

INOVIO Reports Third Quarter 2023 Financial Results and Operational Highlights

11/9/2023

- Achieved significant progress with lead product candidate, INO-3107
 - Received Breakthrough Therapy designation from U.S. Food and Drug Administration (FDA) as a potential treatment for Recurrent Respiratory Papillomatosis (RRP)
 - Received FDA feedback that data from completed Phase 1/2 trial could be used to submit a Biological License Application (BLA) under Accelerated Approval program
 - Accelerating commercialization strategy in preparation for an earlier launch, should regulatory approval be achieved
 - If approved, INO-3107 could revolutionize treatment options for patients with RRP, a debilitating rare disease caused by human papillomavirus (HPV)
 - Could be first DNA medicine available in United States and first commercial product for INOVIO
- Continued to advance corporate strategy to align resources with focus on INO-3107 and late-stage clinical candidates closest to market, with greatest opportunity to deliver on the promise of DNA medicines for patients
- \$167.5 million in cash, cash equivalents and short-term investments as of September 30, 2023
- Investor call today at 4:30 PM ET

PLYMOUTH MEETING, Pa., Nov. 9, 2023 /PRNewswire/ -- INOVIO (NASDAQ:INO), a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-related diseases, cancer, and infectious diseases, today announced its financial results and operational highlights for the third quarter ended September 30, 2023.

"The past quarter has seen significant progress for our lead candidate, INO-3107, for the treatment of Recurrent Respiratory Papillomatosis, or RRP," said INOVIO's President and Chief Executive Officer, Dr. Jacqueline Shea. "Following Breakthrough Therapy designation from the FDA in September and subsequent feedback that we no longer need to complete a Phase 3 trial prior to submitting a BLA under the accelerated approval program, our team is laser-focused on next steps. These steps include holding an Initial Comprehensive Multidisciplinary Breakthrough Therapy Meeting with the FDA in the near future to confirm alignment on our accelerated development plans and to clarify timing associated with potentially making INO-3107 available to patients suffering from this devastating disease."

Shea continued: "The progress we have achieved with INO-3107 exemplifies the strategy we have been implementing over the past year, as we have focused on advancing late-stage candidates and driving toward near, mid- and long-term milestones for our pipeline. In the past 18 months, we have reshaped our company, reduced our operating spend and reprioritized our pipeline with INO-3107 as our lead candidate. I am more confident than ever that our experienced team is prepared to deliver on the next critical steps of development and on the promise of DNA medicine for patients."

INOVIO's Chief Commercial Officer, Mark Twyman, stated: "Now that we are moving toward a BLA submission on an accelerated timeline, we are advancing our commercialization strategy expeditiously. We are implementing all aspects of our plan, including strategies for distribution, payor, specialty pharmacy and field force design, with the goal of being ready to launch rapidly if we receive approval. We are also continuing to deepen our understanding of the RRP market and applying what we have learned from our discussions with healthcare providers and RRP patients. Delivering on this opportunity now is incredibly important for patients suffering from RRP as INO-3107 represents a significant improvement in therapeutic options over the current standard of care."

Regulatory Status of INO-3107

The FDA granted Breakthrough Therapy designation to INOVIO's lead candidate based on clinical evidence indicating INO-3107 may demonstrate substantial improvement over existing therapies for RRP. Breakthrough Therapy designation was created by the FDA to help expedite the development and review of drug candidates that are intended to treat a serious or life-threatening condition and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

INOVIO also received feedback from the FDA that data from its completed Phase 1/2 trial of INO-3107 could support INOVIO's submission of a BLA for review under the FDA's accelerated approval program. The FDA advised that completion of a Phase 3 trial would not be required to support this submission. INOVIO will be required to initiate a confirmatory trial prior to BLA submission for accelerated approval and satisfy all other FDA filing requirements. Subsequent to this feedback, INOVIO has been focused on preparing to file its BLA under the accelerated approval program. The company anticipates additional meetings with the FDA to finalize next steps, including an Initial Comprehensive Multidisciplinary Breakthrough Therapy Meeting, or Type B meeting, which it has requested to be held in the fourth quarter of 2023. INOVIO plans to pursue other benefits offered by Breakthrough Therapy designation to quickly resolve any future questions, as well as take advantage of the opportunity to submit under the FDA's Rolling Review program and request a Priority Review once the BLA is fully submitted.

Commercialization Plans for INO-3107

INOVIO has accelerated its commercialization strategy for INO-3107 as a potential treatment for RRP as a result of the opportunity to file its BLA under the FDA's accelerated approval program. This includes implementing its plans for product distribution and logistics, payor engagement and reimbursement, specialty pharmacy identification, patient and provider awareness and education, customer service programs, and other sales and marketing activities. The company has an experienced commercial team that is actively engaging external partners and service providers to be prepared for launch, should INO-3107 receive regulatory approval.

As part of its commercialization plans, INOVIO is continuing to deepen its market understanding of RRP as a disease and the treatment paradigm in the United States. RRP is a chronic, rare disease caused by HPV-6 and HPV-11. The current standard of care is surgery, with many patients facing a lifetime of repeated surgeries as their only option. The most widely cited U.S. epidemiology data estimated that there were approximately 14,000 active cases of RRP in the United States. A recent publication cites that on average, patients with RRP undergo about 4 surgeries per year.

Based on its ongoing market research, INOVIO believes that laryngologists are the primary healthcare providers treating patients suffering from this condition and that they are comfortable administering drugs and utilizing new tools and devices. The company estimates that approximately 300 to 400 laryngologists conduct the majority of RRP surgical procedures in the United States. Key opinion leaders estimate that approximately one-half of all laryngologists practice in academic institutions. In recent discussions with patients, INOVIO believes that RRP patients may prefer to be treated at these regional academic centers.

About INO-3107

INO-3107 is INOVIO's lead DNA medicine product candidate and is being developed as a potential treatment for RRP. INO-3107 is designed to elicit an antigen targeted T cell response against HPV-6 and HPV-11, the HPV types responsible for causing RRP, among other HPV-related diseases. These targeted T cells are designed to seek out and kill HPV-6 and HPV-11 infected cells, with the aim of potentially preventing or slowing the growth of new papillomas. In addition to being designated a Breakthrough Therapy, INO-3107 has also received Orphan Drug designation from the European Commission and from the FDA.

In a Phase 1/2 clinical trial conducted with INO-3107, 81.3% (26/32) of patients had a decrease in surgical interventions in the year after INO-3107 administration compared to the prior year, including 28.1% (9/32) that required no surgical intervention during or after the dosing window. Patients in the trial had a median range of 4 surgeries (2-8) in the year prior to dosing. After dosing, there was a median decrease of 3 surgical interventions (95% confidence interval -3, -2). At the outset of the study (Day 0), patients could have RRP tissue surgically removed, but any surgery performed after Day 0 during the dosing window was counted against the efficacy endpoint. Treatment with INO-3107 generated a strong immune response in the trial, inducing activated CD4 T cells and activated CD8 T cells with lytic potential. T-cell responses were also observed at Week 52, indicating a persistent cellular memory response. INO-3107 was well tolerated by participants in the trial, resulting in mostly low-grade (Grade 1) treatment-emergent adverse effects such as injection site pain and fatigue.

Advancing INOVIO's Three-Part Strategy to Develop its Pipeline

Since mid-2022, INOVIO has been advancing a three-part strategy to deliver on the promise of DNA medicines and the product candidates in its pipeline. In the near-term, INOVIO is focused on optimizing the opportunity for INO-3107 as a potential treatment for RRP patients. In the mid-term, INOVIO is working to advance eight other clinical-stage candidates targeting a number of HPV-related diseases, cancers and infectious diseases. For the longer term, INOVIO is developing next-generation DNA medicine technology, including DNA encoded monoclonal antibodies (dMAbs) targeting COVID-19, as well as DNA-launched nanoparticles (dLNPs) targeting infectious diseases and cancer vaccines that have various disease targets. INOVIO's commitment to financial discipline and leveraging

strong partnerships are also key components to its corporate strategy.

Third Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Short-term Investments:** As of September 30, 2023, cash, cash equivalents and short-term investments were \$167.5 million compared to \$253.0 million as of December 31, 2022.
- **Revenues:** Total revenues for the three months ended September 30, 2023 were \$388,000, compared to \$9.2 million for the same period in 2022. The revenue generated in the third quarter of 2022 was associated with a Procurement Contract with the U.S. Department of Defense for INOVIO's devices and accessories to be used for delivery of its COVID-19 vaccine candidate, INO-4800, which the company has discontinued.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended September 30, 2023 were \$15.5 million compared to \$33.1 million for the same period in 2022. The decrease in R&D expenses was primarily the result of lower drug manufacturing, clinical trial expenses and outside services related to INO-4800 and other COVID-19 studies and lower employee and consultant compensation, including stock-based compensation, among other variances.
- **General and Administrative (G&A) Expenses:** G&A expenses for the 2023 third quarter were \$9.9 million compared to \$11.8 million for the same period in 2022.
- **Total Operating Expenses:** Total operating expenses were \$35.9 million compared to \$44.9 million for the same period in 2022. During the three months ended September 30, 2023, the company recognized a non-cash goodwill impairment charge of \$10.5 million.
- **Net Loss:** INOVIO's net loss for the quarter ended September 30, 2023 was \$33.9 million, or \$0.13 per basic and diluted share, compared to net loss of \$37.8 million, or \$0.15 per basic and diluted share, for the third quarter of 2022. Excluding the non-cash goodwill impairment expense, net loss for the quarter ended September 30, 2023 would have been \$23.4 million, or \$0.09 per basic and diluted share.
- **Shares Outstanding:** As of September 30, 2023, INOVIO had 269.7 million common shares outstanding and 290.6 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, 2023, which can be accessed at: <http://ir.inovio.com/financials/default.aspx>.

Cash Guidance

Following feedback from the FDA on the accelerated approval pathway for INO-3107, INOVIO now estimates its cash runway to extend into the second quarter of 2025. This projection includes a cash burn estimate of

approximately \$26 million for the fourth quarter of 2023. These cash projections do not include any funds that may be raised through the Company's existing at-the-market program or other capital-raising activities.

Conference Call / Webcast Information

INOVIO's management will host its quarterly conference call and webcast at 4:30 p.m. ET today. A replay of the conference call will be available following the conclusion of the call. The live webcast and replay may be accessed by visiting INOVIO's website at <http://ir.inovio.com/events-and-presentations/default.aspx>.

About INOVIO's DNA Medicines Platform

INOVIO's DNA medicines platform has two innovative components: precisely designed DNA plasmids, delivered by INOVIO's proprietary investigational medical device, CELLECTRA®. INOVIO uses proprietary technology to design its DNA plasmids, which are small circular DNA molecules that work like software the body's cells can download to produce specific proteins to target and fight disease. INOVIO's CELLECTRA® delivery devices help ensure its DNA medicines enter the body's cells for optimal effect, without chemical adjuvants or nanoparticles and without the risk of the anti-vector response seen in viral vector platforms.

About INOVIO

INOVIO is a biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-related diseases, cancer, and infectious diseases. INOVIO's technology optimizes the design and delivery of innovative DNA medicines that teach the body to manufacture its own disease-fighting tools. For more information, visit www.inovio.com.

Contacts

Media: Jennie Willson (267) 429-8567 jennie.willson@inovio.com

Investors: Thomas Hong (267) 440-4298 thomas.hong@inovio.com

Forward-Looking Statements

This press release contains certain forward-looking statements relating to INOVIO's business, including its plans to develop and commercialize DNA medicines and its expectations regarding its research and development programs, including plans to initiate a confirmatory trial for INO-3107 instead of the previously announced Phase 3 trial, expectations with respect to INO-3107 if approved, plans for regulatory submissions, the sufficiency of its cash resources and expected cash burn for the fourth quarter of 2023. 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, 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, INOVIO's ability to support its pipeline of DNA medicine products, the ability of INOVIO's collaborators to attain development and commercial milestones for products INOVIO licenses and product sales that will enable INOVIO to receive future payments and royalties, the adequacy of INOVIO's capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by INOVIO or its collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that INOVIO and its collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide INOVIO

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 INOVIO can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of INOVIO's technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in INOVIO's Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, and other filings INOVIO makes from time to time with the Securities and Exchange Commission. There can be no assurance that INO-3107 or any other product candidate in INOVIO's pipeline will be successfully developed, manufactured, or commercialized, that the 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 INOVIO undertakes no obligation to update or revise these statements, except as may be required by law.

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$18,804,602	\$46,329,359
Short-term investments	148,668,866	206,669,397
Accounts receivable	—	1,701,726
Accounts receivable from affiliated entities	2,143,933	10,036,490
Prepaid expenses and other current assets	5,114,873	50,130,481
Prepaid expenses and other current assets from affiliated entities	34,923	375,227
Total current assets	174,767,197	315,242,680
Fixed assets, net	5,632,511	7,727,997
Investment in affiliated entity	2,994,900	2,007,142
Intangible assets, net	—	2,129,861
Goodwill	—	10,513,371
Operating lease right-of-use assets	9,097,275	10,228,207
Other assets	605,315	684,044
Total assets	\$193,097,198	\$348,533,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$15,553,742	\$79,686,885
Accounts payable and accrued expenses due to affiliated entities	711,720	1,220,439
Accrued clinical trial expenses	5,011,185	10,594,073
Operating lease liability	2,117,971	2,803,973
Grant funding liability	3,806,161	2,475,031
Grant funding liability from affiliated entity	21,918	87,673
Convertible senior notes	16,488,329	—
Total current liabilities	43,711,026	96,868,074
Convertible senior notes	—	16,614,840
Operating lease liability, net of current portion	11,194,413	12,655,586
Deferred tax liabilities	32,046	32,046
Total liabilities	54,937,485	126,170,546
Stockholders' equity:		
Preferred stock	—	—
Common stock	269,730	253,090
Additional paid-in capital	1,736,602,555	1,710,656,191
Accumulated deficit	(1,597,961,498)	(1,487,847,784)
Accumulated other comprehensive loss	(751,074)	(698,741)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	138,159,713	222,362,756
Total liabilities and stockholders' equity	\$193,097,198	\$348,533,302

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue from collaborative arrangements and other contracts	\$388,446	\$9,154,133	\$729,359	\$10,137,602
Operating expenses:				
Research and development	15,503,032	33,087,130	69,423,513	145,530,626
General and administrative	9,925,055	11,824,047	37,338,763	76,234,341
Impairment of goodwill	10,513,371	—	10,513,371	—
Total operating expenses	<u>35,941,458</u>	<u>44,911,177</u>	<u>117,275,647</u>	<u>221,764,967</u>
Loss from operations	(35,553,012)	(35,757,044)	(116,546,288)	(211,627,365)
Other income (expense):				
Interest income	1,938,745	1,365,759	6,314,149	2,893,240
Interest expense	(313,488)	(313,488)	(940,464)	(940,464)
Gain (loss) on investment in affiliated entity	214,374	(305,061)	987,758	(1,776,804)
Net unrealized gain (loss) on available-for-sale equity securities	(219,337)	(1,833,284)	3,921,819	(10,641,026)
Other income (expense), net	2,854	(940,778)	(3,850,688)	(1,097,294)
Net loss before share in net loss of Geneos	(33,929,864)	(37,783,896)	(110,113,714)	(223,189,713)
Share in net loss of Geneos	—	—	—	(2,165,213)
Net loss	<u>\$(33,929,864)</u>	<u>\$(37,783,896)</u>	<u>\$(110,113,714)</u>	<u>\$(225,354,926)</u>
Net loss per share				
Basic and diluted	<u>\$(0.13)</u>	<u>\$(0.15)</u>	<u>\$(0.42)</u>	<u>\$(0.96)</u>
Weighted average number of common shares outstanding				
Basic and diluted	<u>268,622,753</u>	<u>249,351,023</u>	<u>263,842,074</u>	<u>234,634,724</u>

View original content: <https://www.prnewswire.com/news-releases/inovio-reports-third-quarter-2023-financial-results-and-operational-highlights-301983947.html>

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