
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 January 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 office)

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 January 9, 2020, Compugen Ltd. (“Compugen” or the “Company”) issued a press release which highlighted recent accomplishments and previewed upcoming milestones, 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 this Report on Form 6-K is hereby incorporated by reference into the Company’s Registration Statement on Form F-3, File No. 333-233001.

Exhibits

**Exhibit
Number**

Description of Exhibit

[99.1](#) [Press Release dated January 9, 2020 – “Compugen Highlights Recent Accomplishments and Previews Upcoming Milestones”](#)

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: January 9, 2020

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



FOR IMMEDIATE RELEASE

Compugen Highlights Recent Accomplishments and Previews Upcoming Milestones

*Encouraging preliminary COM701 Phase 1 clinical data presented at SITC 2019
demonstrated initial signs of anti-tumor activity in highly refractory patient population*

*Initial data from Phase 1 dose escalation study of COM701 in combination with
Opdivo® (nivolumab) anticipated in 2H 2020*

COM902 on-track to enter Phase 1 monotherapy study in early 2020

HOLON, ISRAEL – January 9, 2020 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today provided an update on upcoming milestones for its COM701 and COM902 clinical programs and highlighted 2019 accomplishments.

“2019 has been a transformative year for Compugen, including our first presentation of preliminary clinical data from our internally discovered and developed lead asset, COM701,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “The report of encouraging initial signs of anti-tumor activity of COM701 monotherapy in a challenging, heavily pretreated population marked an important milestone for the Company. In 2020, we plan to continue our clinical advancement with additional expected milestones, including initial data from the Phase 1 dose escalation study of COM701 with *Opdivo*®, as well as the initiation of a Phase 1 clinical study for COM902, our second internally discovered and developed asset. We are proud of our strong execution and look forward to continued progress as we advance multiple clinical studies to potentially expand the reach of cancer immunotherapy treatments.”

2020 Anticipated Milestones:

- Initiate and complete enrollment in the COM701 Phase 1 monotherapy expansion cohorts in biomarker-driven indications, including non-small cell lung, ovarian, breast and endometrial cancers
 - Present initial data from Phase 1 combination dose escalation study evaluating COM701 with *Opdivo*® in 2H 2020
 - Initiate Phase 1 combination expansion cohorts for COM701 with *Opdivo*®
 - Initiate COM902 Phase 1 study in patients with advanced malignancies in early 2020
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2021 Anticipated Milestones:

- Present initial data from COM701 Phase 1 monotherapy expansion cohort study in 1H 2021
- Present initial data from COM902 Phase 1 monotherapy dose escalation study

Recent Accomplishments:

- Presented encouraging preliminary data from ongoing Phase 1 monotherapy dose escalation study of COM701 demonstrating that COM701 is well-tolerated with initial signs of anti-tumor activity in a heavily pretreated, refractory patient population at SITC 2019
- Completed enrollment of COM701 Phase 1 monotherapy dose escalation at Q3 weekly dosing schedule; enrollment in COM701 Phase 1 monotherapy dose escalation cohort at Q4 weekly dosing schedule is on-going
- Completed enrollment of Q3 weekly dosing schedule of Phase 1 combination dose escalation of COM701 with fixed-dose Opdivo. Enrollment status of Q4 weekly dosing schedule will be presented at a trial-in-progress poster at the *ASCO-SITC* Clinical Immuno-Oncology Symposium on February 6, 2020
- Received FDA clearance for COM902 Investigational New Drug Application
- Strengthened COM701 and COM902 intellectual property portfolio with new composition of matter and method of use patents
- Added computational discovery and business development capabilities and expertise to senior management team

About COM701

COM701 is a humanized antibody that binds with high affinity to PVRIG, a novel immune checkpoint target candidate discovered by Compugen, blocking the interaction with its ligand, PVRL2. Blockade of PVRIG by COM701 has demonstrated potent, reproducible enhancement of T cell activation, consistent with the desired mechanism of action of activating T cells in the tumor microenvironment to generate anti-tumor immune responses. In addition, COM701 combined with antagonist anti-PD-1 antibodies has demonstrated synergistic effects in enhancing human T cell stimulation and inhibiting tumor growth in murine models, indicating an intersection of the PVRIG and PD-1 inhibitory pathways and the potential of these combinations to further enhance immune response against tumors.

PVRIG and TIGIT constitute parallel immune checkpoint pathways that counteract DNAM, a costimulatory molecule on T cells and NK cells. Preclinical data for COM701 suggest that PVRIG may be a dominant checkpoint pathway in diverse patient populations with tumors that express elevated PVRL2, the ligand of PVRIG, as compared to expression of PVR, the ligand of TIGIT. This includes patients with breast, endometrial, and ovarian cancers. In addition, expression studies show that PVRIG, TIGIT, and their respective ligands, are expressed in a broad variety of tumor types, such as those noted above, as well as lung, kidney, and head & neck cancers. In these tumors the blockade of both TIGIT and PVRIG may be required to sufficiently stimulate an anti-tumor immune response, with or without additional PD-1 pathway blockade.

COM701 is in a Phase 1 clinical trial in patients with advanced solid tumors, to evaluate monotherapy and combination therapy with a PD-1 inhibitor. The Phase 1 open-label trial is designed to assess the safety and tolerability of COM701 monotherapy as well as COM701 with Bristol-Myers Squibb's Opdivo® (nivolumab) in patients with advanced solid tumors. Secondary endpoints include preliminary anti-tumor activity, pharmacokinetics and pharmacodynamics of COM701 monotherapy as well as COM701 in combination with Opdivo in patients with selected tumor types, including non-small cell lung cancer, ovarian cancer, breast cancer and endometrial cancer. The Phase 1 study, which is expected to enroll approximately 140 patients, is currently recruiting in the United States. The Phase 1 dose escalation study showed that COM701 is well-tolerated through 10 mg/kg with no dose-limiting toxicities observed. Furthermore, data showed preliminary signs of anti-tumor activity in heavily pretreated patient population (with a median of seven prior anticancer therapies (range of 2-15)), with best timepoint response of stable disease (SD)/disease control rate reported in 9 of 13 patients (69%). Additional information is available at www.clinicaltrials.gov (NCT03667716).

About COM902

COM902, a high affinity, fully human antibody targeting TIGIT, is being developed for combination treatment with COM701. COM902 was shown to have superior binding affinity to T cells with similar and or greater in vitro function compared to several clinical anti-TIGIT antibodies. COM902 is a mouse-cross reactive Ab which inhibited tumor growth and increased survival when combined with anti-PVRIG or anti-PD-L1 antibodies in in vivo studies. Preclinical data demonstrate that TIGIT inhibition, either alone or in combination with other checkpoint inhibitors, can enhance T cell activation and increase anti-tumor immune responses. Parallel inhibition of TIGIT and PVRIG, the two coinhibitory arms of the DNAM axis, results in synergistic effects on effector T cell function and tumor growth inhibition in various model systems that can be further increased with the addition of PD-1 blockade. Based on preclinical data these combinations may be clinically important for enhancing anti-tumor immune response and expanding the patient population responsive to checkpoint inhibition.

Compugen discovered TIGIT in 2009 with its immune checkpoint computational discovery platform through which PVRIG was also discovered. The TIGIT discovery was published by Compugen in October 2009 in the Proceedings of the National Academy of Sciences (PNAS).

Compugen plans to initiate a Phase 1 study in patients with advanced malignancies in early 2020. The study is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of COM902. The study is planned to be conducted at multiple centers in the United States.

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 expected to enter the clinic in early 2020. The Company's therapeutic pipeline also includes early-stage immuno-oncology programs focused largely on myeloid targets. Compugen's business model is to selectively enter into collaborations for its novel targets and related drug product candidates at various stages of research and development. 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.

Opdivo® is a registered trademark of Bristol-Myers Squibb Company.

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. 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 plan to continue our evolution with multiple clinical milestones, including the first data presentation evaluating the potential of COM701 in combination with Opdivo®, as well as the advancement of COM902 to clinical studies, our continued progress as we advance multiple clinical studies to expand the reach of cancer immunotherapy treatments, completing enrollment in the COM701 monotherapy expansion cohorts, presenting data from our studies and initiating COM902 Phase 1 study in patients with advanced malignancies in early 2020. 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 ability to present data derived from collaborations with our partners is dependent in some cases on the agreement of our partners to present such data, and in any event is dependent on our acceptance to present data in relevant conferences, and 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. Moreover, the development and commercialization of therapeutic candidates involve many inherent risks, including failure to progress to clinical trials or, if they progress to or enter clinical trials, failure to advance through clinical development or receive regulatory approval. Some of these and other factors, including the ability to finance the Company, are more fully discussed in the "Risk Factors" section of Compugen's most recent Annual Report on Form 20-F 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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