# Ocugen Provides Business Update & Second Quarter 2022 Financial Results

August 5, 2022

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

- *Dosing patients in U.S. Phase 2/3 COVAXIN ™(BBV152) clinical trial*
- *Completed dosing of patients in Cohort 1 of OCU400 gene therapy product candidate*
- *Expanding product pipeline with the regenerative medicine cell therapy program NeoCart®*

MALVERN, Pa., Aug. 05, 2022 (GLOBE NEWSWIRE) -- Ocugen, Inc. (Ocugen or the Company) (NASDAQ: OCGN), a biotechnology company focused on discovering, developing, and commercializing novel gene and cell therapies and vaccines, today reported financial results for the quarter ended June 30, 2022, and provided a general business update.

“The second quarter was marked by several important milestones,” said Dr. Shankar Musunuri, Chairman, Chief Executive Officer, and Co-Founder of Ocugen. “On the vaccine front, we continued to work diligently with our co-development partner, Bharat Biotech, to ensure we execute our planned clinical and commercial objectives for COVAXIN™ – a whole-virion inactivated COVID-19 vaccine candidate.”

“We are also excited and encouraged by the positive momentum of our investigational modifier gene therapy platform, with the potential to address many different gene mutations in the retina and look forward to bringing hope to patients for whom no treatment options exist,” Dr. Musunuri added.

During the second quarter, Ocugen expanded its dynamic clinical product pipeline with the introduction of NeoCart®, an innovative Phase 3-ready cell therapy platform. The U.S. Food and Drug Administration (FDA) recently granted NeoCart® a Regenerative Medicine Advanced Therapy (RMAT) designation for the repair of full-thickness lesions of the knee cartilage in adults, and this candidate, if approved, offers the potential for a new therapeutic option in this area.

“With our diversified portfolio, Ocugen is well-positioned to advance our product development efforts and we look forward to sharing key data as these programs progress,” Dr. Musunuri concluded.

Clinical and Business Updates

Vaccines

- **COVAXIN™ Development in the United States** – The Phase 2/3 immuno-bridging and broadening clinical trial, OCU-002, for COVAXIN™ is progressing well.
  - The Company is actively engaged in planning for the initiation of an adult safety clinical trial this year.
- **COVAXIN™ Data Published in Scientific Journals** – In June 2022, positive pediatric Phase 2/3 study results in children aged 2-18 years were published in *The Lancet Infectious Diseases*. A study published in *Nature Scientific Reports* in July shows that COVAXIN™ (BBV152) generated a persistent cell mediated memory immune response for up to 12 months. Additionally, a booster dose is safe and ensures persistent immunity to minimize breakthrough infections of COVID-19.

Gene Therapies

- **OCU400 Clinical Trial** – Dosing of subjects with retinitis pigmentosa in Cohort 1 was completed. Previously, the Company reported “first patient, first dose” in late March 2022.
  - The Independent Data and Safety Monitoring Board (DSMB) for the clinical trial recently completed a review of safety data based on dosing from Cohort 1 and recommends proceeding to dosing in Cohort 2. The Company expects to begin dosing in Cohort 2 this month.
- **OCU410 Development Program** – Ocugen is conducting IND-enabling studies as per discussions with the FDA. A clinical trial is scheduled to begin next year, and the Company is currently manufacturing materials to support the clinical trial.
- **Improved Patent Estate** – In June 2022, the Company announced that the United States Patent and Trademark Office issued U.S. Patent No. 11,351,225, which is directed to methods for preventing or treating an ocular disease or disorder associated with retinal degenerative disease. The patent covers the use of a nuclear hormone receptor gene, such as nuclear receptor subfamily 2 group E member 3 (*NR2E3*), RAR-related orphan receptor A (*RORA*), Nuclear Protein 1, Transcriptional Regulator (*NUPR1*), and Nuclear Receptor Subfamily 2 Group C Member 1 (*NR2C1*), in treating retinal

degenerative diseases as well as reducing the risk of developing such diseases.

Cell Therapies

- **Expansion of Product Candidate Pipeline with NeoCart®** – Ocugen added NeoCart®, a Phase 3-ready cell therapy platform technology to its diverse product candidate pipeline. The Company originally acquired NeoCart® as part of the Company's reverse merger with Histogenics Corporation in 2019. Ocugen is currently working with the FDA to finalize the Phase 3 protocol necessary to advance the clinical development program of NeoCart®. Also, the Company entered into a collaborative research agreement with Brigham and Women's Hospital, Harvard Medical School, to support NeoCart ® development and explore expansion of the pipeline.

Other Business

- **At-the-Market Stock Issuance** – In June 2022, the Company announced it had entered into an At Market Issuance Sales Agreement relating to the sale of shares of Ocugen's common stock having an aggregate gross sales price of up to $160.0 million. Proceeds will be used for general corporate purposes.
- **Community Recognition** – In June 2022, the *Philadelphia Business Journal* named Ocugen among the region's "2022 Best Places to Work."

Second Quarter 2022 Financial Results

- The Company's cash, cash equivalents, and restricted cash totaled $115.0 million as of June 30, 2022, compared to $95.1 million as of December 31, 2021. The Company believes that its current cash and cash equivalents balance will enable it to fund its operations into the second quarter of 2023. The Company had 216.1 million shares of common stock outstanding as of June 30, 2022.
- Research and development expenses for the three months ended June 30, 2022, were $9.0 million compared to $18.9 million for the three months ended June 30, 2021. Research and development expenses for the three months ended June 30, 2021, included a $15.0 million upfront 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, 2022, were $10.6 million compared to $6.8 million for the three months ended June 30, 2021.
- Ocugen reported a $0.09 net loss per share for the three months ended June 30, 2022, compared to a $0.13 net loss per share for the three months ended June 30, 2021.

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 executive 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 using the following details:

**Dial-in Numbers:** (800) 715-9871 for U.S. callers and (646) 307-1963 for international callers
**Conference ID:** 7036957
**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 forward-looking statements include, but are not limited to, statements about the potential for NeoCart® (autologous chondrocyte-derived neocartilage), if approved, to provide an innovative new option for the repair of full-thickness lesions of the knee cartilage in adults, as well as Ocugen's intention to begin dosing in Cohort 2 of the OCU400 clinical trial this month. 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)**

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 115,005 | $ 94,958 |
| Prepaid expenses and other current assets | 7,564 | 7,688 |
| Total current assets | 122,569 | 102,646 |
| Property and equipment, net | 3,153 | 1,164 |
| Restricted cash | — | 151 |
| Other assets | 4,366 | 1,800 |
| **Total assets** | $ 130,088 | $ 105,761 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 5,921 | $ 2,312 |
| Accrued expenses | 4,103 | 4,325 |
| Operating lease obligations | 314 | 363 |
| Total current liabilities | 10,338 | 7,000 |
| Non-current liabilities | | |
| Operating lease obligations, less current portion | 3,892 | 1,231 |
| Long term debt, net | 1,750 | 1,712 |
| Total liabilities | 15,980 | 9,943 |
| Stockholders' equity | | |
| Convertible preferred stock | 1 | 1 |
| Common stock | 2,163 | 1,995 |
| Treasury stock | (48) | (48) |
| Additional paid-in capital | 281,139 | 225,537 |
| Accumulated other comprehensive income | 10 | — |
| Accumulated deficit | (169,157) | (131,667) |
| Total stockholders' equity | 114,108 | 95,818 |
| **Total liabilities and stockholders' equity** | $ 130,088 | $ 105,761 |

**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, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses | | | | |
| Research and development | $ 9,007 | $ 18,853 | $ 16,922 | $ 21,725 |
| General and administrative | 10,558 | 6,757 | 20,677 | 10,942 |
| Total operating expenses | 19,565 | 25,610 | 37,599 | 32,667 |
| Loss from operations | (19,565) | (25,610) | (37,599) | (32,667) |
| Other income (expense), net | 94 | (342) | 109 | (362) |
| Net loss | $ (19,471) | $ (25,952) | $ (37,490) | $ (33,029) |
| Shares used in calculating net loss per common share — basic and diluted | 215,862,977 | 195,572,189 | 210,806,330 | 190,960,775 |

| | | | | |
|---|---|---|---|---|
| Net loss per share of common stock — basic and diluted | $ (0.09) | $ (0.13) | $ (0.18) | $ (0.17) |