Ocugen Provides Business Update with First Quarter 2023 Financial Results

May 5, 2023

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

- *Announced Positive Preliminary Safety and Efficacy Results from the Phase 1/2 Trial of OCU400 for the Treatment of Retinitis Pigmentosa (RP) and Leber Congenital Amaurosis (LCA)*
- *Received Orphan Drug Designation (ODD) from the FDA for OCU410ST for the Treatment of ABCA4-Associated Retinopathies Including Stargardt, Retinitis Pigmentosa (RP19), and Cone-Rod Dystrophy 3 (CORD3) Diseases*
- *Submitted Multiple Proposals for Federal Funding of Ocugen's Inhaled Vaccines for COVID-19 and Flu*

MALVERN, Pa., May 05, 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 first quarter 2023 financial results along with a general business update.

"I am excited about our pipeline achievements to date — especially those for our modifier gene therapy platform," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "The preliminary positive efficacy and safety results from our Phase 1/2 trial of OCU400 support the potential for this first-in-class therapeutic approach to be a viable gene-agnostic treatment for RP and LCA patients. Based on proof-of-concept data, we are getting ready to introduce two more programs with the modifier concept into the clinic —including OCU410 for dry age-related macular degeneration."

OCU410ST recently received broad ODD from the FDA for the treatment of *ABCA4*-associated retinopathies including Stargardt, RP19, and CORD3 diseases. This designation acknowledges the potential for OCU410ST to fulfill a significant unmet medical need and represents a noteworthy milestone in our effort to develop innovative treatments for inherited retinal diseases.

Ocugen remains dedicated to our potentially first-in-class ophthalmic programs targeting blindness diseases and vaccines to support public health. Since the beginning of the year, the Company has been leading advocacy efforts and pursuing government funding to potentially bring its inhaled vaccines for COVID-19 and flu to patients and healthcare professionals searching for next generation options. Given the FDA's recent cancellation of emergency use authorizations issued to monovalent vaccines, Ocugen will now focus its efforts solely on the development of the inhaled mucosal vaccine platform, starting with quadrivalent flu and bivalent COVID-19.

"We will continue to deliver on our corporate goals and scientific programs throughout 2023 and look forward to providing updates across our comprehensive portfolio in the coming months," concluded Dr. Musunuri.

Ophthalmic Gene Therapies

- **OCU400** – Preliminary safety and efficacy results among RP patients treated in the first two cohorts of the Phase 1/2 trial indicate positive trend in multi-luminance mobility testing and best-corrected visual acuity scores for OCU400 treated eyes. Received FDA approval to enroll pediatric patients in the ongoing Phase 1/2 trial; dosing to be initiated in the second quarter of 2023. Phase 3 adult trial to be initiated near the end of 2023.
- **OCU410** – Ocugen intends to submit an Investigational New Drug ("IND") application for OCU410 in the second quarter of 2023 to initiate a Phase 1/2 trial.
- **OCU410ST** – FDA granted ODD to OCU410ST for the treatment of *ABCA4*-associated retinopathies including Stargardt, RP19, and CRD3 diseases. Ocugen intends to submit an IND application for OCU410ST in the second quarter of 2023 to initiate a Phase 1/2 trial.

Ophthalmic Biologic Product

- **OCU200** – Submitted an IND application to the FDA in February 2023 to initiate a Phase 1 trial targeting diabetic macular edema. In April, the IND was placed on clinical hold by the FDA as part of its request for additional information related to chemistry, manufacturing, and controls prior to initiating the Phase 1 trial. The company plans to respond to the FDA promptly to get FDA clearance to initiate the Phase 1 trial.

Regenerative Cell Therapies

- **NeoCart®** – Renovations continue on cGMP manufacturing facility for NeoCart, with completion planned for the fourth quarter of 2023.

Vaccines Portfolio

- **OCU500/OCU510/OCU520** – Intend to submit an IND application to the FDA in late 2023/early 2024. Continuing to work with government agencies to obtain government funding.
- **COVAXIN™**– Ocugen has concluded that the development of COVAXIN in North America is not commercially viable as a result of the FDA's recent decision around monovalent vaccines.

First Quarter 2023 Financial Results

- The Company's cash, cash equivalents, and investments totaled $76.7 million as of March 31, 2023 compared to $90.9 million as of December 31, 2022. 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 226.4 million shares of common stock outstanding as of March 31, 2023.
- Total operating expenses for the three months ended March 31, 2023 were $17.8 million and included research and development expenses of $9.6 million and general and administrative expenses of $8.2 million. This compares to total operating expenses for the three months ended March 31, 2022 of $18.0 million that included research and development expenses of $7.9 million and general and administrative expenses of $10.1 million.
- Ocugen reported a $0.07 net loss per common share for the three months ended March 31, 2023 compared to a $0.09 net loss per common share for the three months ended March 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: 4613996
Webcast: Available on the events section of the Ocugen 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 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. Discover more at www.ocugen.com and follow us on Twitter and LinkedIn.

Cautionary Note on 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.

Contact:
Tiffany Hamilton
Head of Communications
IR@ocugen.com

(Tables to follow)

OCUGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 68,259	$ 77,563
Marketable securities	8,462	13,371
Prepaid expenses and other current assets	7,680	7,558
Total current assets	84,401	98,492
Property and equipment, net	7,952	6,053
Other assets	3,946	4,087
Total assets	$ 96,299	$ 108,632
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,092	$ 8,062
Accrued expenses and other current liabilities	5,823	9,900
Operating lease obligations	512	498
Current portion of long term debt	1,256	—
Total current liabilities	15,683	18,460
Non-current liabilities		
Operating lease obligations, less current portion	3,449	3,587
Long term debt, net	1,058	2,289
Other non-current liabilities	309	244
Total liabilities	20,499	24,580
Stockholders' equity		
Convertible preferred stock	1	1
Common stock	2,265	2,217
Treasury stock	(48)	(48)
Additional paid-in capital	303,073	294,874
Accumulated other comprehensive income	25	26
Accumulated deficit	(229,516)	(213,018)
Total stockholders' equity	75,800	84,052
Total liabilities and stockholders' equity	$ 96,299	$ 108,632

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three months ended March 31,	
	2023	2022
Operating expenses		
Research and development	$ 9,558	$ 7,915
General and administrative	8,193	10,119
Total operating expenses	17,751	18,034
Loss from operations	(17,751)	(18,034)
Other income (expense), net	1,253	15
Net loss	$ (16,498)	$ (18,019)
Shares used in calculating net loss per common share — basic and diluted	225,523,627	205,693,498
Net loss per common share — basic and diluted	$ (0.07)	$ (0.09)