Ocugen Provides Business Update and Second Quarter 2021 Financial Results

August 6, 2021

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

- *Rolling regulatory submission to Health Canada completed and review process initiated; U.S. FDA talks continue*
- *Multiple milestones achieved across regulatory and supply chain to support potential commercialization of pipeline assets*
- *The Company experienced organizational growth to reflect new business requirements in clinical development, manufacturing, and commercialization*

MALVERN, Pa., Aug. 06, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc. ("Ocugen" or the "Company") (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 second quarter 2021 financial results along with a general business update.

"The second quarter has proven how dynamic the life sciences sector is during this time of global crisis, and we are undeterred in our efforts to contribute to the public health agenda. Our regulatory submission to Health Canada and our ongoing discussions with the U.S. Food and Drug Administration continue to provide us direction in potentially obtaining regulatory approvals for COVAXIN™ in North America. We are also continuing our forward momentum to take on blindness diseases and are on track to initiate our first gene therapy clinical trial for OCU400 in the latter part of 2021. Overall, I'm very pleased with our growth and efforts to date," said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen.

Business Highlights

FORWARD MOMENTUM FOR COVAXIN™ AND OPHTHALMIC PIPELINE

- The Company's partner, Bharat Biotech of India, completed and posted its Phase 3 clinical trial results for COVAXIN™ demonstrating 77.8% efficacy against overall COVID-19 disease, 93.4% efficacy against severe COVID-19 disease, 63.6% efficacy against asymptomatic COVID-19 disease, and 65.2% efficacy against the Delta variant, B.1.617.2. Adverse events in the COVAXIN™ and control arms of the Phase 3 clinical trial were observed in 12.4% of subjects, with less than 0.5% of subjects experiencing serious adverse side effects. This data was submitted to a peer-reviewed journal for future potential publication.
- In June, an amendment to the agreement with Bharat Biotech was finalized which expanded the Company's rights to develop, manufacture, and commercialize COVAXIN™ into Canada (in addition to the United States). Soon after in July, the Company announced the completion of its regulatory submission to Health Canada for COVAXIN™, which was accepted under the Minister of Health's *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* and transitioned to a New Drug Submission for COVID-19. The submission was conducted through the Company's new affiliate, Vaccigen, Ltd., and the review process has begun in Canada.
- Discussions with the U.S. Food and Drug Administration are ongoing, and the Company is still proceeding with a strategy focused on the agency's requested Biologics License Application pathway and determining what data requirements and U.S.-based clinical trials will be required to support such submission.
- Technology transfer activities are ongoing between Bharat Biotech and Jubilant HollisterStier, which the Company has selected to be its contract manufacturing partner with respect to COVAXIN™.
- The Company's development activities targeting retinal diseases based on its breakthrough modifier gene therapy platform continue to progress. Its first candidate therapy, OCU400, is anticipated to move into two parallel Phase 1/2a clinical trials in the United States later this year. The Company is currently also evaluating options to commence OCU400 clinical trials in Europe in 2022.

COMPANY POSITIONING FOR FUTURE GROWTH

- New management team member, Mike Shine, joined the Company in early June as Senior Vice President, Commercial, bringing nearly 35 years of industry experience. Mr. Shine will lead commercial efforts for the Company's portfolio including

COVAXIN™'s launch in Canada and the United States, if authorized or approved.

- Employee count has grown as the Company establishes enhanced capabilities in Research and Development, Clinical Development, Commercial, Supply Chain, and Communications.
- The Company entered the Russell 2000 and 3000 Indices in June, which reflects the organization's performance, growth, and value.

Second Quarter 2021 Financial Results

- Ocugen's cash, cash equivalents, and restricted cash totaled $115.8 million as of June 30, 2021, compared to $24.2 million as of December 31, 2020. Ocugen had 198.7 million shares of common stock outstanding as of June 30, 2021.
- Research and development expenses for the three months ended June 30, 2021 were $18.9 million compared to $1.6 million for the three months ended June 30, 2020. Research and development expenses for the three months ended June 30, 2021 included a $15.0 million up-front payment to Bharat Biotech for the right and license to COVAXIN™ development, manufacturing, and commercialization in Canada. General and administrative expenses for the three months ended June 30, 2021 were $6.8 million compared to $1.8 million for the three months ended June 30, 2020. Ocugen reported a $0.13 net loss per share for the three months ended June 30, 2021 compared to a $0.19 net loss per share for the three months ended June 30, 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 6663619. 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. and Canadian markets. 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, including the risk that such dates are not met due to impacts from the ongoing COVID-19 pandemic, 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 the results of in-vitro studies will not be duplicated in human clinical trials; 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 we will be able to provide the U.S. Food and Drug Administration ("FDA") with sufficient additional information regarding the design of and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India in order for those trials to support a Biologics License Application ("BLA"); the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a BLA; any additional chemistry, manufacturing, and controls information that we may be required to submit; the timing of our BLA filing; whether and when a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA, an application for authorization under the Interim Order for emergency use may be approved by Health Canada, or a New Drug Submission application may be approved by Health Canada, which authorizations or approvals will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if authorized or approved, whether it will be commercially successful; whether developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, or other jurisdictions; manufacturing capabilities, manufacturing capacity, and supply restrictions, including whether sufficient doses of COVAXIN™ can be manufactured or supplied within our projected time periods; market demand for COVAXIN™ in the United States or Canada; decisions by the FDA or Health Canada impacting labeling, manufacturing processes, safety, and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States or Canada, 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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(tables to follow)

OCUGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 115,642	$ 24,039
Advance for COVAXIN supply	4,988	—
Prepaid expenses and other current assets	996	1,839
Total current assets	121,626	25,878
Property and equipment, net	944	633
Restricted cash	151	151
Other assets	1,530	714
Total assets	$ 124,251	$ 27,376
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 802	$ 395
Accrued expenses and other current liabilities	3,870	2,941
Short-term debt, net	—	234
Operating lease obligation	168	44
Total current liabilities	4,840	3,614
Non-current liabilities		
Operating lease obligation, less current portion	1,328	389
Long term debt, net	1,674	1,823
Total liabilities	7,842	5,826
Stockholders' equity		
Convertible preferred stock	1	—
Common stock	1,988	1,841
Treasury stock	(48)	(48)
Additional paid-in capital	220,799	93,059
Accumulated deficit	(106,331)	(73,302)
Total stockholders' equity	116,409	21,550
Total liabilities and stockholders' equity	$ 124,251	$ 27,376

OCUGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues				
Collaboration revenue	$ —	$ 43	$ —	$ 43
Total revenues	—	43	—	43
Operating expenses				
Research and development	18,853	1,630	21,725	3,282
General and administrative	6,757	1,779	10,942	4,056
Total operating expenses	25,610	3,409	32,667	7,338

Loss from operations	(25,610)	(3,366)	(32,667)	(7,295)
Other income (expense)				
Interest income	10	—	10	—
Interest expense	(20)	(248)	(40)	(263)
Other income (expense)	(332)	—	(332)	—
Total other income (expense)	(342)	(248)	(362)	(263)
Net loss	$ (25,952)	$ (3,614)	$ (33,029)	$ (7,558)
Deemed dividend related to Warrant Exchange	—	(12,546)	—	(12,546)
Net loss to common stockholders	$ (25,952)	$ (16,160)	$ (33,029)	$ (20,104)
Shares used in calculating net loss per common share — basic and diluted	195,572,189	83,537,463	190,960,775	68,082,346
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.19)	$ (0.17)	$ (0.30)