
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 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 February 19, 2021, Compugen Ltd. (“**Compugen**” or the “**Company**”) entered into an Amendment No. 2 (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**”), in combination with Bristol-Myers Squibb’s programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo® (nivolumab), in patients with advanced solid tumors. As of today, the parties have completed the enrollment of patients in the dual combination dose escalation study of COM701 with Opdivo®. Pursuant to the Amendment, the parties agree to pursue the expansion of the Phase 1b combination study designed to evaluate the dual combination of COM701 and Opdivo® in patients with advanced solid tumors (the “**Dual Combination**”), where Compugen will be responsible for and will sponsor the expansion cohort and BMS will provide Opdivo® at no cost to Compugen for this study.

The collaboration is also designed to address potential future combinations, and following the first amendment executed in February 2020, the parties are conducting 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**”).

The Amendment also revises the exclusivity period granted to BMS to include a specific date for termination of exclusivity period, so that it ends at the earlier of (i) six months after the study completion of the Triple Combination and the Dual Combination; or (ii) December 31, 2023.

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. 333-240183.

Exhibits

Exhibit Number	Description of Exhibit
<u>10.1#</u> <u>99.1</u>	<u>Amendment No. 2 to Master Clinical Trial Collaboration Agreement, dated February 19, 2021, by and between Compugen Ltd. and Bristol-Myers Squibb Company, Press Release dated February 22, 2021.</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 22, 2021

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.

EXECUTION VERSION

AMENDMENT NO. 2 TO MASTER CLINICAL TRIAL COLLABORATION AGREEMENT

THIS AMENDMENT NO. 2 TO MASTER CLINICAL TRIAL COLLABORATION AGREEMENT (this “*Amendment*”) is effective as of February 19, 2021 (“*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, as amended (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. 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) the earlier of (i) six (6) months after Study Completion of both the Combination Therapy Study as set forth in Study Plan No. 1 and the Triple Study as set forth in Study Plan No. 2; or (ii) December 31, 2023.
- (b) the effective date of termination of this Agreement pursuant to Section 12.2, Section 12.3 or Section 12.4.”

- 3. Study Plan No. 1 previously attached to the Agreement is hereby replaced with the Revised Study Plan No. 1 attached as Attachment A hereto.
- 4. Clause (a) of Exhibit E to the Agreement is hereby amended and restated in its entirety as follows:

“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. 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 with respect to a Subsequent Study involving both of the BMS Compounds included in the Triple Study, both of such BMS Compounds 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.

5. The Parties have agreed on a press release having the content set forth in Attachment B hereto, which will be issued at a time agreed by the Parties.
6. Except as amended by this Amendment, the Agreement shall continue in full force and effect pursuant to its terms.
7. 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.
8. 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]

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

COMPUGEN LTD.

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ _____
Name: _____
Title: _____

By: /s/ _____
Name: _____
Title: _____

Attachment A

Revised Study Plan No. 1

[*]

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.

Attachment B

FOR IMMEDIATE RELEASE

Compugen Expands Clinical Collaboration Agreement with Bristol Myers Squibb with Phase 1b Combination Study of COM701 with Opdivo®*Cohort expansion study expected to commence in the second quarter of 2021*

HOLON, ISRAEL – February 22, 2021 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, announced today the expansion of its clinical collaboration agreement with Bristol Myers Squibb. Under the amended agreement, Bristol Myers Squibb will supply Opdivo® (nivolumab), its PD-1 inhibitor, for Compugen's Phase 1b cohort expansion study designed to assess COM701, Compugen's first-in-class anti-PVRIG antibody, in combination with Opdivo® in selected cancer indications. Study initiation is expected in the second quarter of 2021.

"We are excited to further expand our clinical program evaluating COM701, our first-in-class anti PVRIG inhibitor," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "While our triple checkpoint blockade study of COM701 combined with Bristol Myers Squibb's PD-1 and TIGIT inhibitors currently advancing in the clinic offers the ultimate test of our science-driven hypothesis, translational research at Compugen suggests that certain patients may not require a triple therapy combination. With the enrollment in the dose escalation arm of COM701 in combination with Opdivo® completed and preliminary signs of antitumor activity previously disclosed, we are ready to continue our evaluation of this dual combination and move to the cohort expansion phase of the study. Testing COM701 in three settings – as a monotherapy, dual combination, and triple combination therapy – may provide additional insights on the contribution of components as well as the opportunity to broaden COM701 treatment options to address patients' needs. We are proud to be moving quickly to initiate this biomarker and data-informed study in indications we believe are most likely to respond to dual PVRIG and PD-1 blockade, enhancing our leadership position in the DNAM-1 axis space."

Dr. Cohen-Dayag continued, “Bristol Myers Squibb continues to be a valued partner for our COM701 clinical program as we advance the immunotherapy treatment landscape of patients with cancer.”

Under the terms of the amendment, Bristol Myers Squibb will continue to supply Opdivo® to the Compugen-sponsored study. The Phase 1b study, a part of Compugen’s COM701 monotherapy and combination therapy dose escalation and expansion program ([NCT03667716](#)), will examine fixed doses of COM701 and Opdivo®, as determined by Compugen’s Phase 1a combination dose escalation study. Based on Compugen’s translational analyses and preliminary antitumor activity in dose escalation, the study will enroll patients with ovarian, breast, endometrial and microsatellite-stable colorectal cancers.

Separately, Compugen and Bristol Myers Squibb are also investigating COM701 in a triple combination study with Opdivo® and BMS-986207, Bristol Myers Squibb’s investigational anti-TIGIT antibody.

Opdivo® is a registered trademark of Bristol Myers Squibb.

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. These forward-looking statements, including but not limited to statements about the initiation, procedures and potential results of the cohort expansion study, 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.

Company contact:

Elana Holzman

Director, Investor Relations and Corporate Communications Compugen Ltd.

Email: elanah@cgen.com

Tel: +972 (3) 765-8124

Investor Relations contact:

Bob Yedid

LifeSci Advisors, LLC

Email: bob@lifesciadvisors.com

Tel: +1 (646) 597-6989

Media contact:

Josephine Belluardo, Ph.D.

LifeSci Communications

Email: jo@lifescicomms.comTel: +1 (646) 751-4361



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Company contact:

Elana Holzman
Director, Investor Relations and Corporate Communications Compugen Ltd.
Email: elanah@cgen.com
Tel: +972 (3) 765-8124

Investor Relations contact:

Bob Yedid
LifeSci Advisors, LLC
Email: bob@lifesciadvisors.com
Tel: +1 (646) 597-6989

Media contact:

Josephine Belluardo, Ph.D.
LifeSci Communications
Email: jo@lifescicomms.com
Tel: +1 (646) 751-4361
