Ocugen Provides Business Update and First Quarter 2021 Financial Results

May 7, 2021

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

- *COVAXIN demonstrates 100% efficacy against severe COVID-19 disease (including hospitalization)*
- *Master File submitted for U.S. Food and Drug Administration review prior to a planned Emergency Use Authorization application for COVAXIN*
- *$100.0 million in gross proceeds raised through a registered direct offering of common stock*
- *Key talent acquired representing an instrumental step to position Ocugen for future growth*

MALVERN, Pa., May 07, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. ("Ocugen") (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19, today reported first quarter 2021 financial results along with a general business update.

"We continue our dedication to help save lives from COVID-19 by bringing COVAXIN to the U.S. market while simultaneously driving our ophthalmology gene therapy pipeline toward the clinic. We shared compelling second interim analysis results of Bharat Biotech's Phase 3 clinical trial in India as well as positive data from in-vitro studies regarding COVAXIN's ability to neutralize emerging variants. We continue to make progress toward Emergency Use Authorization for COVAXIN while also considering clinical development in special populations, such as children, as well as booster doses. We are delighted to have raised additional capital to fund our ongoing and future operations and to allow us to recruit key talent during this important stage of our growth," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen.

Business Highlights

- COVAXIN Demonstrates Positive Efficacy and Variant Neutralization Results — In April 2021, Ocugen announced that its co-development partner, Bharat Biotech International Limited ("Bharat Biotech"), shared positive results from the second interim analysis of its Phase 3 clinical trial of COVAXIN showing 78% overall efficacy against COVID-19 disease, 100% efficacy against severe COVID-19 disease (including hospitalization), and 70% efficacy against asymptomatic COVID-19 infection, indicating the potential to significantly reduce virus transmission. COVAXIN has additionally demonstrated a remarkable safety profile with several million doses administered to date in India. Moreover, in-vitro studies conducted by the Indian Council of Medical Research-National Institute of Virology have provided data suggesting effectiveness in neutralizing the double mutant India variant, the U.K. variant, and the Brazil variant. Based on broad immunogenicity, Ocugen believes that COVAXIN has the potential to be effective against other emerging variants. COVAXIN is based on proven technology and Ocugen plans to consider clinical development in special populations, such as children, as well as booster doses.
- Continued Progress Toward U.S. Emergency Use Authorization ("EUA") — Ocugen is currently in discussions with the U.S. Food and Drug Administration ("FDA") regarding the development of COVAXIN and has submitted key information and data to date as a Master File for FDA review prior to a planned EUA application once additional data is received from Bharat Biotech from the ongoing Phase 3 clinical trial. Ocugen is additionally in discussions with the Biomedical Advanced Research and Development Authority, commonly known as BARDA, regarding the U.S. government's support of COVAXIN.
- Capital Raised — In April 2021, Ocugen sold an aggregate of 10.0 million shares of its common stock priced at a premium to market at $10.00 per share in a registered direct offering. The registered direct offering generated net proceeds of $93.4 million, after deducting placement agent's fees and other offering expenses payable by Ocugen, further strengthening Ocugen's balance sheet and further extending its cash runway.
- Attracted and Hired Significant Key Talent — Ocugen has increased its headcount to 26 full-time employees as of as of the date of this press release, including the addition of John Paul Gabriel as the Senior Vice President of Manufacturing and Supply Chain. Mr. Gabriel is an established biopharma and vaccines operations leader, who will be instrumental in the technology transfer from Bharat Biotech for the manufacturing of COVAXIN for the U.S. market. Ocugen will continue to expand its headcount this year as necessary for the development and commercialization of COVAXIN and the advancement of the ophthalmology pipeline into the clinic.
- Continued Advancement of Ophthalmology Pipeline — Ocugen's ophthalmology pipeline continues to advance toward the initiation of four Phase 1/2 clinical trials by the end of 2022 including OCU400, Ocugen's lead gene therapy candidate, entering the clinic in the second half of this year. Ocugen has continued to make progress in preclinical development including sharing promising preclinical results for OCU200 at the Wet Age-Related Macular Degeneration Conference in April 2021.

First Quarter 2021 Financial Results

- Ocugen's cash, cash equivalents, and restricted cash totaled $44.9 million as of March 31, 2021, compared to $24.2 million as of December 31, 2020. Ocugen had 188.2 million shares of common stock outstanding as of March 31, 2021.
- Research and development expenses for the three months ended March 31, 2021 were $2.9 million compared to $1.7 million for the three months ended March 31, 2020. General and administrative expenses for the three months ended March 31, 2021 were $4.2 million compared to $2.3 million for the three months ended March 31, 2020. Ocugen reported a $0.04 net loss per share for the three months ended March 31, 2021 compared to a $0.07 net loss per share for the three months ended March 31, 2020.

Conference Call and Webcast Details

Ocugen has scheduled a conference call and webcast for 8:30 a.m. eastern time 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.

The call can be accessed by dialing (844) 873-7330 (U.S.) or (602) 563-8473 (international) and providing the conference ID 9757658. To access a live audio webcast of the call on the "Investors" section of the Ocugen website, please click here. A replay of the webcast will be archived on Ocugen's website for approximately 45 days following the call.

About Ocugen, Inc.
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to save lives from COVID-19. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with one drug — "one to many," and our novel biologic product candidate aims to offer better therapy to patients with underserved diseases such as wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. We are co-developing Bharat Biotech's COVAXIN vaccine candidate for COVID-19 in the U.S. market. For more information, please visit www.ocugen.com.

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 forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from Bharat Biotech's clinical trials will be published in scientific journal publications and, if so, when and with what modifications; whether the FDA will be satisfied with the design of and results from preclinical and clinical studies of COVAXIN, which have been conducted by Bharat Biotech in India; whether and when any Biologics License and/or EUA applications may be filed in the United States for COVAXIN; whether and when any such applications may be approved by the FDA; decisions by the FDA impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN in the United States, including development of products or therapies by other companies. 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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CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 44,792	$ 24,039
Advance for COVAXIN supply	4,988	—
Prepaid expenses and other current assets	1,576	1,839
Total current assets	51,356	25,878
Property and equipment, net	762	633
Restricted cash	151	151
Other assets	1,578	714
Total assets	$ 53,847	$ 27,376
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,040	$ 395
Accrued expenses and other current liabilities	2,703	2,941
Short-term debt, net	374	234
Operating lease obligation	164	44
Total current liabilities	4,281	3,614
Non-current liabilities		
Operating lease obligation, less current portion	1,375	389
Long term debt, net	1,702	1,823
Total liabilities	7,358	5,826
Stockholders' equity		
Convertible preferred stock	1	—
Common stock	1,883	1,841
Treasury stock	(48)	(48)
Additional paid-in capital	125,032	93,059
Accumulated deficit	(80,379)	(73,302)
Total stockholders' equity	46,489	21,550
Total liabilities and stockholders' equity	$ 53,847	$ 27,376

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three months ended March 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 2,872	$ 1,652
General and administrative	4,185	2,277
Total operating expenses	7,057	3,929
Loss from operations	(7,057)	(3,929)
Other income (expense)		
Interest expense	(20)	(15)
Total other income (expense)	(20)	(15)
Net loss	$ (7,077)	$ (3,944)
Shares used in calculating net loss per common share — basic and diluted	186,298,122	52,627,228
Net loss per share of common stock — basic and diluted	$ (0.04)	$ (0.07)