
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 OR 15 (d)
of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **May 6, 2022**

OCUGEN, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

**263 Great Valley Parkway
Malvern, Pennsylvania 19355
(484) 328-4701**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	OCGN	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2022, Ocugen, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. The Company has scheduled a conference call and webcast for 8:30 a.m. eastern time on May 6, 2022 to discuss these financial results and business updates. The Company will use presentation materials in connection with the conference call and webcast, which presentation materials will be posted on the Company's website at www.ocugen.com. Copies of the press release and presentation materials are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any Company filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing

Item 8.01 Other Events.

Attached as Exhibit 99.3 and incorporated herein by reference is a presentation that the Company will post on its website on May 6, 2022 and may use from time to time in presentations or discussions with investors, analysts, and other parties.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being filed or furnished (as applicable) herewith:

(d) Exhibits

<u>Exhibit No.</u>	<u>Document</u>
99.1	Press Release of Ocugen, Inc. dated May 6, 2022.
99.2	Earnings Release Presentation issued May 6, 2022.
99.3	Ocugen, Inc. Presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2022

OCUGEN, INC.

By: /s/ Shankar Musunuri
Name: Shankar Musunuri
Title: Chief Executive Officer and Chairman

Ocugen Provides Business Update and First Quarter 2022 Financial Results

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 6, 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.

Ocugen Contact:

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Head, Investor Relations & Communications
+1 484 237 3398
ken.inchausti@ocugen.com

Please submit investor-related inquiries to: IR@ocugen.com

(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)



Courageous Innovation
Q1 2022 Update

May 2022
NASDAQ: OCGN



Forward Looking Statement

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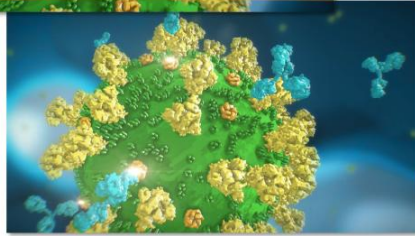
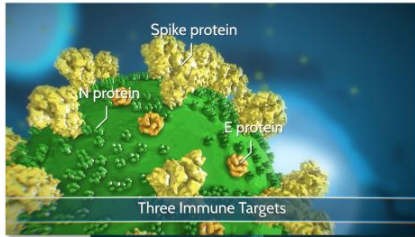
We're Here to Make an Impact Through
Courageous Innovation



ocugen

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Business update on COVAXIN™ (BBV152)

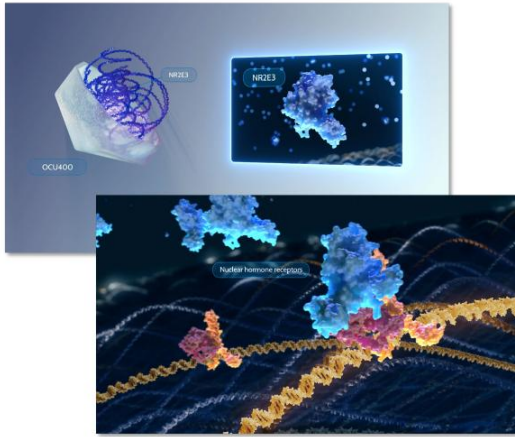


The Company is working with the FDA to address questions arising from WHO's inspection of BBIL's manufacturing facility in order to continue with OCU-002 clinical trial

Planning to commercialize COVAXIN™ in Mexico in 2022, following the broadening of the Ocugen Territory which now covers all of North America

Teams are poised for continuing OCU-002 once path forward is clarified with regulators

Business update on the Ophthalmology Portfolio



First and second patients dosed in Phase 1/2 clinical trial studying OCU400 for the treatment of retinitis pigmentosa resulting from genetic mutations of *NR2E3* and *RHO*

Data Monitoring and Safety Board recommended OCU400-101 clinical trial to proceed with enrolling the remaining study subjects in the current cohort at the target dose level

OCU410 initiating IND-enabling studies to support a future Phase 1/2 clinical trial

Financial Update

Financial Update

Statement of Operations	Three months ended March 31,	
	2022	2021
Research and development expense	\$7.9	\$2.9
General and administrative expense	10.1	4.2
Net loss	\$(18.0)	\$(7.1)
Net loss per share of common stock – basic and diluted	\$(0.09)	\$(0.04)

Balance Sheet Data	March 31, 2022	December 31, 2021
Cash, cash equivalents, and restricted cash	\$129.9	\$95.1
Debt	\$1.7	\$1.7
Shares outstanding	215.6	199.4

Unaudited; in millions, except per share amounts



Questions & Answers



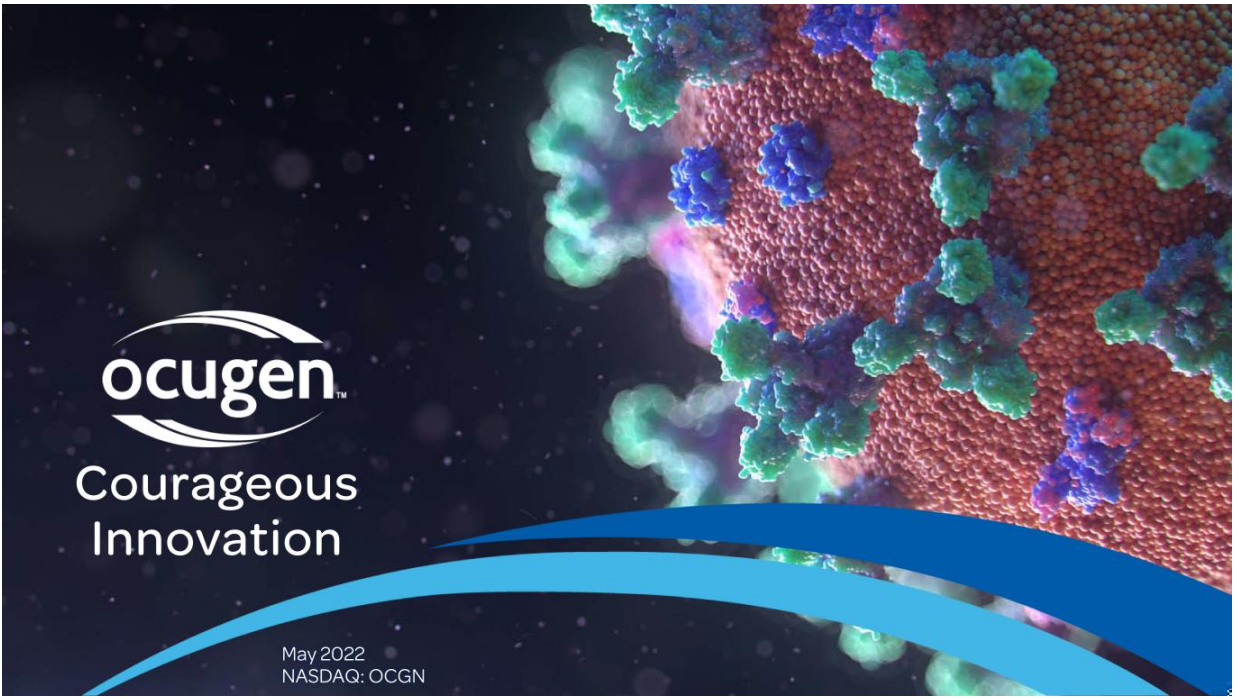
Thank you!

May 2022
NASDAQ: OCGN



Courageous
Innovation

May 2022
NASDAQ: OCGN



Forward Looking Statement

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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 the data and results from preclinical and clinical studies of COVAXIN™, which have been conducted by Bharat Biotech in India, will be accepted by the U.S. Food and Drug Administration ("FDA") or otherwise sufficient to support our Investigational New Drug applications ("IND") or planned Biologics License Applications ("BLA"), as applicable; whether and when we are able to resolve the clinical hold on our Phase 2/3 immuno-bridging and broadening clinical trial for COVAXIN™; the size, scope, timing and outcome of any additional trials or studies that we may be required to conduct to support a for COVAXIN™, including our Phase 2/3 immuno-bridging and broadening clinical trial and planned safety-bridging clinical trial; any additional chemistry, manufacturing, and controls information that we may be required to submit; whether and when a BLA for COVAXIN™ will be submitted to the FDA; whether and when a BLA may be approved by the FDA, whether a New Drug Submission application may be approved by Health Canada, and whether the additional information that we provide to Health Canada will be sufficient to support an approval by Health Canada of COVAXIN™ and any delays associated therewith; our ability to successfully commercialize COVAXIN™ in Mexico for adults over the age of 18 pursuant to our agreement with Bharat Biotech, and whether and when we will obtain Emergency Use Authorization approval for COVAXIN™ in Mexico for children between 2 and 18 years of age; the 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, Mexico 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, Canada or Mexico; decisions by the FDA, Health Canada or the Federal Commission for Protection against Sanitary Risks in Mexico 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 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 presentation speak only as of the date of this presentation. Except as required by law, we assume no obligation to update forward-looking statements contained in presentation whether as a result of new information, future events, or otherwise, after the date of this presentation.



We're Here to Make an Impact Through *Courageous Innovation*

Mission

At Ocugen, we are developing novel solutions to medical challenges, approaching healthcare innovation with purpose and agility to deliver new options for people facing disease.

Vision

We are fostering a future where no one feels hopeless in the face of disease. From genetic disorders to new diseases, our expertise and tenacity are creating choices – for people and for global communities.






Pioneering a breakthrough modifier gene therapy for several genetic forms of vision impairment

Innovating a novel biologic to treat eye diseases that can lead to vision loss for millions of people

Co-developing a COVID-19 vaccine



Pipeline Overview

	 Asset/Program	 Indication	 Status
Vaccine	COVAXIN™ (BBV152) Whole-Virion Inactivated Vaccine	COVID-19	<ul style="list-style-type: none"> EUA for adults in Mexico; EUA for 2-18 year olds under review* US Phase 2/3 clinical trial* (Temporarily paused dosing/clinical hold) Health Canada NDS under review*
Modifier Gene Therapy Platform	OCU400 *** AAV-hNR2E3	Gene mutation-associated retinal degeneration**	
		<i>NR2E3 Mutation</i>	Phase 1/2
		<i>RHO Mutation</i>	Phase 1/2
		<i>CEP290 Mutation</i>	To be submitted
	OCU410 AAV-hRORA	Dry Age-Related Macular Degeneration (Dry AMD)**	Preclinical
Novel Biologic	OCU200 Transferrin – Tumstatin	Diabetic Macular Edema	Preclinical
		Diabetic Retinopathy	Preclinical
		Wet Age-Related Macular Degeneration (Wet AMD)	Preclinical

* Based on Bharat Biotech-sponsored clinical trials in India
** No approved therapies exist

<https://www.aao.org/eye-health/diseases/retinitis-pigmentosa-treatment> | <https://www.aao.org/eye-health/diseases/amd-treatment>

*** ORPHAN DRUG DESIGNATION in the US; Broad ORPHAN MEDICINAL PRODUCT DESIGNATION by the EC for the treatment of retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA)



COVAXIN™ (BBV152)

A Whole-Virion Inactivated COVID-19 Vaccine Candidate
Licensed from Bharat Biotech (BBIL) for the US and Canadian Markets





Product Profile

COVAXIN™ (BBV152): Whole Virion Inactivated SARS-CoV-2 Antigen & Adjuvant: 6ug/SHD + Algel-IMDG (TLR7/8 Agonist)



Proposed indication

Prevention of COVID-19 caused by SARS-CoV-2



Target population

Pediatric: 2-18 years of age
Adult: 18 years of age and older



Dose Level and Regimen

6 ug per 0.5 mL suspension;
2 Doses: Day 0 & Day 28



Presentation

Ten doses per vial



Expected Shelf Life

Two years in storage conditions of 2°- 8°C and stable for six months at room temp (25°C)

Why COVAXIN™ (BBV152)?

Designed to augment our North American arsenal of vaccines against COVID-19

DESIGNED FOR BROAD SPECTRUM IMMUNE RESPONSE

- Adult and pediatric phase 2/3 data suggest both humoral & cellular responses generated against multiple viral proteins
- Data support that the vaccine induces a Th1 response (cell-mediated immunity) which can be vital for durable protection

RESULTS SHOW PREVENTION OF SEVERE COVID-19 DISEASE

- Phase 3 data suggest prevention of hospitalizations caused by COVID-19
- Booster dose provides robust neutralizing antibody responses against Omicron and Delta variants

KNOWN SAFETY PROFILE USING VERO CELL PLATFORM

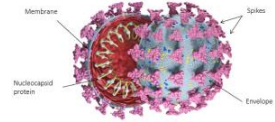
- Data demonstrate strong safety profile within adult and pediatric populations
- Technology platform used to produce Polio, Influenza and Rabies vaccines

TRANSPORTATION AND STORAGE EASE

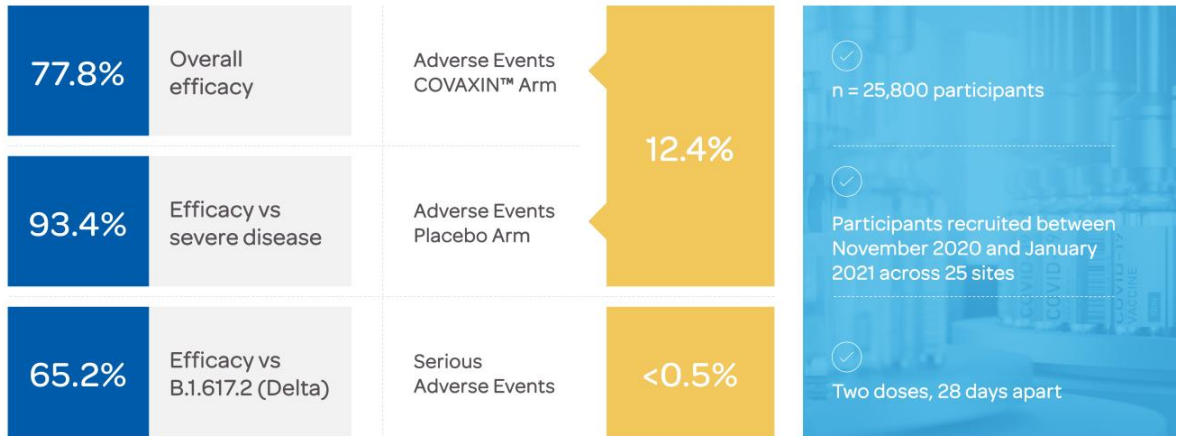
- 10 dose vial that can be stored and shipped at 2°- 8° C with a 2-year shelf life and 6-month stability at room temperature



Image for illustrative purposes only



Why COVAXIN™ (BBV152)? Phase 3 Clinical Trial Highlights



Source: Ella, Reddy, Blackwelder, Potdar, Yadav, Sarangi et al. (2021) Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial; *The Lancet*. Advanced online publication. [https://doi.org/10.1016/S0140-6736\(21\)00000-0](https://doi.org/10.1016/S0140-6736(21)00000-0) Accessed November 11, 2021



Pathway for COVAXIN™ (BBV152) development

NCT: 05258669

OCU-002

A Phase 2/3, Observer-Blind, Immuno-bridging, and Broadening Study of a Whole, Inactivated Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Vaccine (BBV152) in Healthy Adults

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	400 participants
Allocation	Randomized
Intervention Model	Parallel assignment
Intervention Model Description	1:1 randomization ratio
Primary Purpose	Prevention

Immuno-bridging and broadening
(OCU-002)

Booster and Safety*

Proposed
Interim
Analysis

BLA Submission
Window



*Protocol to be submitted

MODIFIER GENE THERAPY PLATFORM

Breakthrough technology designed to address many rare diseases
as well as complex diseases that affect millions

Our Focus: Nuclear Hormone Receptor Genes (NHRs)



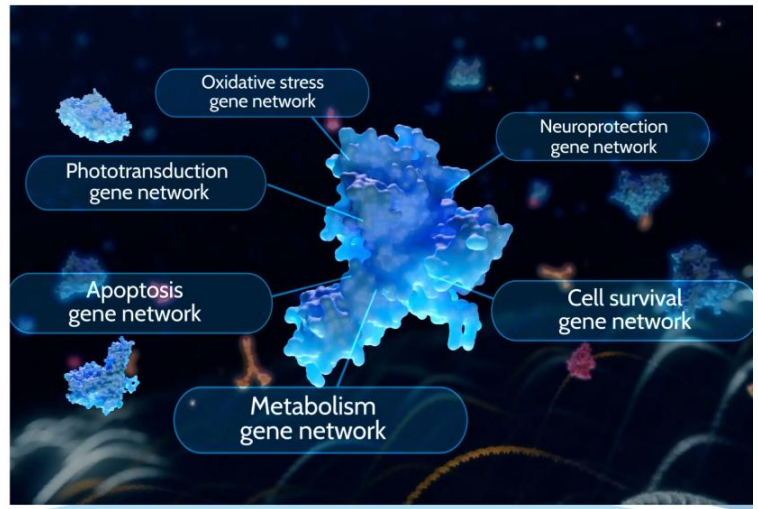
NHRs are modulators of retinal development & function, acting as “master genes” in the retina



Molecular reset of key transcription factors and associated gene networks – retinal homeostasis



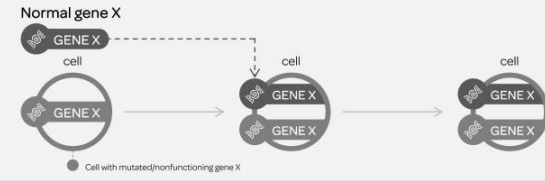
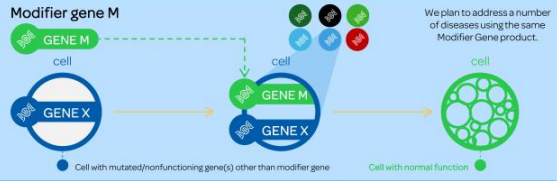
Gene modifier concept including, its impact on clinical phenotypes, is well known in other disease areas, such as cystic fibrosis and spinal muscular atrophy



*References:
<https://pubmed.ncbi.nlm.nih.gov/28556246/> | <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5409219/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4339951/> |
<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0183526>

Our Vision:

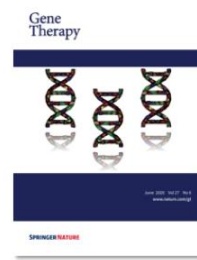
Modifier Gene Therapy vs Traditional Gene Augmentation

<p>Gene Augmentation: Transfer functional version of a non-functional gene into the target cells.</p>  <p>Normal gene X</p> <p>Cell with mutated/nonfunctioning gene X</p>	<p>Modifier Gene Therapy: Designed to introduce a functional gene to modify the expression of many genes, gene-networks and regulate basic biological processes in retina.</p>  <p>Modifier gene M</p> <p>Cell with mutated/nonfunctioning gene(s) other than modifier gene</p> <p>Cell with normal function</p> <p>We plan to address a number of diseases using the same Modifier Gene product.</p>
<p>Traditional Gene Therapy</p> <p>ONE Disease</p>	<p>OCU400</p> <ul style="list-style-type: none"> NR2E3 Mutation-Associated Retinal Disease Rhodopsin Mutation-Associated Retinal Disease CEP290 Mutation-Associated Retinal Disease PDE6B Mutation-Associated Retinal Disease <p><i>Broad Spectrum Therapy for RP</i></p>
<ul style="list-style-type: none"> Traditional approach that targets one individual gene mutation at a time Regulatory pathway focused on specific product for one disease Longer time to recoup development costs 	<ul style="list-style-type: none"> Novel approach that targets nuclear hormone genes (NHRs), which regulate multiple functions within the retina Smother regulatory pathway due to ability to target multiple diseases with one product Ability to recoup development costs over multiple therapeutic indications



Our Proof of Principle: Published in Nature Gene Therapy

- Efficacy results shown in 5 unique mouse models of RP
- Technology developed at Harvard Medical School, Dr. Neena Haider's Lab
- Study suggests potency of modifier gene therapy to elicit broad-spectrum therapeutic benefits in early and advanced stages of RP
- Results suggest evidence of vision rescue in Early & Advanced Stages of disease



Important milestone for development of therapy; demonstrated proof of principle



Protection elicited in multiple animal models of degeneration caused by different mutations



Potential to represent first broad-spectrum therapy and to provide rescue even after disease onset

natureresearch

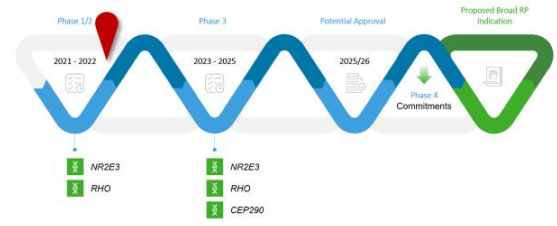
<https://www.nature.com/articles/s41434-020-0134-z>

OCU400 – Pathway to Phase 3 Clinical Trials

✓ Just 30 days to receive FDA clearance for Phase 1/2 gene therapy clinical trial

OCU400
A Phase 1/2 Study to Assess the Safety and Efficacy of OCU400 for Retinitis Pigmentosa Associated With NR2E3 (Nuclear Receptor Subfamily 2 Group E Member 3) and RHO (Rhodopsin) Mutations

Study Type	Interventional (Clinical Trial)
Estimated Enrollment	18 participants
Allocation	Non-randomized
Intervention Model:	Sequential assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment



- NCT: 05203939
- Seven clinical trial sites being activated
- Escalation study involving low, medium, high doses
- First patient dosed by end of Q1 2022
- Periodic updates available starting in Q3 2022
- Enrollment concludes by YE 2022



Summary of activities at Ocugen

COVAXIN™ (BBV152)	<ul style="list-style-type: none">» Planning to commercialize COVAXIN™ in Mexico in 2022, following the broadening of the Ocugen Territory which now covers all of North America» The Company is working with the FDA to address questions arising from WHO's inspection of BBIL's manufacturing facility in order to continue with OCU-002 clinical trial» Health Canada NDS review continues
OCU400/410	<ul style="list-style-type: none">» First and second patients dosed in Phase 1/2 clinical trial studying OCU400 for the treatment of retinitis pigmentosa resulting from genetic mutations of <i>NR2E3</i> and <i>RHO</i>» Successfully completed manufacturing at commercial scale (200L) at CanSinoBio to support clinical studies» Expanded manufacturing agreement with CanSinoBio to include support for OCU410

Experienced Leadership



Shankar Musunuri, PhD, MBA
Chairman, CEO, & Co-Founder



Jessica Crespo, CPA
Chief Accounting Officer
& SVP, Finance



Bruce Forrest, MD
Acting Chief Medical Officer



J.P. Gabriel
SVP, Technical Operations



Zara Gaudio, SHRM-CP
AVP, Human Resources,
Chief of Staff



Nirdosh Jagota, PhD
SVP, Regulatory Affairs,
Compliance and Safety



Huma Qamar, MD, MPH, CMI
AVP, Clinical Development



Mike Shine
SVP, Commercial



Arun Upadhyay, PhD
SVP, Research & Development





Thank you!

May 2022
NASDAQ: OCGN

