



NEWS RELEASE

# INOVIO Reports Third Quarter 2021 Financial Results

11/9/2021

INOVIO receives U.S. FDA authorization to proceed with INNOVATE Phase 3 segment for its COVID-19 vaccine candidate, INO-4800, in the U.S.

INOVIO has regulatory authorization for global Phase 3 trial for INO-4800 in seven countries, including most recently announced Thailand; Dosing for INNOVATE Phase 3 underway

INO-4800 is one of two vaccine candidates initially selected for WHO's Phase 3 Solidarity Trial Vaccines

Investor Call Today at 4:30 PM ET

PLYMOUTH MEETING, Pa., Nov. 9, 2021 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to help protect people from infectious diseases and treat people with cancer, and HPV-associated diseases, today reported financial results for the quarter ended September 30, 2021. INOVIO's management will host a live conference call and webcast at 4:30 p.m. Eastern Time today to discuss financial results and provide a general business update. The live webcast and replay may be accessed by visiting INOVIO's website at <http://ir.inovio.com/events-and-presentations/default.aspx>.

Dr. J. Joseph Kim, President and CEO of INOVIO, said, "This morning, INOVIO announced that the U.S. Food and Drug Administration (FDA) provided authorization to proceed for INOVIO's INNOVATE Phase 3 segment for its COVID-19 vaccine candidate, INO-4800, in the U.S. We're pleased to have the opportunity for U.S. clinical trial participants to potentially contribute to the enrollment in our INNOVATE Phase 3 segment. Today's U.S. announcement builds on our intensive global efforts in India, Brazil, Philippines, Mexico, Colombia, and Thailand where we have received authorizations to date.

"With much of the world still requiring broader access to vaccines, INO-4800 is particularly well-positioned to address global vaccine needs, having been shown, in clinical trials to-date, to be well-tolerated and to generate balanced immune responses which comprise both T and B cell engagement. In addition, INO-4800 has demonstrated a favorable thermostability profile that could facilitate global distribution. I am pleased to share that the dosing for INNOVATE Phase 3 segment is underway and we aim to have interim efficacy data in the first half 2022."

## INOVIO Key Updates & Third Quarter 2021 Highlights

### Key Updates

- INOVIO announced that the U.S. FDA provided authorization to proceed for INOVIO's INNOVATE Phase 3 segment for INO-4800 in the U.S. INOVIO now has the opportunity for U.S. clinical trial participants to potentially contribute to the enrollment in the INNOVATE Phase 3 segment. Since August 2021, INOVIO has received authorization to conduct its INNOVATE Phase 3 global efficacy segment in: **Brazil, Colombia, Mexico, the Philippines, India**, the U.S. and, most recently, **Thailand**. Dosing is underway and the company aims to have interim efficacy data in the first half 2022.
- The WHO shared on October 26, 2021 that INO-4800 is one of two vaccine candidates initially selected for its randomized, global Phase 3 clinical trial, **Solidarity Trial Vaccines**. More information can be found on the WHO's [website](#).
- Subsequent to the quarter end, INOVIO's Phase 1 clinical data on homologous boosting of INO-4800 was **posted** as a pre-print in MedRxiv. The paper, titled "SARS-CoV-2 DNA Vaccine INO-4800 Induces Durable Immune Responses Capable of Being Boosted in a Phase 1 Open-Label Trial," found that among the full Phase 1 cohort of 120 participants –99 (82.5%) participants, received an optional booster (or third) dose – INO-4800 produced broad-based immune responses and was well-tolerated as both a two-dose series and as a homologous booster dose in adults of all ages.
- INOVIO's partner Advaccine **received** regulatory approval to conduct two clinical trials in China investigating boosting with INO-4800. The studies will include prime-boost sequential immunizations using INO-4800 and an inactivated COVID-19 vaccine.
- Subsequent to the quarter end, INOVIO **completed** enrollment (n=220) of its Phase 1B clinical trial for INO-4500, its DNA vaccine candidate for Lassa fever. This trial (LSV-002) is the first vaccine clinical trial for Lassa fever conducted in West Africa, where the viral illness is endemic. INOVIO is advancing INO-4500 with full funding from the Coalition for Epidemic Preparedness Innovations (CEPI).
- INOVIO, with Regeneron, continues to evaluate findings from the Phase 1/2 novel combination trial of DNA medicines INO-5401 and INO-9012 in combination with PD-1 inhibitor cemiplimab – which is being jointly developed by Regeneron and Sanofi – for the treatment of newly diagnosed Glioblastoma Multiforme (GBM).

### INOVIO Third Quarter 2021 and Subsequent Program Updates

#### DNA Vaccine Candidates

##### INO-4800: COVID-19 Vaccine Candidate in Solidarity Trial Vaccines

INOVIO's INO-4800 is one of two initial vaccine candidates included in the WHO's Solidarity Trial Vaccines, which is

designed to "rapidly evaluate the efficacy and safety of promising new candidate vaccines selected by an independent vaccine prioritization advisory group composed of leading scientists and experts." Recruitment for the trial has begun in Colombia, Mali and the Philippines; enrollment is expected at more than 40 sites across the three countries. According to the WHO, the trial "has the additional potential to uncover second-generation vaccines with greater efficacy, conferring greater protection against variants of concern, offering longer duration of protection, and/or using needle-free routes of administration."

#### INO-4800 in INNOVATE Phase 3 Trial

With the FDA's authorization to proceed for INOVIO's INNOVATE Phase 3 segment for INO-4800 in the U.S., INOVIO now has the opportunity for U.S. clinical trial participants to potentially contribute to the enrollment in this global Phase 3 trial. The FDA has lifted the partial clinical hold following the FDA's review of additional non-clinical, clinical, and device information provided by INOVIO. U.S. announcement builds on our intensive global efforts in India, Brazil, Philippines, Mexico, Colombia, and Thailand where we have received authorizations to date.

Dosing is underway and the company aims to have interim Phase 3 efficacy data from INNOVATE in the first half of 2022. Pending favorable clinical efficacy data, the company plans to apply for emergency use authorization in the respective countries, where such mechanism is available.

In addition to receiving regulatory approval to proceed with INNOVATE Phase 3 in Colombia, INOVIO also **signed** a non-binding MOU with Colombia's Ministry of Health and Social Protection, reflecting the intent to advance efforts to combat the continued threat posed by COVID-19 and to better prepare for future public health emergencies within Colombia. The agreement creates a framework for a collaborative arrangement under which INOVIO and Colombia's government plan to explore knowledge sharing, technology licensing, and capacity building towards developing and producing vaccines along with biopharmaceuticals in Colombia. The potential results of these efforts include developing local manufacturing capabilities for INOVIO's DNA medicines and related products and technologies.

#### Boosting

INOVIO continues to study the boosting capabilities of INO-4800 following an initial primary vaccination series using a different COVID-19 vaccine series (heterologous) or with INO-4800 (homologous). During the third quarter, INOVIO's partner Advaccine **received** regulatory authorization to conduct two clinical trials in China investigating boosting with INO-4800. The studies will include prime-boost sequential immunizations using INO-4800 and an inactivated COVID-19 vaccine.

INOVIO's Phase 1 clinical data on homologous boosting of INO-4800 was **posted** in pre-print form at

**MedRxiv.org** after quarter end. The paper, titled "SARS-CoV-2 DNA Vaccine INO-4800 Induces Durable Immune Responses Capable of Being Boosted in a Phase 1 Open-Label Trial," reports that among the full Phase 1 cohort of 120 participants – of which 82.5%, or 99 participants, received an optional booster (or third) dose – INO-4800 produced balanced immune responses and was well-tolerated as both a two-dose series and as a homologous booster dose in adults of all ages.

Notably, a durable anti-SARS-CoV-2 antibody response was observed six months following the second dose, and a homologous booster dose administered between six-to-10.5 months following the second dose also significantly increased humoral and T cell responses. Furthermore, INO-4800 was reported to be well-tolerated, with no treatment-related serious adverse events. Most adverse events were mild in severity and did not increase in frequency with age and subsequent dosing. The newly reported results are consistent with previously shared data from the Phase 2 segment of INOVIO's INNOVATE Phase 2/3 trial.

#### INO-4500: Lassa Fever

Subsequent to the quarter end, the company **announced** full enrollment in its Phase 1B clinical trial for INO-4500, its DNA vaccine candidate for Lassa fever. This trial (LSV-002) is ongoing at the Noguchi Memorial Institute for Medical Research in Accra, Ghana, and is the first vaccine clinical trial for Lassa fever conducted on the African continent. The viral illness is endemic in West Africa. The Phase 1B clinical trial enrolled 220 adult participants who are 18-50 years old, with the primary endpoints of evaluating safety and immunogenicity in an African population. The dosing regimen involves two vaccinations at Days 0 and 28 with either 1.0 mg or 2.0 mg dosing levels. In addition to providing insights on INO-4500's safety and immunogenicity profile, the trial will inform dose selection for subsequent Phase 2 testing in West Africa. INOVIO is advancing INO-4500 with funding from CEPI, with INOVIO and CEPI planning to establish a stockpile for emergency use after a Phase 2 trial, if successful.

#### HPV-associated Diseases

##### VGX-3100: Cervical, Vulvar, and Anal HSIL

##### REVEAL 1 / REVEAL 2 (Cervical HSIL)

INOVIO has completed follow-up of subjects in REVEAL 1 (Randomized Evaluation of VGX-3100 and Electroporation for the treatment of Cervical HSIL), a Phase 3 pivotal trial evaluating VGX-3100 for the treatment of cervical high-grade squamous intraepithelial lesions caused by HPV-16 and/or HPV-18, for safety and durability of virological clearance for 18 months following the last administration. The company expects to present its findings later this year.

Additionally, INOVIO is advancing its partnership with QIAGEN to co-develop an in-vitro diagnostic tool based on a bio-marker to guide clinical decision-making for the use of VGX-3100 in cervical HSIL.

REVEAL 2 is on track to complete enrollment of 198 adult women with histologically confirmed cervical HSIL before year end. Participants will be evaluated for evidence of cervical HSIL on histology as well as evidence of HPV-16 or HPV-18 in cervical samples by type-specific HPV testing at the Week 36 visit accompanied with a one-month safety follow-up.

## Immuno-oncology

### INO-5401: Newly Diagnosed Glioblastoma Multiforme (GBM)

INOVIO, along with our collaborator Regeneron, continues to evaluate findings from the Phase 1/2 novel combination trial of DNA medicines INO-5401 (DNA plasmid encoding for HTERT, WT1, and PSMA cancer antigens) and INO-9012 (DNA plasmid encoding IL-12), two of INOVIO's immunotherapeutic agents, in combination with PD-1 inhibitor cemiplimab – which is being jointly developed by Regeneron and Sanofi – for the treatment of newly diagnosed GBM. Two-year (24 months) overall survival data, including correlative immunology and tissue data, will be presented at a pre-conference workshop of the Society of Immunotherapy of Cancer's (SITC) 36th Annual Meeting this month.

## Third Quarter 2021 Financial Results

Total revenue was \$292,000 for the three months ended September 30, 2021, compared to \$236,000 for the same period in 2020. Total operating expenses were \$60.2 million compared to \$36.6 million for the same period in 2020.

INOVIO's net loss for the quarter ended September 30, 2021 was \$60.2 million, or \$0.29 per basic and diluted share, compared to net income of \$19.2 million, or \$0.12 per basic and \$0.11 diluted share, for the quarter ended September 30, 2020.

The net income for the 2020 quarter was primarily due to the \$35.3 million change in fair value of the derivative liability related to the embedded conversion feature in our August 2019 Convertible Bonds, which was revalued at each reporting period and then immediately prior to the full conversion of these bonds into shares of the Company's common stock in August 2020. The Company also recorded a gain on investment in affiliated entities of \$27.0 million during the quarter, primarily related to the sale of its equity interest in GeneOne. Without the non-cash gain on derivative liability and the gain on investment in affiliated entities, the Company's net loss for the quarter would have been \$43.1 million and basic net loss per share would have been \$0.26.

## Operating Expenses

Research and development (R&D) expenses for the three months ended September 30, 2021, were \$47.1 million compared to \$26.5 million for the same period in 2020. The increase in R&D expenses was primarily related to higher drug manufacturing, outside services and clinical study expenses related to INO-4800, an increase in drug manufacturing and clinical study expenses related to INO-4802 and higher employee and contractor compensation. The increase was also due to a decrease in contra-research and development expense recorded from grant agreements of \$2.4 million, among other variances

General and administrative (G&A) expenses were \$13.2 million for the three months ended September 30, 2021, versus \$10.1 million for the same period in 2020. The increase in G&A expenses was primarily related to an increase in employee compensation, including non-cash stock-based compensation, partially offset by lower expenses for work performed related to corporate marketing and communications, among other variances.

## Capital Resources

As of September 30, 2021, cash and cash equivalents and short-term investments were \$394.9 million compared to \$411.6 million as of December 31, 2020. As of September 30, 2021, the Company had 210.4 million common shares outstanding and 227.0 million common shares outstanding on a fully diluted basis, after giving effect to the exercise, vesting and conversion, as applicable, of its outstanding options, restricted stock units, convertible preferred stock, and convertible debt.

INOVIO's balance sheet and statement of operations are provided below. Additional information is included in INOVIO's quarterly report on Form 10-Q for the quarter ended September 30, 2021, which can be accessed at: <http://ir.inovio.com/financials/default.aspx>.

## Conference Call / Webcast Information

INOVIO's management will host a live conference call and webcast at 4:30 p.m. Eastern Time today to discuss INOVIO's financial results and provide a general business update.

The live webcast and a replay may be accessed by visiting INOVIO's website at <http://ir.inovio.com/events-and-presentations/default.aspx>.

## About INOVIO

INOVIO is a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to

treat and protect people from infectious diseases, cancer, and diseases associated with HPV. INOVIO is the first company to have clinically demonstrated that a DNA medicine can be delivered directly into cells in the body via a proprietary smart device to produce a robust and tolerable immune response. Specifically, INOVIO's lead therapeutic candidate VGX-3100 met primary and secondary endpoints for all evaluable subjects in REVEAL 1, the first of two, Phase 3 trials for precancerous cervical dysplasia, demonstrating ability to destroy and clear both high-grade cervical lesions and the underlying high-risk HPV-16/18. INOVIO is also evaluating INO-4800, a DNA vaccine candidate against COVID-19, in a Phase 2/3 clinical trial; the Phase 3 segment of which has received regulatory approvals to proceed in Colombia, Mexico, Brazil, Philippines, India, Thailand, and the United States. INOVIO's partners, Advaccine Biopharmaceuticals and International Vaccine Institute, are also evaluating INO-4800 in ongoing clinical trials in China and South Korea, respectively.

Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations, Defense Advanced Research Projects Agency/Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense/Department of Defense, HIV Vaccines Trial Network, International Vaccine Institute, Kaneka Eurogentec, Medical CBRN Defense Consortium, National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Ology Bioservices, the Parker Institute for Cancer Immunotherapy, Plumblin Life Sciences, Regeneron, Richter-Helm BioLogics, Thermo Fisher Scientific, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. For more information, visit [www.inovio.com](http://www.inovio.com).

## CONTACTS:

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This press release contains certain forward-looking statements relating to our business, including our plans to develop DNA medicines, our expectations regarding our research and development programs, including the planned initiation and conduct of preclinical studies and clinical trials and the availability and timing of data from those studies and trials, and our ability to successfully manufacture and produce large quantities of our product candidates if they receive regulatory approval. Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials, product development programs and commercialization activities and outcomes, our ability to secure sufficient manufacturing capacity to mass produce our product candidates, the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of electroporation technology as a delivery mechanism or develop viable DNA medicines, our ability to support our pipeline of DNA medicine products, the ability of our collaborators to attain development and commercial milestones for products we license and product

sales that will enable us to receive future payments and royalties, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that we and our collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide us with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether we can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of our technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and other filings we make from time to time with the Securities and Exchange Commission. There can be no assurance that any product candidate in our pipeline will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and we undertake no obligation to update or revise these statements, except as may be required by law.

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INOVIO Pharmaceuticals, Inc.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021	December 31, 2020
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 67,941,337	\$ 250,728,118
Short-term investments	326,999,236	160,914,935
Accounts receivable	4,770,773	18,559,967
Accounts receivable from affiliated entities	2,354,316	503,782

Prepaid expenses and other current assets	85,331,311	40,357,456
Prepaid expenses and other current assets from affiliated entities	—	106,432
Total current assets	<u>487,396,973</u>	<u>471,170,690</u>
Fixed assets, net	17,579,013	11,348,144
Investment in affiliated entity	3,886,710	4,460,366
Investment in Geneos	—	434,387
Intangible assets, net	2,753,126	3,146,770
Goodwill	10,513,371	10,513,371
Operating lease right-of-use assets	11,878,236	12,741,296
Other assets	1,755,083	25,957,448
Total assets	<u>\$ 535,762,512</u>	<u>\$ 539,772,472</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable and accrued expenses	\$ 28,654,864	\$ 21,203,808
Accounts payable and accrued expenses due to affiliated entities	491,645	642,969
Accrued clinical trial expenses	13,618,825	9,950,345
Deferred revenue	77,878	46,628
Operating lease liability	2,536,399	2,329,394
Grant funding liability	5,964,931	7,474,310
Grant funding liability from affiliated entity	31,250	58,500
Total current liabilities	<u>51,375,792</u>	<u>41,705,954</u>
Deferred revenue, net of current portion	68,075	79,214
Convertible senior notes	14,479,334	14,139,988
Convertible bonds	—	4,515,834
Operating lease liability, net of current portion	16,133,245	18,063,515
Deferred tax liabilities	32,046	32,046
Grant funding liability from affiliated entity, net of current portion	37,500	37,500
Other liabilities	64,141	57,663

Total liabilities	82,190,133	78,631,714
Stockholders' equity:		
Preferred stock	—	—
Common stock	210,362	186,851
Additional paid-in capital	1,556,527,891	1,367,406,869
Accumulated deficit	(1,102,907,942)	(906,196,812)
Accumulated other comprehensive loss	(257,932)	(256,150)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	453,572,379	461,140,758
Total liabilities and stockholders' equity	\$ 535,762,512	\$ 539,772,472

INOVIO Pharmaceuticals, Inc.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Revenue under collaborative research and development arrangements	\$ 81,447	\$ 21,490	\$ 203,985	\$ 167,092
Revenue under collaborative research and development arrangements with affiliated entities	95,136	103,684	219,872	1,370,956
Other revenue	115,115	111,004	511,786	292,591
Total revenues	291,698	236,178	935,643	1,830,639
Operating expenses:				
Research and development	47,088,669	26,455,112	156,941,505	67,942,875

General and administrative	13,156,183	10,110,506	39,703,718	28,630,370
Total operating expenses	<u>60,244,852</u>	<u>36,565,618</u>	<u>196,645,223</u>	<u>96,573,245</u>
Loss from operations	<u>(59,953,154)</u>	<u>(36,329,440)</u>	<u>(195,709,580)</u>	<u>(94,742,606)</u>
Other income (expense):				
Interest income	766,271	896,710	2,463,618	2,380,678
Interest expense	(476,374)	(1,984,046)	(1,456,134)	(7,634,442)
Change in fair value of derivative liability	—	35,306,000	—	(75,670,977)
Gain (loss) on investment in affiliated entities	(21,999)	26,951,898	(573,656)	36,250,341
Net unrealized gain (loss) on available-for-sale equity securities	(455,299)	1,315,980	(1,166,764)	624,522
Other income (expense), net	(28,486)	(136,644)	165,773	(714,246)
Gain on deconsolidation of Geneos	—	—	—	4,121,075
Loss on extinguishment of convertible bonds	—	(8,177,043)	—	(8,177,043)
Gain on extinguishment of convertible senior notes	—	3,087,595	—	3,087,595
Net income (loss) before income tax benefit and share in net loss of Geneos	<u>(60,169,041)</u>	<u>20,931,010</u>	<u>(196,276,743)</u>	<u>(140,475,103)</u>
Share in net loss of Geneos	—	(1,759,674)	(434,387)	(2,661,431)
Net income (loss)	<u>(60,169,041)</u>	<u>19,171,336</u>	<u>(196,711,130)</u>	<u>(143,136,534)</u>
Net loss attributable to non-controlling interest	—	—	—	1,063,757
Net income (loss) attributable to Inovio Pharmaceuticals, Inc.	<u>(60,169,041)</u>	<u>19,171,336</u>	<u>(196,711,130)</u>	<u>(142,072,777)</u>
Net income (loss) per share attributable to Inovio Pharmaceuticals, Inc. stockholders				
	<u>(0.29)</u>	<u>0.12</u>	<u>(0.95)</u>	<u>(0.96)</u>
Basic	<u>(0.29)</u>	<u>0.11</u>	<u>(0.95)</u>	<u>(0.96)</u>
Diluted				
Weighted average number of common shares outstanding				
	<u>210,304,836</u>	<u>165,355,540</u>	<u>207,455,684</u>	<u>148,656,454</u>
Basic	<u>210,304,836</u>	<u>174,376,402</u>	<u>207,455,684</u>	<u>148,656,454</u>
Diluted				

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