



Ocugen Provides Business Update with Fourth Quarter and Full Year 2022 Financial Results

February 28, 2023

Conference Call and Webcast Today at 8:30 a.m. ET

- *Completed retinitis pigmentosa patient enrollment in OCU400 Phase 1/2 clinical trial*
- *Continued progress for programs targeting eye diseases with the submission of an IND application for OCU200*
- *Expanded portfolio now includes inhaled vaccines for COVID-19, seasonal flu, and a combination COVID-19+seasonal flu vaccine*

MALVERN, Pa., Feb. 28, 2023 (GLOBE NEWSWIRE) -- Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines, today reported fourth quarter and full year 2022 financial results along with a general business update.

"We continue to grow and advance as a diversified biotechnology organization as reflected in our accomplishments of 2022," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "Our pipeline has been expanded to appropriately address the current challenges and gaps in the fight against COVID-19, application of OCU410 to address Stargardt (a rare eye disease), and our novel approach to address dry age-related macular degeneration (dAMD)—a disease affecting vision in over 266 million people worldwide.

"Following FDA concurrence in the fourth quarter of 2022 on a confirmatory Phase 3 clinical trial design for NeoCart[®], we are developing internal capabilities to move our regenerative medicine asset, NeoCart[®], into the clinic next year."

"The FDA has granted expanded orphan drug designations to OCU400 for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)," said Dr. Musunuri. "These broad, gene-agnostic designations are encouraging at this stage in the development of OCU400."

"During our first decade, we have built a strong foundation for addressing the diseases and conditions we aim to treat. We delivered on our promise to file an OCU200 IND in the first quarter of 2023 and look forward to delivering on important milestones in 2023, especially regarding preliminary efficacy data for gene therapy product OCU400, as we progress toward realizing our long-term vision to address unmet medical needs through courageous innovation," Dr. Musunuri concluded.

Business Updates

Ophthalmic Gene Therapies

- **OCU400** – Established the high dose as the maximum tolerable dose, completed retinitis pigmentosa patient enrollment, and continuing to enroll patients with LCA to receive the high dose. Ocugen intends to initiate a Phase 3 clinical trial near the end of 2023.
- **OCU410 and OCU410ST** – Executing IND-enabling studies and intend to submit IND applications in the second quarter of 2023 to initiate Phase 1/2 clinical trials in dry AMD (geographic atrophy) and Stargardt disease.

Ophthalmic Biologic Product

- **OCU200** – Submitted an IND application on February 27, 2023 to initiate a Phase 1 clinical trial targeting diabetic macular edema.

Regenerative Cell Therapies

- **NeoCart[®]** – Received concurrence from the FDA on the confirmatory Phase 3 clinical trial design. Ocugen intends to initiate the Phase 3 clinical trial in the first half of 2024. Ocugen is renovating its facility to accommodate cGMP manufacturing of NeoCart[®] for clinical trials and beyond.

Vaccines Portfolio

- **OCU500 Series** – Developing a novel mucosal vaccine platform which includes OCU500, a bivalent COVID-19 inhaled vaccine; OCU510, a seasonal quadrivalent flu inhaled vaccine; and OCU520 a combination quadrivalent seasonal flu and bivalent COVID-19 inhaled vaccine.

- **COVAXIN™(BBV152)** – Completed enrollment in Phase 2/3 immuno-bridging and broadening clinical trial in fourth quarter 2022.

Financial Results

- **Fourth quarter** — Research and development expenses for the three months ended December 31, 2022, were \$17.2 million compared to \$7.1 million for the three months ended December 31, 2021. General and administrative expenses for the three months ended December 31, 2022, were \$6.9 million compared to \$7.5 million for the three months ended December 31, 2021. Ocugen reported a \$0.10 net loss per common share for the three months ended December 31, 2022, compared to a \$0.07 net loss per common share for the three months ended December 31, 2021.
- **Full year** — Research and development expenses for the year ended December 31, 2022, were \$49.8 million compared to \$35.1 million for the year ended December 31, 2021. General and administrative expenses for the year ended December 31, 2022, were \$35.1 million compared to \$22.9 million for the year ended December 31, 2021. Ocugen reported a \$0.38 net loss per common share for the year ended December 31, 2022, compared to a \$0.30 net loss per common share for the year ended December 31, 2021.
- Ocugen’s cash, cash equivalents, restricted cash, and investments totaled \$90.9 million as of December 31, 2022, compared to \$95.1 million as of December 31, 2021. The Company estimates that its current cash, cash equivalents, and investments will enable it to fund its operations into the first quarter of 2024. The Company had 221.6 million shares of common stock outstanding as of December 31, 2022.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the financial results and recent business highlights. Ocugen’s senior management team will host the call, which will be open to all listeners. There will also be a question-and-answer session following the prepared remarks.

Attendees are invited to participate on the call or webcast using the following details:

Dial-in Numbers: (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers

Conference ID: 8912239

Webcast: Available on Ocugen’s [investor site](#)

A replay of the call and archived webcast will be available for approximately 45 days following the event on the Ocugen [investor site](#).

About Ocugen, Inc.

Ocugen, Inc. is a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies, biologics, and vaccines that improve health and offer hope for patients across the globe. We are making an impact on patient’s lives through courageous innovation —forging new scientific paths that harness our unique intellectual and human capital. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with a single product, and we are advancing research in infectious diseases to support public health and orthopedic diseases to address unmet medical needs.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks, and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (SEC), including the risk factors described in the section entitled “Risk Factors” in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events, or otherwise, after the date of this press release.

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(Tables to follow)

OCUGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	As of December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	\$ 77,563	\$ 94,958
Marketable securities	13,371	—
Prepaid expenses and other current assets	7,558	7,688
Total current assets	98,492	102,646
Property and equipment, net	6,053	1,164
Restricted cash	—	151
Other assets	4,087	1,800
Total assets	\$ 108,632	\$ 105,761
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 8,062	\$ 2,312
Accrued expenses and other current liabilities	9,900	4,325
Operating lease obligations	498	363
Total current liabilities	18,460	7,000
Non-current liabilities		
Operating lease obligations, less current portion	3,587	1,231
Long term debt, net	2,289	1,712
Other non-current liabilities	244	—
Total liabilities	24,580	9,943
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,217	1,995
Treasury stock	(48)	(48)
Additional paid-in capital	294,874	225,537
Accumulated other comprehensive income	26	—
Accumulated deficit	(213,018)	(131,667)
Total stockholders' equity	84,052	95,818
Total liabilities and stockholders' equity	\$ 108,632	\$ 105,761

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three months ended		Year ended December 31,	
	December 31,		December 31,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 17,213	\$ 7,102	\$ 49,757	\$ 35,108
General and administrative	6,937	7,470	35,111	22,920
Total operating expenses	24,150	14,572	84,868	58,028
Loss from operations	(24,150)	(14,572)	(84,868)	(58,028)
Other income (expense), net	2,211	(9)	3,517	(389)
Loss before income taxes	(21,939)	(14,581)	(81,351)	(58,417)
Income tax benefit	—	—	—	(52)
Net loss	\$ (21,939)	\$ (14,581)	\$ (81,351)	\$ (58,365)
Shares used in calculating net loss per common share — basic and diluted	220,072,823	199,207,502	214,600,051	195,013,043
Net loss per common share — basic and diluted	\$ (0.10)	\$ (0.07)	\$ (0.38)	\$ (0.30)