Compugen Reports Third Quarter 2023 Results

- Rilvegostomig, AstraZeneca's (LSE/STO/Nasdaq: AZN) PD-1/TIGIT bi-specific derived from Compugen's COM902, has progressed into Phase 3 as adjuvant therapy for biliary tract cancer after resection in combination with chemotherapy
- Clinical data presented at SITC 2023 reinforces COM701 (anti-PVRIG) mediated anti-tumor activity in tumors typically not responding to immunotherapy and initial data suggest PVRL2 as a potential biomarker for COM701 combinations in certain indications
- Enrollment completed in proof-of-concept study evaluating triple blockade of DNAM-1 axis with COM701 + COM902 (anti-TIGIT) + pembrolizumab in patients with metastatic microsatellite stable colorectal cancer
- Pre-clinical data presented at SITC 2023 highlights COM503's potential leading edge with an antibody approach to harness IL-18 cytokine biology to treat cancer

HOLON, ISRAEL – November 7, 2023 - Compugen Ltd. (Nasdaq: CGEN) (TASE: CGEN) a clinical-stage cancer immunotherapy company and a pioneer in computational target discovery, today announced financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"In the second half of 2023, we continue to execute, and are delighted to see the continued advancement in the development of rilvegostomig derived from COM902 by our partner AstraZeneca who has progressed it into Phase 3 as adjuvant therapy for biliary tract cancer after resection in combination with chemotherapy," said Anat Cohen-Dayag, Ph.D., President, and Chief Executive Officer of Compugen. "We completed patient enrollment in our microsatellite stable colorectal cancer proof-of-concept study with our unique triple immunotherapy combination and we are on track to report data in the first half of 2024. We presented new clinical data at SITC last week reinforcing previous data suggesting COM701 mediated anti-tumor activity in patients typically not responding to immunotherapy. For the first time, we presented initial data showing the association between baseline PVRL2 levels and clinical benefit, suggesting the potential of PVRL2 as a predictive biomarker to help enrich for patients who may derive benefit from COM701 combinations in certain indications. This initial finding has potential to inform future direction of our studies employing a biomarker driven strategy."

Dr. Cohen-Dayag, added, "At SITC, during both oral and poster presentations, we presented data supporting our approach to harness IL-18 biology to fight cancer and address the challenges that led to past failures by others with the systemic dosing of cytokines. Our data suggest that our potentially first-in-class anti-IL18BP antibody approach has a leading edge in inhibiting tumor growth, while avoiding peripheral toxicity associated with administration of a recombinant IL-18 cytokine."

Dr. Cohen-Dayag concluded, “Moving into next year, we look forward to presenting data in the first half of 2024 from our proof-of-concept study in metastatic colorectal cancer and completing enrollment of up to 20 patients from our platinum resistant ovarian cancer proof-of-concept study and to present data in 2024. Additionally, we are on track for IND filing in 2024.”

Corporate Update

- **Q4 2023:** Rilvegostomig, AstraZeneca’s PD-1/TIGIT bi-specific derived from Compugen’s COM902 progressed into Phase 3 as adjuvant therapy for biliary tract cancer after resection in combination with chemotherapy.
- **Q4 2023:** Microsatellite stable colorectal cancer study; enrollment of 20 patients complete.
- **Q3-Q4 2023:** Activation of additional sites in platinum resistant ovarian cancer study resulting in increase in enrollment. However, enrollment completion of up to 20 patients will move into 2024.
- **SITC 2023:** Presentation of new translational data and initial biomarker data from platinum resistant ovarian cancer studies evaluating COM701 + nivolumab ± BMS anti-TIGIT, supporting a COM701 mediated clinical benefit and initial data to suggest PVRL2 as a potential biomarker to help enrich for patients who may derive benefit from COM701 combinations.
- **SITC 2023:** Presentation of longer-term patient follow up from platinum resistant ovarian cancer study evaluating COM701 + nivolumab + BMS anti-TIGIT showing clinically meaningful durable responses, with a trend that compares favorably to standard of care.
- **SITC 2023:** Presentation of new data from the metastatic breast cancer cohort expansion study of patients treated with COM701 and nivolumab, another indication showing clinical benefit in patients typically not responding to immunotherapy with initial data showing that baseline PVRL2 levels are higher in patients with clinical benefit supporting the findings in platinum resistant ovarian cancer patients.
- **SITC 2023:** Presentation of new data from COM503, Compugen’s lead pre-clinical program, showing sufficient levels of tumor IL-18 to provoke anti-tumor activity following antibody blockade of IL-18BP with potential favorable therapeutic window compared to recombinant cytokines.
- **ESMO October 2023:** Presentation of additional clinical data by partner AstraZeneca on rilvegostomig, a PD-1/TIGIT bispecific derived from COM902, establishing its safety and pharmacokinetic profile and showing anti-tumor activity in checkpoint inhibitor experienced NSCLC patients who typically do not respond to immunotherapy.

Next Planned Milestones

- Report data from ongoing triple combination (COM701 + COM902 + pembrolizumab) proof-of-concept study in microsatellite stable colorectal in H1 2024.
- Complete enrollment of up to 20 patients and present data from ongoing triple combination (COM701 + COM902 + pembrolizumab) proof-of-concept study platinum resistant ovarian cancer in 2024.
- File IND for COM503 in 2024

Financial Results

As of September 30, 2023, cash, cash equivalents and cash investments were approximately $57.5 million, compared with approximately $83.7 million as of December 31, 2022. The Company expects its existing cash and cash related balances to be sufficient to fund its current operating plan

at least through the end of 2024. During the three months ended September 30, 2023, the Company sold approximately 0.1 million ordinary shares under its "at-the-market offering" (ATM) facility pursuant to a sales agreement entered into with Leerink Partners on January 31, 2023, with an average price of approximately $1.30 per share.

Compugen has no debt.

R&D expenses for the third quarter ended September 30, 2023 were approximately $8.3 million, a decrease from $9.3 million for the comparable period in 2022. The decrease is mainly due to lower expenses associated with CMC activities, offset by an increase in clinical trial expenses and the end of the amortization of the deferred participation in R&D expenses following the termination of the agreement with Bristol Myers Squibb in the third quarter of 2022.

General and administrative expenses for the third quarter ended September 30, 2023, were approximately $2.3 million, a decrease from approximately $2.6 million for the comparable period in 2022.

Net loss for the third quarter ended September 30, 2023 was approximately $9.9 million, or $0.11 per basic and diluted share, compared with a net loss of approximately $11.7 million, or $0.14 per basic and diluted share, for the comparable period in 2022.

Full financial tables are included below

Conference call and webcast information

The Company will hold a conference call today, November 7, 2023, at 8:30 AM ET to review its third quarter 2023 results. To access the live conference call by telephone, please dial 1-866-744-5399 from the U.S., or +972-3-918-0644 internationally. The call will be available via live webcast through Compugen's website, located at the following link. Following the live 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 capabilities to identify new drug targets and biological pathways for developing cancer immunotherapies. Compugen has developed two proprietary product candidates: COM701, a potential first-in-class anti-PVRIG antibody and COM902, a potential best-in-class antibody targeting TIGIT for the treatment of solid tumors. Compugen also has a clinical stage partnered program, rilvegostomig (previously AZD2936), a PD-1/TIGIT bi-specific derived from COM902, in Phase 3 development by AstraZeneca through a license agreement for the development of bi-specific and multi-specific antibodies. In addition, the Company's therapeutic pipeline of early-stage immuno-oncology programs consists of programs aiming to address various mechanisms of immune resistance. The most advanced program, COM503 is in IND enabling studies. COM503 is a potential first-in-class, high affinity antibody which blocks the interaction between IL-18 binding protein and IL-18, thereby freeing natural IL-18 to inhibit cancer growth in the tumor microenvironment. Compugen is headquartered in Israel, with offices in San Francisco, CA. Compugen's shares are listed on Nasdaq and the Tel Aviv Stock Exchange under the ticker symbol CGEN.

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 using 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, statement regarding the possibility that COM701 may mediate anti-tumor activity in patients typically not responding to immunotherapy; statements regarding the association between baseline PVRL2 levels and clinical benefit and the potential of PVRL2 as a predictive biomarker to help enrich for patients who may derive benefit in certain indications; statements regarding future direction of studies with a biomarker driven strategy; statements regarding the development of Compugen's triplet regimen in certain patients; statements regarding our expectation to report data in the first half of 2024 on our ongoing triple combination (COM701 + COM902 + pembrolizumab) proof-of-concept study in microsatellite stable colorectal cancer; our belief that we can complete enrollment of up to 20 patients and present data from our ongoing triple combination (COM701 + COM902 + pembrolizumab) proof-of-concept study platinum resistant ovarian cancer in 2024; our expectation to file IND for COM503 in 2024; and our expectation that existing cash and cash related balances will be sufficient to fund our operating plan through at least the end of 2024. 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: In the near term, Compugen is highly dependent on the success of COM701 and of COM902; Compugen may not be able to advance its internal clinical stage programs through clinical development or manufacturing or successfully partner or commercialize them, or obtain marketing approval, either alone or with a collaborator, or may experience significant delays in doing so; 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 expect to continue to rely on third parties to conduct its clinical trials and these third parties may not successfully or professionally 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 has limited experience in the development of therapeutic product candidates, and it may be unable to implement its business strategy; the general market, political and economic conditions in the countries in which Compugen operates, including Israel; and the effect of the evolving nature of the recent wear in Gaza between Israel and Hamas. 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 September 30,		Nine Months Ended, September 30,	
	2023	**2022**	**2023**	**2022**
	Unaudited	**Unaudited**	**Unaudited**	**Unaudited**
Operating expenses				
Research and development expenses	8,338	9,339	23,544	23,321
Marketing and business development expenses	18	263	183	741
General and administrative expenses	2,272	2,610	7,249	7,783
Total operating expenses	**10,628**	**12,212**	**30,976**	**31,845**
Financial and other income, net	776	464	2,473	1,243
Loss before taxes on income	**(9,852)**	**(11,748)**	**(28,503)**	**(30,602)**
Tax benefit	-	-	36	-
Net loss	**(9,852)**	**(11,748)**	**(28,467)**	**(30,602)**
Basic and diluted net loss per ordinary share	(0.11)	(0.14)	(0.33)	(0.35)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	88,310,329	86,624,643	87,372,604	86,532,622

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

	September 30, 2023 Unaudited	December 31, 2022
ASSETS		
Current assets		
Cash, cash equivalents, short-term bank deposits and restricted cash	47,782	83,708
Investment in marketable securities	9,725	-
Other accounts receivable and prepaid expenses	2,763	2,417
Total current assets	60,270	86,125
Non-current assets		
Long-term prepaid expenses	1,906	1,899
Severance pay fund	2,772	2,794
Operating lease right to use asset	1,432	1,826
Property and equipment, net	1,231	1,532
Total non-current assets	7,341	8,051
Total assets	**67,611**	**94,176**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Other accounts payable, accrued expenses and trade payables	9,784	10,981
Current maturity of operating lease liability	592	613
Short-term deferred participation in R&D expenses	-	325
Total current liabilities	10,376	11,919
Non-current liabilities		
Long-term operating lease liability	818	1,312
Accrued severance pay	3,190	3,265
Total non-current liabilities	4,008	4,577
Total shareholders' equity	53,227	77,680
Total liabilities and shareholders' equity	**67,611**	**94,176**