

INOVIO Announces Second Quarter 2023 Financial Results and Provides Strategic Update

8/9/2023

Preparing to initiate pivotal Phase 3 trial of INO-3107 in adult RRP patients in first quarter of 2024; INO-3107 received Orphan Drug Designation from European Commission in second quarter

Scaling resources and headcount to align with strategic focus on INO-3107 and late-stage clinical candidates closest to market and with greatest opportunity to deliver on the promise of DNA medicines for patients

Following biomarker analysis from REVEAL2, INOVIO is stopping investment in VGX-3100 for cervical HSIL for U.S. market; Remains committed to supporting partner ApolloBio's non-biomarker strategy for Chinese market

\$194.9 million in cash, cash equivalents and short-term investments at quarter end; Headcount reduction and reallocation of resources expected to lower future cash burn and extend cash runway into third quarter of 2025

Investor call today at 4:30 PM EDT

PLYMOUTH MEETING, Pa., Aug. 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 for the second quarter ended June 30, 2023 and provided a strategic update.

"We continue to make progress with INO-3107, our candidate for the treatment of recurrent respiratory papillomatosis (RRP). Following positive results from our Phase 1/2 trial earlier this year, we are pleased to announce that we are targeting to have the first patient dosed in a Phase 3 trial in adults in the first quarter of 2024, moving us one step closer to delivering on the promise of DNA medicines for patients suffering from this debilitating disease," said Dr. Jacqueline Shea, INOVIO's President and Chief Executive Officer. "Based on our interactions with the U.S. Food and Drug Administration (FDA) we believe that we have an acceptable trial design.

We are addressing what we believe to be their final questions before we commence our pivotal Phase 3 trial for patients with RRP."

"As we move forward with our pipeline, we are focused on making sure our company is scaled for success in light of the challenging funding environment, particularly for pre-commercial biotech companies like INOVIO," Dr. Shea continued. "With that in mind, we made the difficult decision to further reduce our headcount and operational spending to better align with our strategic priorities. We believe that with the pipeline reprioritization announced today, we are well-positioned to execute on our development plans for INO-3107 while also advancing other promising candidates, such as INO-3112, INO-5401, VGX-3100 for anal HSIL and INO-4201. We expect that our existing cash resources will allow us to achieve important catalysts for these programs. I would like to extend my deepest gratitude to all of our employees – past and present – for their efforts on behalf of the company and contributions to the important progress we're making."

Pipeline Reprioritization and Corporate Reorganization

INO-3107 – Recurrent Respiratory Papillomatosis (RRP)

- INOVIO has announced today that it is further reprioritizing its pipeline to focus on its highest potential, closest to market programs, specifically its late-stage clinical program for INO-3107 as a treatment for RRP. In a Phase 1/2 trial involving RRP patients, treatment with INO-3107 resulted in a statistically significant reduction in the number of surgical interventions required to manage the disease. INOVIO is targeting to commence its pivotal Phase 3 trial in adult patients with RRP, subject to clearance by regulators, in the first quarter of 2024.
- On May 5, 2023, data from the Phase 1/2 trial of INO-3107 were presented by lead investigator Dr. Ted Mau at the scientific program of the American Broncho-Esophagological Association (ABEA) at the Combined Otolaryngology Spring Meetings (COSM) in Boston, Massachusetts. The presentation highlighted the safety profile of INO-3107, which was well tolerated by participants in the trial and resulted in mostly low-grade (Grade 1) treatment-emergent adverse effects (TEAEs) such as injection site pain and fatigue. There were no high-grade TEAEs deemed related to treatment and no TEAEs leading to treatment discontinuation. Treatment with INO-3107 induced cellular immune responses against both HPV-6 and HPV-11, with activated CD4 and CD8 T cells, including cytotoxic CD8 T cells thought to be important for clearance of virally infected cells. Preliminary analysis indicates a potential correlation between T-cell responses and reduction of surgeries. T-cell responses were also observed at Week 52, indicating a persistent cellular memory response.
- Also in May 2023, INO-3107 was granted orphan drug designation by the European Commission (EU) as a

potential treatment for RRP. INO-3107 was granted orphan drug designation from the FDA in July 2020, making it the first RRP product candidate to receive designations from both U.S. and EU regulatory bodies.

VGX-3100 – Cervical High-Grade Squamous Intraepithelial Lesions (HSIL)

- INOVIO has decided to cease all further development of VGX-3100 as a potential treatment for cervical HSIL in the United States. This decision is driven by a number of factors, including the recent analysis of biomarker data from REVEAL2 indicating that substantial work would be needed to refine this novel biomarker before it could be used in any further Phase 3 trials. Previously, the U.S. FDA indicated that at least one or more additional well-controlled trials would need to be conducted in the biomarker-positive population before being considered for registration. Given these factors, INOVIO has determined that its resources are best invested in other pipeline candidates with a faster potential path to market. INOVIO remains encouraged by the data collected in both of its completed Phase 3 trials for VGX-3100 in cervical HSIL (**REVEAL1** and **REVEAL2**). In these trials, the data showed that VGX-3100 could clear both virus and lesions, which INOVIO believes could be supportive evidence for pursuing regulatory approval in other global markets.
- For non-U.S. markets, where the access to and options for treatment differs, INOVIO believes that VGX-3100 could be a valuable treatment option for cervical HSIL should current and future trials continue to show potential efficacy and achieve regulatory approvals. For the Chinese market, INOVIO's partner ApolloBio continues to advance the development of VGX-3100 for cervical HSIL in a Phase 3 trial. This trial is designed to use a similar protocol to that of REVEAL1 and does not utilize the novel biomarker used in INOVIO's REVEAL2 trial. INOVIO also continues to discuss the clinical development of VGX-3100 with potential partners in other global markets.

Other VGX-3100 Indications and Clinical Pipeline Candidates

- Pending discussions with regulators, INOVIO plans to investigate opportunities to advance VGX-3100 as a potential treatment for anal HSIL, an indication that continues to have significant unmet need. Results published in the New England Journal of Medicine in June 2022 from a multi-year study sponsored by the National Cancer Institute, called the ANCHOR study, showed "for the first time that treating anal HSIL is effective at reducing the incidence of anal cancer in a very high-risk group of people – people living with HIV" (**NCI press release, June 15, 2022**). INOVIO has observed that this study produced results that are moving the medical community away from the historical practice of actively monitoring anal HSIL and toward a more proactive approach in treating lesions that can progress to cancer. The challenge for patients and their healthcare providers in taking a more proactive approach is that there are few effective options available to treat anal HSIL. VGX-3100 has the ability to clear HPV-16/18 lesions and virus, which was not only observed in the cervical HSIL Phase 3 trials, but also in an open-label Phase 2 anal HSIL trial in HIV negative people. VGX-

3100 is currently being investigated in an ongoing Phase 2 trial in HIV-positive anal HSIL patients being conducted by the AIDS Malignancy Consortium.

- INOVIO is also working to advance its oncology product candidates, specifically INO-5401 and INO-3112, which target glioblastoma (GBM) and HPV-related cancers, respectively, as well as other candidates in its early-stage clinical pipeline targeting infectious diseases, in particular the company's Ebola vaccine candidate, INO-4201. Progress for these candidates has continued in the areas of manufacturing, regulatory submissions, and partnership discussions. The next stage of clinical development will most likely require additional funding or partnerships.

Corporate Restructuring

- As a result of the decision to focus its resources on its late-stage candidates with the greatest likelihood of success, including stopping the development of VGX-3100 in cervical HSIL for the U.S. market, INOVIO has taken steps to further conserve its capital resources. The company recently announced plans to further reduce its workforce by 58 employees, or 30%. The company estimates the cost savings from the headcount reduction will provide annual savings of approximately \$9.9 million, which alongside other reductions in spending would allow the company to extend its cash runway into the third quarter of 2025.

Second Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Short-term Investments:** As of June 30, 2023, cash, cash equivalents and short-term investments were \$194.9 million compared to \$253.0 million as of December 31, 2022.
- **Revenues:** Total revenues for the three months ended June 30, 2023 were \$226,000, compared to \$784,000 for the same period in 2022.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended June 30, 2023 were \$23.7 million compared to \$56.5 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 second quarter were \$13.5 million compared to \$48.5 million for the same period in 2022. The decrease in G&A expenses was primarily related to significant one-time costs in the second quarter of 2022 related to the settlement of the class action litigation and related legal expenses, as well as severance expenses incurred in 2022 in connection with the

separation of the company's former president and chief executive officer, among other variances.

- **Total Operating Expenses:** Total operating expenses were \$37.3 million compared to \$104.9 million for the same period in 2022.
- **Net Loss:** INOVIO's net loss for the quarter ended June 30, 2023 was \$35.5 million, or \$0.13 per basic and diluted share, compared to net loss of \$108.5 million, or \$0.46 per basic and diluted share, for the second quarter of 2022.
- **Shares Outstanding:** As of June 30, 2023, INOVIO had 268.1 million common shares outstanding and 290.0 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 June 30, 2023, which can be accessed at: <http://ir.inovio.com/financials/default.aspx>.

Cash Guidance

INOVIO estimates that the cost savings announced today will enable it to fund its operations into the third quarter of 2025. This projection includes a cash burn estimate of approximately \$34.0 million for the third quarter of 2023 and the expectation that cash burn will decrease incrementally throughout the remainder of 2023 and 2024. 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

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 DNA medicines in development are delivered using its investigational proprietary smart device, CELLECTRA®, to produce immune responses against targeted pathogens and cancers. For more information, visit www.inovio.com.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to our business, including our plans to develop and commercialize DNA medicines and our expectations regarding our research and development programs, including the planned initiation and conduct of pre-clinical studies and clinical trials and the availability and timing of data from those studies and trials, the need for third-party funding to continue certain development programs, expectations with respect to annual savings from corporate restructuring activities, projected cash burn for the third quarter of 2023 and reductions in spending through 2024, and the sufficiency of our cash resources to fund operations into the third quarter of 2025. 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, 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 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, 2022, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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 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 we undertake no obligation to update or revise these statements, except as may be required by law.

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$52,712,543	\$46,329,359
Short-term investments	142,212,907	206,669,397
Accounts receivable	5,947	1,701,726
Accounts receivable from affiliated entities	5,110,279	10,036,490
Prepaid expenses and other current assets	3,230,882	50,130,481
Prepaid expenses and other current assets from affiliated entities	11,928	375,227
Total current assets	203,284,486	315,242,680
Fixed assets, net		
Investment in affiliated entity	6,303,949	7,727,997
Intangible assets, net	2,780,526	2,007,142
Goodwill	—	2,129,861
Operating lease right-of-use assets	10,513,371	10,513,371
Other assets	9,488,738	10,228,207
	666,890	684,044
Total assets	\$233,037,960	\$348,533,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$21,265,150	\$79,686,885
Accounts payable and accrued expenses due to affiliated entities	1,686,375	1,220,439
Accrued clinical trial expenses	6,172,382	10,594,073
Operating lease liability	2,351,449	2,803,973
Grant funding liability	3,704,781	2,475,031
Grant funding liability from affiliated entity	43,836	87,673
Convertible senior notes	16,708,329	—
Total current liabilities	51,932,302	96,868,074
Convertible senior notes	—	16,614,840
Operating lease liability, net of current portion	11,702,044	12,655,586
Deferred tax liabilities	32,046	32,046
Total liabilities	63,666,392	126,170,546
Stockholders' equity:		
Preferred stock	—	—
Common stock	268,072	253,090
Additional paid-in capital	1,733,826,392	1,710,656,191
Accumulated deficit	(1,564,031,634)	(1,487,847,784)
Accumulated other comprehensive loss	(691,262)	(698,741)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	169,371,568	222,362,756
Total liabilities and stockholders' equity	\$233,037,960	\$348,533,302

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue from collaborative arrangements and other contracts	\$225,971	\$784,395	\$340,914	\$983,469
Operating expenses:				
Research and development	23,743,970	56,464,885	53,920,481	112,443,496
General and administrative	13,523,098	48,456,836	27,413,708	64,410,294
Total operating expenses	37,267,068	104,921,721	81,334,189	176,853,790
Loss from operations	(37,041,097)	(104,137,326)	(80,993,275)	(175,870,321)
Other income (expense):				
Interest income	2,168,233	857,667	4,375,404	1,527,481

Interest expense	(313,488)	(313,488)	(626,976)	(626,976)
Gain (loss) on investment in affiliated entity	156,745	(934,015)	773,384	(1,471,743)
Net unrealized gain (loss) on available-for-sale equity securities	922,941	(3,967,101)	4,141,156	(8,807,742)
Other expense, net	(1,427,867)	(3,048)	(3,853,543)	(156,516)
Net loss before share in net loss of Geneos	(35,534,533)	(108,497,311)	(76,183,850)	(185,405,817)
Share in net loss of Geneos	—	—	—	(2,165,213)
Net loss	<u>\$(35,534,533)</u>	<u>\$(108,497,311)</u>	<u>\$(76,183,850)</u>	<u>\$(187,571,030)</u>
Net loss per share				
Basic and diluted	<u>\$(0.13)</u>	<u>\$(0.46)</u>	<u>\$(0.29)</u>	<u>\$(0.83)</u>
Weighted average number of common shares outstanding				
Basic and diluted	<u>264,353,833</u>	<u>235,278,276</u>	<u>261,412,116</u>	<u>227,154,616</u>

View original content:<https://www.prnewswire.com/news-releases/inovio-announces-second-quarter-2023-financial-results-and-provides-strategic-update-301897181.html>

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