# Ocugen Provides Business Update and First Quarter 2022 Financial Results

May 6, 2022

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

- *OCU400 Phase 1/2 clinical trial for groundbreaking modifier gene therapy for the treatment of NR2E3 and RHO-related retinitis pigmentosa is advancing after DSMB review*
- *Ocugen's exclusive territory for COVAXIN™ (BBV152) marketing expanded to include all of North America*

MALVERN, Pa., May 06, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. ("Ocugen" or the "Company") (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene therapies, biologicals, and vaccines, today reported first quarter 2022 financial results along with a general business update.

*"We've made significant progress this quarter across multiple areas and we remain confident in the long-term opportunities and growth that we believe our pipeline will unlock,"* said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. "*I am very proud of our dedicated team for moving our breakthrough gene therapy into the clinic and for their commitment to advancing COVAXIN™ to fight against COVID-19."*

Business Updates

- OCU400 Clinical Trial — The Company achieved a key milestone in its Phase 1/2 clinical trial for OCU400 of "first patient, first dose" in late March 2022. The Data and Safety Monitoring Board for the clinical trial reviewed safety data based on dosing to date and recommended that the study proceed with enrolling the remaining study subjects in the current cohort at the target dose level. A second patient was dosed in May 2022.
- COVAXIN™ Rights Expanded to include Mexico — In April 2022, the Company expanded its rights to develop manufacture, and commercialize COVAXIN™ to include Mexico, where the vaccine is already authorized for emergency use in adults and is currently under review by local regulators for emergency pediatric use. The company is now working on commercializing the vaccine in Mexico. The Company's exclusive territory for COVAXIN™ now encompasses the entire North American region.
- COVAXIN™ in the United States — The Company is actively engaged in discussions with the U.S. Food and Drug Administration (the "FDA") to address its questions and resume the Company's Phase 2/3 immuno-bridging and broadening clinical trial for COVAXIN™, OCU-002. In addition, the Company intends to continue working with the FDA to finalize the additional studies required for a Biologics License Application ("BLA").
- COVAXIN™ in Canada — Discussions with Health Canada regarding COVAXIN™ are ongoing. The Company is in discussions with Canadian officials regarding financial support for the potential acquisition of a manufacturing facility in Belleville, Ontario, Canada that would be transformed to become a manufacturing and research and development hub to support both the Company's current and future product candidate pipeline.
- Organizational Growth — Nearly 20 employees joined Ocugen in the first quarter to fill key roles that support operational needs, including clinical trials and regulatory milestones. The number of employees now totals 79.
- Addition to the Board of Directors — In March 2022, Marna C. Whittington, Ph.D., former Chief Executive Officer of Allianz Global Investors Capital, joined the Company's Board of Directors. Dr. Whittington is a renowned financial sector leader and her experience and expertise will be exceedingly important to the Company's growth strategy.

First Quarter 2022 Financial Results

- The Company's cash, cash equivalents, and restricted cash totaled $129.9 million as of March 31, 2022, compared to $95.1 million as of December 31, 2021. The Company had 215.6 million shares of common stock outstanding as of March 31, 2022.
- Research and development expenses for the three months ended March 31, 2022 were $7.9 million compared to $2.9 million for the three months ended March 31, 2021. General and administrative expenses for the three months ended March 31, 2022 were $10.1 million compared to $4.2 million for the three months ended March 31, 2021. Ocugen reported

a $0.09 net loss per share for the three months ended March 31, 2022 compared to a $0.04 net loss per share for the three months ended March 31, 2021.

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 updates. 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 6995784. 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 biotechnology company focused on discovering, developing, and commercializing novel gene therapies, biologicals and vaccines that improve health and offer hope for people and global communities. We are making an impact through courageous innovation, taking science in new directions in service of patients. Our breakthrough modifier gene therapy platform has the potential to treat multiple diseases with one drug and we are advancing research in other therapeutic areas to offer new options for people with 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. Ocugen 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, but are not limited to, statements about Ocugen's progress in advancing the review of COVAXIN™ and its other product candidates with the FDA, and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements, including, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, ability to timely enroll clinical trial participants, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates; the risk that Health Canada does not accept its New Drug Submission ("NDS") for COVAXIN™ or that Ocugen may not be able to adequately resolve the deficiencies noted by Health Canada with respect to its NDS, for which Ocugen has provided responses that are currently under review by Health Canada; the risk that Ocugen may not be able to successfully commercialize COVAXIN™ in Mexico for adults over the age of 18 pursuant to Ocugen's agreement with Bharat Biotech and the risk that Ocugen does not obtain emergency pediatric use for COVAXIN™ in Mexico for children between two and 18 years of age on a timely basis, if at all; the risk that the FDA does not lift the clinical hold on Ocugen's Phase 2/3 immuno-bridging and broadening clinical trial for COVAXIN™ on a timely basis, if at all; 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 is 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 data and results from the preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by regulatory authorities or otherwise sufficient to support Ocugen's submissions for regulatory approvals or authorizations in the United States, Canada or Mexico; the size, scope, timing and outcome of any additional clinical trials or studies that Ocugen may be required to conduct to support regulatory approvals or authorizations; any additional chemistry, manufacturing, and controls information that Ocugen may be required to submit to regulatory authorities ; whether and when a BLA for COVAXIN™ will be submitted to or approved by the FDA; the risk that Ocugen may not be able to successfully negotiate and execute definitive transaction agreements for the acquisition of the manufacturing site on acceptable terms, if at all, and the ultimate terms and timing for closing of the transactions contemplated thereby; the risk that Ocugen will not be able to successfully close the acquisition of the manufacturing site; risks associated with the planned development and refurbishing of the manufacturing site, including that the expected costs for such development may be greater than currently contemplated or that the planned development may take longer than expected or fail to be completed on a timely basis, if at all; and the risk that Ocugen will not be able to scale production for such manufacturing site to adequately support manufacturing of its product candidates or the other products that may in the future be manufactured at such manufacturing site; whether developments with respect to the COVID-19 pandemic will affect the regulatory pathway available for vaccines in the United States, Canada, Mexico or other jurisdictions; market demand for COVAXIN™ in the United States, Canada or Mexico; decisions by the regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of COVAXIN™ in the United States, Canada or Mexico, including development of products or therapies by other companies. These and other risks and uncertainties are more fully described in Ocugen's 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 Ocugen files with the SEC. Any forward-looking statements that Ocugen makes in this press release speak only as of the date of this press release. Except as required by law, Ocugen assumes 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)**

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 129,771 | $ 94,958 |
| Prepaid expenses and other current assets | 8,256 | 7,688 |
| Total current assets | 138,027 | 102,646 |
| Property and equipment, net | 1,921 | 1,164 |
| Restricted cash | 151 | 151 |
| Other assets | 1,628 | 1,800 |
| **Total assets** | $ 141,727 | $ 105,761 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 3,896 | $ 2,312 |
| Accrued expenses | 3,537 | 4,325 |
| Operating lease obligations | 254 | 363 |
| Total current liabilities | 7,687 | 7,000 |
| Non-current liabilities | | |
| Operating lease obligations, less current portion | 1,180 | 1,231 |
| Long term debt, net | 1,731 | 1,712 |
| Total liabilities | 10,598 | 9,943 |
| Stockholders' equity | | |
| Convertible preferred stock | 1 | 1 |
| Common stock | 2,158 | 1,995 |
| Treasury stock | (48) | (48) |
| Additional paid-in capital | 278,704 | 225,537 |
| Accumulated deficit | (149,686) | (131,667) |
| Total stockholders' equity | 131,129 | 95,818 |
| **Total liabilities and stockholders' equity** | $ 141,727 | $ 105,761 |

**OCUGEN, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**(in thousands, except share and per share amounts)**

**(Unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Operating expenses | | |
| Research and development | $ 7,915 | $ 2,872 |
| General and administrative | 10,119 | 4,185 |
| Total operating expenses | 18,034 | 7,057 |
| Loss from operations | (18,034) | (7,057) |
| Other income (expense), net | 15 | (20) |
| Net loss and comprehensive loss | $ (18,019) | $ (7,077) |
| Shares used in calculating net loss per common share — basic and diluted | 205,693,498 | 186,298,122 |
| Net loss per share of common stock — basic and diluted | $ (0.09) | $ (0.04) |