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 25, 2021, Compugen Ltd. (the "Company") issued a press release announcing a data update from the Company's COM701 Phase 1 clinical trial, 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, fourth, fifth, sixth and seventh paragraphs 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.

On February 25, 2021, the Company also issued a press release reporting the Company's fourth quarter and full year 2020 results, a copy of which is furnished as Exhibit 99.2 to this Report on Form 6-K.

The information included in this Report on Form 6-K (including Exhibit 99.2 hereto) that is furnished shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Report on Form 6-K (including Exhibit 99.2 hereto) that is furnished shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

Exhibits

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Number

Description of Exhibit

99.1 Press Release Dated February 25, 2021 – "Compugen Announces Data Update from COM701 Phase 1 Clinical Trial."
 99.2 Press Release Dated February 25, 2021 – "Compugen Reports Fourth Quarter and Full Year 2020 Results."

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 25, 2021 By: <u>/s/ Eran Ben Dor</u>

Eran Ben Dor General Counsel



FOR IMMEDIATE RELEASE

Compugen Announces Data Update from COM701 Phase 1 Clinical Trial

Durable responses observed with COM701 in combination with Opdivo® including a confirmed complete response in a patient with prior progression on Opdivo®

COM701 monotherapy demonstrates signals of antitumor activity supporting the potential role of PVRIG inhibition in patients who have exhausted all available standard therapies

Data across tumor types and unresponsive patient populations further support Compugen's clinical approach with double and triple combination trials evaluating PVRIG, TIGIT and PD-L1 checkpoints

HOLON, ISRAEL – February 25, 2021 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, reported today 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). COM701 is a first-in-class investigational therapeutic antibody targeting PVRIG, a novel immune checkpoint discovered computationally by Compugen.

"The data generated to date across our COM701 clinical program suggest that PVRIG may be an important immune checkpoint in patients who are unresponsive or refractory to currently available immunotherapies," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "We are highly encouraged by our updated results from the COM701 plus Opdivo® combination dose escalation, which now include a confirmed complete response in a patient with prior progression on Opdivo® and a previously reported patient with a durable confirmed partial response for almost a year. Combined with a disease control rate of 66.7% and ongoing durable signals of activity beyond or approaching one year in multiple patients and across indications, these results leave us increasingly confident that dual blockade of PVRIG and PD-1 may be key to driving anti-tumor immune responses in certain patient populations. Based on these encouraging results, we will be further evaluating this dual combination regimen in patients with ovarian, breast, endometrial and microsatellite-stable colorectal cancers with the initiation of the COM701 and Opdivo® cohort expansion study in the second quarter of 2021, as part of our collaboration with Bristol Myers Squibb."

Dr. Cohen-Dayag continued, "Our monotherapy cohort expansion study was an important milestone in our COM701 monotherapy evaluation. This data, together with data from our previously reported dose escalation study, which includes a confirmed partial response with treatment ongoing for over one year as of our new data cutoff date, demonstrate durable signals of antitumor activity in tumor types typically unresponsive to immune checkpoint inhibitors, including patients with prior progression on these treatments. We will leverage these data, along with future data from our ongoing correlative assessments of biological samples from patients, to inform our clinical approach and next steps as we execute across our broad combination strategy, which includes dual and triple blockade regimens of COM701 with TIGIT and PD-1. Importantly, as the only company with wholly owned clinical candidates targeting both PVRIG and TIGIT, we are uniquely capable and on track to conduct this comprehensive evaluation of the synergistic blockade of the DNAM axis with PD-1, and we look forward to continued progress in potentially expanding the reach of immunotherapy."

Data highlights from the Phase 1 dose escalation studies as of the data cutoff of December 14, 2020 include:

COM701 and Opdivo® combination dose escalation arm:

- In 15 patients with a median of five prior anticancer therapies (range of 2-10), 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).
- A patient with anal squamous cell carcinoma with confirmed SD as reported at American Association for Cancer Research (AACR) 2020, now with confirmed CR and remains on treatment at 79 weeks. This patient progressed on Opdivo® prior to enrolling in our study.
- A patient with microsatellite stable (MSS)-colorectal cancer with durable confirmed partial response previously reported at AACR 2020 remained on study treatment at 44 weeks.
- Durable responses of confirmed SD of six months or more in three patients. One patient with renal cell carcinoma remains on treatment at 58 weeks, and one patient with non-small cell lung cancer (NSCLC) (squamous) who failed prior treatment with immune checkpoint inhibitors remained on treatment at 36 weeks, and one patient with endometrial cancer remained on treatment at 46 weeks.

COM701 monotherapy arm dose escalation update since AACR 2020:

- · The patient with primary peritoneal cancer (platinum resistant, MSS) with durable confirmed partial response remains on study treatment at 62 weeks.
- The patient with pancreatic cancer, refractory to all three prior lines of standard of care (SOC) therapy with durable confirmed SD was on study treatment for 31 weeks.

Data highlights from the monotherapy expansion cohort as of the data cutoff of December 14, 2020 include:

- 20 patients enrolled in biomarker and data informed indications; four patients of each: endometrial cancer, NSCLC, ovarian cancer, breast cancer and colorectal cancer.
- · Six of the 20 patients (30%) had best responses of SD, one patient with endometrial cancer, three patients with NSCLC and two patients with ovarian cancer.
- Two patients with SD remain on treatment as of the data cutoff date; one patient with NSCLC who had >3 prior lines of SOC therapy; including prior treatment with immune checkpoint inhibitors with treatment ongoing at 26 weeks, and one patient with ovarian cancer with treatment ongoing at 20 weeks.
- Two additional patients remain on treatment as of the data cutoff date
- · No new safety findings were observed.

Additional clinical data and initial correlative assessments of biological samples from patients are planned to be presented at the American Society of Clinical Oncology 2021 annual meeting, to which an abstract was submitted.

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, including but not limited to statements related to the potential importance of the PVRIG checkpoint and dual blockade of PVRIG and PD-1 in treating patients, the expected initiation of the COM701 and Opdivo® cohort expansion study in the second quarter of 2021, and the potential and expected timing and results of future clinical data and results, 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 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 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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FOR IMMEDIATE RELEASE

Compugen Reports Fourth Quarter and Full Year 2020 Results

Encouraging signals of anti-tumor activity demonstrated across COM701 Phase 1 combination and monotherapy studies with durable responses, including a complete response, in tumor types typically unresponsive to checkpoint inhibitors

Expansion of DNAM axis clinical programs to include Phase 1b cohort expansion of COM701 with Opdivo® in Q2 2021 and Phase 1 COM701 with COM902 dual combination study in 2H 2021

Initial data from ongoing dose escalation studies of triple combination of COM701 with Bristol Myers Squibb's Opdivo® and TIGIT Inhibitor, and COM902 monotherapy, both on track for Q4 2021

HOLON, ISRAEL – February 25, 2021 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today reported financial results for the fourth quarter and full year ended December 31, 2020.

"Our encouraging new data reinforces our conviction in our clinical development strategy to comprehensively evaluate dual and triple blockade of DNAM axis members, PVRIG and TIGIT, along with the intersecting PD-1 pathway, across our clinical studies," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "We have now observed durable responses in patients treated with COM701 as a monotherapy and in combination with Opdivo®, including a patient with a confirmed complete response we reported earlier today. Most notably, the durable responses and signals of anti-tumor activity reported across our COM701 studies were achieved in highly refractory patients in indications usually unresponsive to available checkpoint inhibitors. These encouraging signals demonstrate that COM701 is clinically active and strengthen our hypothesis that PVRIG is an important new checkpoint target for immunotherapy and served as the basis for expanding our collaboration with Bristol Myers Squibb."

Dr. Cohen-Dayag added, "With these data in hand, we are now focused on executing across our expanded clinical programs. Most importantly, as the only company with wholly owned clinical assets targeting PVRIG and TIGIT, we are uniquely positioned to evaluate PVRIG in monotherapy and in dual blockade with PD-1 or TIGIT, as well as the triple blockade of PVRIG with PD-1 and TIGIT. We expect to initiate our combination study for COM701 with COM902 in the second half of this year and to share initial data from our COM902 monotherapy and triple combination dose escalation studies in the fourth quarter of this year. We look forward to further revealing the potential of DNAM axis blockade to expand the reach of immunotherapy to patients unresponsive or refractory to current treatment options."

Recent and Fourth Quarter 2020 Corporate Highlights

- Announced updated data from COM701 monotherapy and combination with Opdivo® (nivolumab) studies
- Announced expansion of clinical collaboration agreement with Bristol Myers Squibb with planned Phase 1b cohort expansion study evaluating COM701 with Opdivo® in patients with
 ovarian, breast, endometrial and microsatellite-stable colorectal cancers. The study is on track to initiate in the second quarter of 2021
- · Announced first development milestone of \$2 million received under the license agreement with AstraZeneca for the development of bispecific and multi-specific antibody products
- Presented preclinical data at the 2020 TIGIT Therapies Digital Summit demonstrating the potential of PVRIG inhibition to enhance T cell priming and infiltration into both inflamed and less inflamed tumors, as well as providing further support for the therapeutic combination of TIGIT and PD-1 inhibitors to address patient populations who do not benefit from available immune checkpoint inhibitors
- Expanded IP portfolio for COM902 with composition of matter patent in China, in addition to composition of matter and use patents for COM902 previously issued in the United States and Europe

Financial Results

Revenues for the fourth quarter ended December 31, 2020, were \$2.0 million, related to the milestone payment in the license agreement with AstraZeneca for the development of bispecific and multi-specific antibody products.

R&D expenses for the fourth quarter and year ended December 31, 2020, were \$8.1 million, and \$22.8 million, respectively, compared with \$4.3 million and \$19.8 million for the comparable periods in 2019. The increase in both cases is attributed mostly to increase in expenses associated with our various Phase 1 clinical studies, COM701 and COM902 manufacturing and other chemistry, manufacturing and controls activities.

General and administrative expenses for the fourth quarter and year ended December 31, 2020, were \$2.7 million, and \$9.8 million, respectively, compared with \$2.2 million and \$8.4 million for the comparable periods in 2019. The increase in both the quarterly and annual periods is attributed mainly to headcount-related expenses and increased corporate-related expenses.

Net loss for the fourth quarter of 2020 was \$8.6 million, or \$0.10 per basic and diluted share, compared with a net loss of \$6.5 million, or \$0.10 per basic and diluted share, in the comparable period of 2019. Net loss for the year ended December 31, 2020 was \$29.7 million, or \$0.37 per basic and diluted share, compared with a net loss of \$27.3 million, or \$0.43 per basic and diluted share, for the year ended December 31, 2019.

As of December 31, 2020, cash, cash related accounts, short-term and long-term bank deposits totaled approximately \$124.4 million, compared with approximately \$43.9 million on December 31, 2019. The Company has no debt.

Opdivo® is a registered trademark of Bristol Myers Squibb.

Conference Call and Webcast Information

The Company will hold a conference call today, February 25, 2021, at 8:30 AM ET to review its fourth quarter and full year 2020 results. To access the conference call by telephone, please dial 1-866-744-5399 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.

(Tables to follow)

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.

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${\bf COMPUGEN\ LTD.}$ ${\bf CONDENSED\ CONSOLIDATED\ STATEMENTS\ OF\ OPERATIONS}$

(U.S. dollars in thousands, except for share and per share amounts)

	Three Months Ended December 31,		Year Ended, December 31,	
	2020	2019	2020	2019
<u>-</u>	Unaudited	Unaudited		
Revenues	2,000	-	2,000	-
Cost of revenues	60	<u> </u>	60	-
Gross profit	1,940	-	1,940	-
Operating expenses				
Research and development expenses	8,099	4,314	22,760	19,816
Marketing and business development expenses	238	159	871	651
General and administrative expenses	2,694	2,220	9,805	8,412
Total operating expenses	11,031	6,693	33,436	28,879
Operating loss	(9,091)	(6,693)	(31,496)	(28,879)
Financial and other income, net	528	232	1,798	820
Loss before taxes on income	(8,563)	(6,461)	(29,698)	(28,059)
Taxes on income	-	-	-	722
Net loss	(8,563)	(6,461)	(29,698)	(27,337)
Basic and diluted net loss per ordinary share	(0.10)	(0.10)	(0.37)	(0.43)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	83,644,998	67,644,946	79,591,187	63,636,673

COMPUGEN LTD. CONDENSED CONSOLIDATED BALANCE SHEETS DATA

(U.S. dollars, in thousands)

	December 31,	December 31,
	2020	2019
ASSETS		
Current assets		
Cash, cash equivalents, short-term bank deposits and restricted cash	124,432	43,879
Trade receivables	2,000	-
Other accounts receivable and prepaid expenses	2,658	1,121
Total current assets	129,090	45,000
Non-current assets		
Long-term prepaid expenses	1,880	693
Severance pay fund	2,863	2,485
Operating lease right to use asset	2,772	3,247
Property and equipment, net	1,711	2,338
Total non-current assets	9,226	8,763
Total assets	138,316	53,763
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Other accounts payable, accrued expenses and trade payables	9,216	5,445
Current maturity of operating lease liability	639	600
Short-term deferred participation in R&D expenses	668	774
Total current liabilities	10,523	6,819
Non-current liabilities		
Long-term deferred participation in R&D expenses	1,968	2,691
Long-term operating lease liability	2,527	2,978
	3,516	2,954
		9.633
Accrued severance pay Total non-current liabilities	8,011	8,623
Accrued severance pay	8,011 119,782	38,321