
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 May 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 May 13, 2021, Compugen Ltd. (the “**Company**”) issued a press release reporting the Company’s first quarter 2021 results, a copy of which is furnished as Exhibit 99.1 to this Report on Form 6-K.

The information contained in the first, fourth, fifth, sixth, seventh, eighth and ninth paragraphs, the tables with the financial information 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
<u>99.1</u>	<u>Press Release Dated May 13, 2021 - “Compugen Reports First Quarter 2021 Results.”</u>

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: May 13, 2021

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



Compugen Reports First Quarter 2021 Results

Updated data from COM701 Phase 1 combination and monotherapy studies to be presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting

Milestone rich 2021 to include data readouts from ongoing COM701 triple combination study and COM902 monotherapy study in Q4 2021

Initiation of Phase 1b cohort expansion study of COM701 with Opdivo® in Q2 2021 and Phase 1 COM701 with COM902 dual combination study in 2H 2021 will expand systematic DNAM axis clinical evaluation

HOLON, ISRAEL – May 13, 2021 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today reported financial results for the first quarter ended March 31, 2021.

“2021 will be an important year of milestones and execution for Compugen,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “During this year we expect to share data readouts for COM701 in monotherapy, dual and triple combination studies, as well as our COM902 monotherapy study. These important readouts will build upon our earlier COM701 clinical data which have shown durable responses, including a confirmed complete response, in a highly refractory patient population in indications unlikely to respond to checkpoint inhibitors. Our data shared to date reinforce our confidence that COM701 is clinically active, and that PVRIG has the potential to act as an important and untapped target in the immune-oncology space.”

Dr. Cohen-Dayag continued, “Our strong execution also includes two new studies: the Phase 1b cohort expansion of COM701 with Opdivo® to be initiated in the second quarter of 2021 and the Phase 1 COM701 with COM902 dual combination study to be initiated in the second half of this year. With these programs in place, we will have made tremendous strides in creating a clinical program that comprehensively evaluates the roles of DNAM axis members, PVRIG and TIGIT, with the intersecting PD-1 pathway. We will continue to push forward as leaders in the DNAM axis space, advancing our wholly owned PVRIG and TIGIT assets to potentially drive cancer immunotherapy responses in new and expanded patient populations.”

Recent and First Quarter 2021 Corporate Highlights

- Announced encouraging updated data from COM701 monotherapy and in combination with Opdivo® (nivolumab) studies with durable responses, including a complete response, in tumor types typically unresponsive to checkpoint inhibitors
- 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 be initiated in the second quarter of 2021
- Announced the expansion of the Company's ongoing research collaboration with Johns Hopkins University to explore the underlying biology and mechanism of action of a novel myeloid target for cancer immunotherapy discovered by Compugen
- Published peer-reviewed preclinical data in *Cancer Immunology, Immunotherapy*, which demonstrate the synergistic effect of COM902 with PVRIG and PD-1 blockade. *In vitro* and *in vivo*, the reduced Fc receptor engagement of COM902 does not result in T cell depletion. *In vitro* COM902 enhances human T and NK cell function and enhances anti-tumor lymphocyte responses and inhibits tumor growth *in vivo*
- Published a review on the biology and potential therapeutic relevance of the DNAM-1 axis in *Cancer Immunotherapy*
- Announced upcoming oral presentation of updated data from COM701 Phase 1 monotherapy and combination study at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting
- Announced upcoming participation at the Society for Immunotherapy of Cancer (SITC) Targets for Cancer Immunotherapy: A Deep Dive Seminar Series. Eran Ophir, Ph.D., Vice President Research and Drug Discovery, Compugen, will participate in a seminar titled "The TIGIT Pathway: A Deep Dive in Cancer Immunotherapy Targets".

Financial Results

R&D expenses for the first quarter ended March 31, 2021, were \$7.3 million compared with \$4.7 million for the comparable period in 2020. The increase is attributed mostly to drug manufacturing activities and clinical related activities.

General and administrative expenses for the first quarter ended March 31, 2021, were \$2.7 million compared with \$2.5 million for the comparable period in 2020. The increase is attributed mainly to increased corporate-related expenses.

Net loss for the first quarter ended March 31, 2021 was \$9.9 million, or \$0.12 per basic and diluted share, compared with a net loss of \$7.1 million, or \$0.10 per basic and diluted share, in the comparable period of 2020.

As of March 31, 2021, cash, cash related accounts, short-term and long-term bank deposits totaled approximately \$119.4 million, compared with approximately \$124.4 million as of December 31, 2020. 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, May 13, 2021, at 8:30 AM ET to review its first quarter 2021 results. To access the conference call by telephone, please dial 1-866-744-5399 from the United States, or +972-3-918-0644 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.

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 regarding the timing for the initiation or expansion of clinical trials and reporting of clinical trial data, 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 expectation that 2021 will be an important year of milestones and execution for Compugen, statements regarding data readouts that Compugen expects to share in 2021, statements regarding expected timeline to initiate the Phase 1b cohort expansion study of COM701 with Opdivo® and the Phase 1 study of COM701 with COM902, statements that with COM701 and COM902 programs in place we will have made tremendous strides in creating a clinical program that comprehensively evaluates the roles of DNAM axis members and statements that we will continue to push forward as leaders in the DNAM axis space, advancing our wholly owned PVRIG and TIGIT assets to potentially drive cancer immunotherapy responses in new and expanded patient populations. 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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COMPUGEN LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except for share and per share amounts)

	Three Months Ended	
	March 31,	
	2021	2020
	Unaudited	Unaudited
Revenues	-	-
Cost of revenues	-	-
Gross profit	-	-
Operating expenses		
Research and development expenses	7,326	4,712
Marketing and business development expenses	224	210
General and administrative expenses	2,714	2,476
Total operating expenses	10,264	7,398
Operating loss	(10,264)	(7,398)
Financial and other income, net	359	270
Loss before taxes on income	(9,905)	(7,128)
Taxes on income	-	-
Net loss	(9,905)	(7,128)
Basic and diluted net loss per ordinary share	(0.12)	(0.10)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	83,680,332	70,276,521

COMPUGEN LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS DATA
(U.S. dollars, in thousands)

	<u>March 31,</u> <u>2021</u> <u>Unaudited</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Current assets		
Cash, cash equivalents, short-term bank deposits and restricted cash	119,353	124,432
Trade receivables	-	2,000
Other accounts receivable and prepaid expenses	1,735	2,658
Total current assets	<u>121,088</u>	<u>129,090</u>
Non-current assets		
Long-term prepaid expenses	1,879	1,880
Severance pay fund	2,832	2,863
Operating lease right to use asset	2,573	2,772
Property and equipment, net	1,602	1,711
Total non-current assets	<u>8,886</u>	<u>9,226</u>
Total assets	<u>129,974</u>	<u>138,316</u>
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Other accounts payable, accrued expenses and trade payables	10,134	9,216
Current maturity of operating lease liability	694	639
Short-term deferred participation in R&D expenses	547	668
Total current liabilities	<u>11,375</u>	<u>10,523</u>
Non-current liabilities		
Long-term deferred participation in R&D expenses	1,987	1,968
Long-term operating lease liability	2,266	2,527
Accrued severance pay	3,484	3,516
Total non-current liabilities	<u>7,737</u>	<u>8,011</u>
Total shareholders' equity	<u>110,862</u>	<u>119,782</u>
Total liabilities and shareholders' equity	<u>129,974</u>	<u>138,316</u>