
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 February 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 February 14, 2020, Compugen Ltd. (“**Compugen**” or the “**Company**”) entered into an amendment (the “**Amendment**”) to the Master Clinical Trial Collaboration Agreement dated October 10, 2018 (the “**Agreement**”) by and between the Company and Bristol-Myers Squibb Company, a Delaware corporation (“**Bristol-Myers Squibb**” or “**BMS**”). A copy of the press release announcing the amendment is furnished as Exhibit 99.1 to this Form 6-K.

Under the Agreement, the parties agreed to evaluate the safety and tolerability of Compugen’s COM701, a first-in-class investigational anti-PVRIG antibody (“**COM701**” or the “**Compugen Compound**”), in combination with Bristol-Myers Squibb’s programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo® (nivolumab), in patients with advanced solid tumors. As previously disclosed, the collaboration was also designed to address potential future combinations, including trials sponsored by Bristol-Myers Squibb to investigate combined inhibition of checkpoint mechanisms, such as PVRIG and TIGIT. Each study carried out pursuant to the Agreement is referred to as a “**Combined Therapy Study**.”

Under the Amendment, the parties have agreed to initiate a triple combination study to evaluate the safety and tolerability of COM701, Opdivo®, and BMS’ anti-TIGIT antibody known as BMS-986207 (collectively, the “**Triple Combination**”), instead of the planned expansion of the Combined Therapy Study designed to evaluate the dual combination of COM701 and Opdivo®. Pursuant to the Amendment, instead of sponsoring the expansion of the Combined Therapy Study designed to evaluate the dual combination of COM701 and Opdivo®, Compugen will be responsible for and will sponsor a two-part Phase 1/2 trial which includes the evaluation of the Triple Combination, in patients with advanced solid tumors. BMS will provide Opdivo® and BMS-986207 at no cost to Compugen for this trial.

As previously agreed, ownership of, and global commercial rights to, the Compugen Compound remain solely with Compugen (subject to the rights granted to BMS as hereinafter described). Pursuant to the Amendment, if Compugen wishes to license the right to commercialize the Compugen Compound in any territory during the time prior to the end of the Triple Combination plus six months (the “**Exclusivity Period**”), Compugen must first negotiate with BMS, for a period of three months (the “**Negotiation Period**”), to grant an exclusive license to develop and commercialize the Compugen Compound in that territory. If BMS and Compugen do not reach an agreement for an exclusive license within the Negotiation Period, then BMS will have no further first negotiation rights, and Compugen will be free to license the Compugen Compound (subject to the exclusivity provisions and all other rights afforded to BMS under the Agreement) to other parties, in such territory. After the expiration of the Exclusivity Period, Compugen is free to license the Compugen Compound without any further obligation to BMS.

All other terms of the Agreement remain unchanged.

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
<u>10.1[#]</u>	<u>Amendment No. 1 to Master Clinical Trial Collaboration Agreement, dated February 14, 2020, by and between Compugen Ltd. and Bristol-Myers Squibb Company.</u>
<u>99.1</u>	<u>Press Release dated February 20, 2020.</u>
#	Portions of this exhibit (indicated by asterisks) have been omitted because the Registrant has determined they are not material and would likely cause competitive harm to the Registrant if publicly disclosed, and certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

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: February 20, 2020

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

Certain confidential information contained in this document, marked by [*], has been omitted because Compugen Ltd. has determined that the information is (i) not material and (ii) would likely cause competitive harm to Compugen Ltd. if publicly disclosed.

AMENDMENT NO. 1 TO MASTER CLINICAL TRIAL COLLABORATION AGREEMENT

THIS AMENDMENT NO. 1 TO MASTER CLINICAL TRIAL COLLABORATION AGREEMENT (this “*Amendment*”) is effective as of February 14, 2020 (“*Amendment Effective Date*”) by and between **Compugen Ltd.**, an Israeli corporation with a place of business at Azrieli Center, 26 Harokmim Street, Building D, Holon 5885849, Israel (“**Compugen**”), and **Bristol-Myers Squibb Company**, a Delaware corporation, headquartered at 430 E. 29th Street, 14FL, New York, N.Y. 10016 (“**BMS**”).

BACKGROUND

- A. BMS and Compugen entered into that certain Master Clinical Trial Collaboration Agreement, dated as of October 10, 2018 (the “*Agreement*”).
- B. The Parties have mutually agreed to amend the Agreement as follows in accordance with Section 13.7 of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings contained herein, and on the terms and subject to the conditions set forth herein, the Parties hereby agree as follows:

- 1. Capitalized terms used and not otherwise defined herein shall have the meaning given to such terms in the Agreement.
- 2. Section 1.34 shall be deleted in its entirety from the Agreement.
- 3. The definition of “Exclusive Collaboration Period” as set forth in Section 1.48 is hereby amended and restated in its entirety as follows:

“1.48 “**Exclusive Collaboration Period**” means the period commencing on the Effective Date and ending on the earliest of:

- (a) six (6) months after Study Completion of the Triple Study as set forth in Study Plan No. 2; or
 - (b) the effective date of termination of this Agreement pursuant to Section 12.2, Section 12.3 or Section 12.4.”
- 4. Study Plan No. 1 previously attached to the Agreement is hereby replaced with the revised Study Plan No. 1 attached as Attachment A hereto.
 - 5. Clause (a) of Exhibit E to the Agreement is hereby amended and restated in its entirety as follows:

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“Neither Party is obligated to conduct additional studies of the Combined Therapy with the other Party upon completion of a Combined Therapy Study, subject to the following provisions of this Exhibit E; provided that the provisions of this Exhibit E are not applicable to any Combined Therapy Study other than the Triple Study. The provisions as set forth in this Exhibit E shall only be in effect (and the Parties will only have the rights set forth below in this Exhibit E) with respect to each Subsequent Study for which (x) the proposed protocol synopsis has been submitted by the Proposing Party to the Other Party (as set forth below) within the earlier of (i) [*] or (ii) [*]; provided that the proposed Subsequent Study must be commenced [*] within [*] of such protocol synopsis being provided to the Other Party and (y) at the time the proposed protocol synopsis has been submitted by the Proposing Party to the Other Party (as set forth below), the Other Party’s Compound is commercialized or in active development; *provided* that, in the case of BMS, both of the BMS Compounds included in the Triple Study must be commercialized or in active development. For clarity, a Subsequent Study may be conducted only for a Combined Therapy for which the Parties agreed to conduct a Combined Therapy Study under this Agreement; provided that neither Party has the rights or obligations set forth below in this Exhibit E with respect to any Combined Therapy Study other than the Triple Study. For clarity, if Compugen conducts a study of a therapy using both the Compugen Compound and the BMS Compound in addition to the Combined Therapy Study as described in Study Plan No. 1 and BMS does not supply any BMS Compound pursuant to this Agreement for such study, such study shall not be considered a Combined Therapy Study pursuant to this Agreement.

6. Clause (d)(iv) of Exhibit E to the Agreement is hereby amended and restated in its entirety as follows:

“(iv) for the Subsequent Studies where Compugen is the non-Participating Other Party, [*]”

7. Clause (d)(v) of Exhibit E to the Agreement is hereby amended and restated in its entirety as follows:

“(v) for the Subsequent Studies where BMS is the non-Participating Other Party, [*]”

8. Except as amended by this Amendment, the Agreement shall continue in full force and effect pursuant to its terms.

9. This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Amendment may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature.

10. This Amendment shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

[Signature page follows]

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IN WITNESS WHEREOF, BMS and Compugen have duly executed this Amendment as of the Amendment Effective Date.

COMPUGEN LTD.

BRISTOL-MYERS SQUIBB COMPANY

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____

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Attachment A
STUDY PLAN NO. 1
[*]

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FOR IMMEDIATE RELEASE

**Compugen Announces Phase 1/2 Triple Combination Study to Evaluate
COM701 in Combination with Bristol-Myers Squibb's Opdivo®
(Nivolumab) and TIGIT Inhibitor**

*Triple combination study intended to evaluate Compugen's PVRIG pathway discovery
and DNAM axis hypothesis in patients with advanced solid tumors*

Study expected to commence in the second half of 2020

Company will host conference call today at 8:30 AM ET

HOLON, Israel – February 20, 2020 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and leader in predictive target discovery, today announced its plan to initiate a Phase 1/2 study evaluating a triple combination of Compugen's COM701, an investigational anti-PVRIG antibody, in combination with Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor *Opdivo*® (nivolumab) and BMS-986207, Bristol-Myers Squibb's investigational anti-TIGIT antibody.

The triple combination study is designed to evaluate the blockade of the three immune checkpoint pathways – PVRIG, TIGIT and PD-1, and will accelerate the clinical evaluation of Compugen's science-driven DNAM axis hypothesis in various advanced solid tumors. The study is expected to commence in the second half of 2020, following the clearance of a new Investigational New Drug Application by the U.S. Food and Drug Administration. Compugen will be the study sponsor with *Opdivo*® and BMS-986207 supplied by Bristol-Myers Squibb.

"We are excited to expand our collaboration with Bristol-Myers Squibb with this biomarker-informed triple combination study to accelerate the clinical evaluation of COM701," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "The triple combination regimen allows us to ultimately test our science-driven hypothesis that the dual inhibition of the DNAM axis with PVRIG and TIGIT blockers, together with the inhibition of the PD-1 pathway, will enable robust activation of T cells leading to anti-tumor immune responses in cancer patients who are non-responsive or refractory to PD-1 blockers."

"The initial encouraging signals of anti-tumor activity observed in heavily pretreated patients in the monotherapy dose escalation arm of our ongoing Phase 1 study, paired with our strong scientific rationale and preclinical data, support to our decision to evaluate whether the combination of these three immune checkpoint inhibitors improve patient outcomes and broaden the patient population that will respond to immunotherapies," added Dr. Cohen-Dayag.

Under the existing collaboration with Bristol-Myers Squibb, COM701 is being investigated as a monotherapy and in combination with *Opdivo*® in an ongoing Phase 1 study. Following the Companies' joint decision to move forward with a triple combination study, Compugen will complete the dose escalation arm of the dual combination of COM701 with *Opdivo*® under its ongoing Phase 1 study. Future studies evaluating COM701 in combination with a PD-1 inhibitor in specific tumor types will be assessed at a later date. As previously indicated, Compugen plans to present initial data from the combination dose escalation study of COM701 with *Opdivo*® in the second half of 2020. Compugen will continue to advance the biomarker informed monotherapy expansion arm of the ongoing COM701 Phase 1 study, as planned.

The planned open-label Phase 1/2 trial is designed to evaluate the safety, tolerability and antitumor activity of COM701 in combination with *Opdivo*® and BMS-986207. The study will evaluate a safe and tolerable dose of the combination during dose escalation and antitumor activity in selected tumor types in the expansion cohorts (ovarian cancer, endometrial cancer and a biomarker-driven arm of tumor types with high expression of PVRL2). 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.

About COM701

COM701 is a humanized antibody that binds with high affinity to PVRIG, a novel immune checkpoint discovered computationally 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. PVRIG and TIGIT, also discovered by Compugen's computational discovery platform in 2009, constitute parallel immune checkpoint pathways that counteract DNAM, a costimulatory molecule on T cells and NK cells. As such, preclinical data suggest that the inhibition of PVRIG together with TIGIT and/or PD-1 has the potential to further enhance anti-tumor immune response and improve patient outcomes in a broad variety of tumor types.

COM701 is being evaluated as a monotherapy and in combination with Opdivo® (nivolumab), Bristol-Myers Squibb's PD-1 inhibitor in a Phase 1 open-label clinical trial in patients with advanced solid tumors. Primary end points of the trial are safety and tolerability; secondary endpoints include preliminary anti-tumor activity, pharmacokinetics and pharmacodynamics in patients with selected tumor types. Data from the monotherapy dose escalation study (n=13) presented at SITC 2019 showed that COM701 is well-tolerated and demonstrated preliminary signs of anti-tumor activity in heavily pretreated patient population. Additional information is available at www.clinicaltrials.gov (NCT03667716).

Conference Call and Webcast Information

Compugen management will hold a conference call today, February 20, 2020, at 8:30 AM ET. To access the conference call by telephone, please dial 1-888-407-2553 from the United States, or +972-3-918-0610 internationally. The call will also be available via live webcast through Compugen's website, located at the following link. Following the live audio webcast, a replay will be available on the Company's website.

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, as amended, 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 Compugen’s expected schedule to commence the triple combination study, Compugen’s expected schedule to present initial data from the combination dose escalation study of COM701 with Opdivo®, Compugen’s continuing to advance the monotherapy expansion arm of the ongoing COM701 Phase 1 study and the companies’ planned cohorts for the open-label Phase 1/2 trial. 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 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 expected and Compugen’s ability to present data derived from collaborations with its partners is dependent in some cases on the agreement of our partners to present such data, and Compugen’s business model is substantially dependent on entering into collaboration agreements with third parties. These risks and other risks are more fully described 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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