arm.
- Levels of IFN γ , a cytokine which plays a key role in antitumor immunity, were upregulated following combination treatment of COM701 with Opdivo®, with a dose response trend with increasing doses of COM701, suggesting the observed activity is derived from the combination treatment and not Opdivo® alone.
- Anti-tumor activity was observed in PD-L1 low, PVRL2 positive patients, suggesting COM701 treatment may drive anti-tumor immunity even in patients with less inflamed tumor microenvironment.

The presentation presented at the ASCO 2021 Annual Meeting can be found at the Company's website and is not considered a part of this press release.

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. Compugen'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. Compugen's therapeutic pipeline also includes early stage immuno-oncology programs focused largely on myeloid targets. Compugen is headquartered in Israel, with offices in South San Francisco, CA. Compugen's shares are listed on 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 regarding our strengthened confidence that PVRIG blockade through COM701 may provide meaningful clinical benefit in tumor types typically unresponsive to immune checkpoint inhibitors, including in patients with prior progression on these treatments, statements suggesting that targeting PVRIG may extend the benefit of immunotherapy to patient populations and tumor types which are typically unresponsive to COM701, statements regarding the suggestion that the demonstrated immune activity is derived from the combination regimen and not the effect of Opdivo® alone, statements regarding our belief that the results support our hypothesis that dual blockade of PVRIG and PD-1 may be key to driving immune responses in certain patient populations and statements regarding biomarker data suggesting that COM701 as monotherapy, and in combination with Opdivo®, has the potential to drive durable clinical activity in patients with PD-L1 low, PVRL2 positive tumors. 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: the global COVID-19 pandemic may continue to negatively impact the global economy and may also adversely affect Compugen’s business; 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 these third parties may not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, and Compugen may experience significant delays in the conduct of its clinical trials as well as significant increased expenditures; 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; Compugen’s approach to the discovery of therapeutic products is based on its proprietary computational target discovery infrastructure, which is unproven clinically; and Compugen does not know whether it will be able to discover and develop additional potential product candidates or products of commercial value. 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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