

# INOVIO Pharmaceuticals Reports 2019 Fourth Quarter and Year-End Financial Results

3/12/2020

PLYMOUTH MEETING, Pa., March 12, 2020 /PRNewswire/ -- INOVIO Pharmaceuticals, Inc. (NASDAQ: INO), a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat, cure, and protect people from diseases associated with HPV, cancer, and infectious diseases, today reported financial results for the fourth quarter and year ended December 31, 2019. 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.

## INOVIO Highlights

### VGX-3100: Cervical, vulvar, and anal HSIL

REVEAL 2 Phase 3 clinical trial evaluating VGX-3100 for treatment of HPV-related cervical high-grade squamous intraepithelial lesions (HSIL) has a total of 43 sites opened globally for recruitment, which includes newly opened sites in Brazil and South Africa, along with four new U.S.-based sites. Top-line efficacy data from REVEAL 1 Phase 3 clinical trial is expected to be reported by the fourth quarter of 2020.

INOVIO is also evaluating VGX-3100 in two Phase 2 trials for the treatment of vulvar HSIL and anal HSIL. Preliminary efficacy and safety data are planned to be presented later this month at The American Society for Colposcopy and Cervical Pathology (ASCCP) 2020 Scientific Meeting on Anogenital & HPV-Related Diseases.

### INO-3107: Recurrent respiratory papillomatosis (RRP)

In February 2020, INOVIO announced that the U.S. Food and Drug Administration (FDA) accepted its Investigational New Drug (IND) application to evaluate INO-3107 in a Phase 1/2 trial for treatment of recurrent respiratory papillomatosis (RRP). The Phase 1/2 trial is expected to enroll approximately 63 subjects in the United States and will evaluate the efficacy, safety, tolerability, and immunogenicity of INO-3107 in subjects with HPV 6 and/or 11-

associated RRP who have required at least two surgical interventions per year for the past three years for the removal of associated papilloma(s). As RRP is a rare, orphan disease, INOVIO plans to work with the FDA's Office of Orphan Products Development (OOPD) in an effort to attain Orphan Disease designation for INO-3107.

INOVIO and its collaborators published data from a pilot, compassionate use clinical trial for the treatment of RRP in the scientific journal Vaccines (MDPI). The article, entitled "Immune Therapy Targeting E6/E7 Oncogenes of Human Papillomavirus Type 6 (HPV-6) Reduces or Eliminates the Need for Surgical Intervention in the Treatment of HPV-6 Associated Recurrent Respiratory Papillomatosis," detailed the clinical efficacy observed in the pilot study of two patients with RRP.

### INO-4800: COVID-19

In January 2020, INOVIO was awarded a grant of up to \$9 million from the Coalition for Epidemic Preparedness Innovations (CEPI) to develop a vaccine against COVID-19, the disease caused by the novel coronavirus. This initial CEPI funding is anticipated to support INOVIO's preclinical and clinical development through a Phase 1 clinical trial of INO-4800, INOVIO's COVID-19 vaccine candidate, in the United States.

Subsequent to the grant from CEPI, INOVIO announced a collaboration agreement with Beijing Advaccine Biotechnology Co. to advance the development of INO-4800 in China. The goal of this collaboration is to leverage Beijing Advaccine's expertise to run a Phase 1 trial in China in parallel with INOVIO's ongoing clinical development efforts in the United States.

In March 2020, INOVIO received a new \$5 million grant from the Bill and Melinda Gates Foundation anticipated to fund accelerated testing and scale up of INOVIO's CELLECTRA® 3PSP proprietary smart device for the intradermal delivery of INO-4800, in order to support large scale manufacturing of INO-4800 doses by end of 2020.

### INO-5401: Newly diagnosed glioblastoma multiforme (GBM)

In November 2019, INOVIO reported positive interim data for INO-5401 from its ongoing Phase 2 trial in patients with newly diagnosed glioblastoma multiforme (GBM) at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting. The Phase 2 trial is evaluating INO-5401, a T cell-activating immunotherapy candidate encoding for three tumor-specific antigens (hTERT, WT1, and PSMA), and INO-9012, an immune activator encoding IL-12, in combination with Libtayo®, a PD-1 blocking antibody produced by Regeneron Pharmaceuticals in collaboration with Sanofi.

Key interim data from the 52-patient clinical trial showed that 80% (16 of 20) of MGMT gene promoter methylated patients and 75% (24 of 32) of unmethylated patients were progression-free at six months measured from the time

of their first dose, substantially exceeding historical standard-of-care data (approximately 60% of MGMT promoter methylated patients and 40% of unmethylated patients historically were progression-free at six months). INOVIO expects to report 12-month overall survival data in June 2020, followed by 18-month overall survival data in the fourth quarter of 2020.

Dr. J. Joseph Kim, INOVIO's President & CEO, said, "The company remains well-positioned for 2020 to be a transformational year for INOVIO. Following our very encouraging, albeit early, positive data for INO-5401 in our GBM study, we look forward to presenting 12-month overall survival data next quarter. We also continue to expand our capabilities in treating HPV-associated diseases, with IND acceptance from the FDA for a Phase 2 trial evaluating INO-3107 for the rare, orphan disease RRP. We also look forward to sharing interim efficacy and safety data from our Phase 2 study in HPV-associated vulvar HSIL and anal HSIL at ASCCP later this month."

"The evolving situation following the outbreak of COVID-19 has allowed us to further showcase INOVIO's technology capabilities and versatility in fighting emerging infectious diseases. We are very grateful for both the financial and moral support from CEPI to take steps toward tackling this global pandemic. Our DNA medicine platform has been selected among a small group of important vaccine technologies for rapidly impacting emerging infectious diseases outbreaks such as COVID-19, having already advanced INO-4700, our vaccine candidate against MERS-CoV, another coronavirus, to a Phase 1/2a clinical trial. We look forward to sharing more on INO-4800's development along with our broader pipeline initiatives and achievements in the future."

## Fourth Quarter 2019 Financial Results

Total revenue was \$279,000 and \$4.1 million for the quarter and year ended December 31, 2019, respectively, compared to \$2.5 million and \$30.5 million for the same periods in 2018, respectively. Total operating expenses were \$30.7 million and \$115.2 million for the quarter and year ended December 31, 2019, respectively, compared to \$32.0 million and \$124.6 million for the same periods in 2018, respectively.

INOVIO's net loss for the quarter and year ended December 31, 2019 was \$37.7 million, or \$0.38 per basic and diluted share, and \$119.4 million, or \$1.21 per basic and diluted share, respectively, as compared to \$33.0 million, or \$0.34 per basic and diluted share, and \$97.0 million, or \$1.05 per basic and diluted share, for the same periods in 2018, respectively.

## Revenue

The year-over-year decrease in revenue under collaborative research and development (R&D) arrangements was primarily due to the recognition of a one-time upfront payment of \$23.0 million from ApolloBio during the second quarter of 2018.

## Operating Expenses

R&D expenses for the quarter and year ended December 31, 2019 were \$22.0 million and \$88.0 million, respectively, compared to \$26.4 million and \$95.3 million for the same periods in 2018, respectively. The year-over-year decrease in R&D expenses was primarily due to decreases in employee compensation expense and drug manufacturing expense related to our partnership with AstraZeneca, among other variances. These decreases were offset by an increase in expenses related to clinical trials and a personnel-related restructuring charge in connection with the one-time employee termination costs incurred during the third quarter of 2019.

General and administrative expenses were \$8.7 million and \$27.2 million, respectively, for the quarter and year ended December 31, 2019 versus \$5.6 million and \$29.3 million, respectively, for the same periods in 2018.

## Capital Resources

As of December 31, 2019, cash and cash equivalents and short-term investments were \$89.5 million compared to \$93.8 million as of September 30, 2019. As of December 31, 2019, the Company had 101.4 million common shares outstanding and 132.1 million common shares outstanding on a fully diluted basis, after giving effect to outstanding options, restricted stock units and convertible preferred stock.

During the year ended December 31, 2019, the Company sold 3,340,678 shares of common stock under its "at-the-market" (ATM) common stock sales agreement for aggregate net proceeds of \$9.1 million.

From January 1, 2020 through March 11, 2020, the Company sold 43,148,952 shares of common stock under its ATM agreement for net proceeds of \$208.2 million. The sales were made at a weighted average price of \$4.92 per share. As of March 11, 2020, there is no remaining capacity under the ATM agreement.

INOVIO's balance sheet and statement of operations are provided below. Additional information is included in INOVIO's annual report on Form 10-K for the year ended December 31, 2019, which can be accessed at: <http://ir.inovio.com/investors/financial-reports/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/investors/events/default.aspx>. Telephone replay will be available approximately one hour

after the call at 877-344-7529 (US toll-free) or 412-317-0088 (international toll) using replay access code 10139836.

## About INOVIO Pharmaceuticals, Inc.

INOVIO is a biotechnology company focused on rapidly bringing to market precisely designed DNA medicines to treat, cure, and protect people from diseases associated with HPV, cancer, and infectious diseases. INOVIO is the first and only 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 immune response to destroy and clear high-risk HPV 16 and 18, which are responsible for 70% of cervical cancer, 90% of anal cancer and 69% of vulvar cancer. In addition to HPV, INOVIO's optimized plasmid design and delivery technology have been demonstrated to consistently activate robust and fully functional T cell and antibody responses against targeted cancers and pathogens. INOVIO's most advanced clinical program, VGX-3100, is in Phase 3 development for the treatment of HPV-related cervical pre-cancer. Also in development are Phase 2 immuno-oncology programs targeting HPV-related cancers, GBM, and prostate cancer, as well as externally funded vaccine development programs in Zika, MERS, Lassa, HIV, and COVID-19. Partners and collaborators include Advaccine, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Defense Advanced Research Projects Agency, GeneOne Life Science, HIV Vaccines Trial Network, Medical CBRN Defense Consortium (MCDC), National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Plumblin Life Sciences, Regeneron, Roche/Genentech, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. INOVIO also is a proud recipient of 2020 Women on Boards "W" designation recognizing companies with more than 20% women on their board of directors. For more information, visit [www.inovio.com](http://www.inovio.com).

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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 clinical trials, and the availability and timing of data from those trials. 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 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, 2019 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

INOVIO Pharmaceuticals, Inc.

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,196,097	\$ 23,693,633
Short-term investments	67,338,017	57,538,852
Accounts receivable	700,073	3,316,361
Accounts receivable from affiliated entities	1,332,044	738,583
Prepaid expenses and other current assets	1,584,598	1,406,590
Prepaid expenses and other current assets from affiliated entities	1,050,140	1,120,805

Total current assets	94,200,969	87,814,824
Fixed assets, net	12,773,017	15,949,014
Investments in affiliated entities	6,315,356	9,405,913
Intangible assets, net	3,693,851	4,760,145
Goodwill	10,513,371	10,513,371
Operating lease right-of-use assets	13,783,009	—
Other assets	2,672,024	2,669,998
Total assets	<u>\$ 143,951,597</u>	<u>\$ 131,113,265</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Accounts payable and accrued expenses	\$ 18,237,258	\$ 23,134,733
Accounts payable and accrued expenses due to affiliated entities	729,729	977,792
Accrued clinical trial expenses	4,049,727	5,671,764
Deferred revenue	92,353	223,577
Deferred revenue from affiliated entities	31,775	33,575
Deferred rent	—	1,065,387
Operating lease liability	2,074,842	—
Grant funding liability	6,065,212	4,165,848
Grant funding liability from affiliated entities	708,425	27,083
Total current liabilities	<u>31,989,321</u>	<u>35,299,759</u>
Deferred revenue, net of current portion	101,567	150,793
Convertible senior notes	64,180,325	—
Convertible bonds	12,842,592	—
Derivative liability	8,819,023	—
Deferred rent, net of current portion	—	8,518,207
Operating lease liability, net of current portion	20,409,922	—
Deferred tax liabilities	32,046	24,766
Grant funding liability from affiliated entity, net of current portion	135,000	—

Other liabilities	36,943	87,333
Total liabilities	<u>138,546,739</u>	<u>44,080,858</u>
Commitments and contingencies		
INOVIO Pharmaceuticals, Inc. stockholders' equity:		
Preferred stock—par value \$0.001; Authorized shares: 10,000,000, issued and outstanding shares: 23 at December 31, 2019 and December 31, 2018	—	—
Common stock—par value \$0.001; Authorized shares: 600,000,000 at December 31, 2019 and December 31, 2018, issued and outstanding: 101,361,034 at December 31, 2019 and 97,225,810 at December 31, 2018	101,361	97,226
Additional paid-in capital	742,646,785	707,794,215
Accumulated deficit	(739,785,655)	(620,426,436)
Accumulated other comprehensive income (loss)	472,608	(528,867)
Total INOVIO Pharmaceuticals, Inc. stockholders' equity	<u>3,435,099</u>	<u>86,936,138</u>
Non-controlling interest	1,969,759	96,269
Total stockholders' equity	<u>5,404,858</u>	<u>87,032,407</u>
Total liabilities and stockholders' equity	<u>\$ 143,951,597</u>	<u>\$ 131,113,265</u>

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

For the Year ended December 31,

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Revenues:			
Revenue under collaborative research and development arrangements	\$ 3,636,945	\$ 29,860,785	\$ 28,407,388
Revenue under collaborative research and development arrangements with affiliated entities	235,649	449,524	765,828
Grants and miscellaneous revenue	237,536	171,588	10,474,539

Grants and miscellaneous revenue from affiliated entity	1,800	—	2,572,331
Total revenues	<u>4,111,930</u>	<u>30,481,897</u>	<u>42,220,086</u>
Operating expenses:			
Research and development	88,017,319	95,257,876	98,572,618
General and administrative	27,203,156	29,315,159	28,290,369
Gain on sale of assets	—	—	(1,000,000)
Total operating expenses	<u>115,220,475</u>	<u>124,573,035</u>	<u>125,862,987</u>
Loss from operations	<u>(111,108,545)</u>	<u>(94,091,138)</u>	<u>(83,642,901)</u>
Other income (expense):			
Interest income	2,605,981	2,264,747	1,836,451
Interest expense	(7,948,539)	—	(25,933)
Change in fair value of common stock warrants	—	360,795	806,819
Change in fair value of derivative liability	(1,763,652)	—	—
Loss on investment in affiliated entities	(3,090,557)	(1,988,567)	(6,982,664)
Other income (expense), net	496,200	(1,343,856)	(197,544)
Net loss before income tax benefit/(provision for income tax)	<u>(120,809,112)</u>	<u>(94,798,019)</u>	<u>(88,205,772)</u>
Income tax benefit (provision for income taxes)	257,335	(2,169,811)	—
Net loss	<u>(120,551,777)</u>	<u>(96,967,830)</u>	<u>(88,205,772)</u>
Net loss attributable to non-controlling interest	1,192,558	—	—
Net loss attributable to INOVIO Pharmaceuticals, Inc.	<u>\$ (119,359,219)</u>	<u>\$ (96,967,830)</u>	<u>\$ (88,205,772)</u>
Net loss per share attributable to INOVIO Pharmaceuticals, Inc. stockholders			
Basic	\$ (1.21)	\$ (1.05)	\$ (1.08)
Diluted	<u>\$ (1.21)</u>	<u>\$ (1.05)</u>	<u>\$ (1.09)</u>
Weighted average number of common shares outstanding			
Basic	98,717,999	92,539,997	81,777,493
Diluted	<u>98,717,999</u>	<u>92,539,997</u>	<u>81,918,022</u>

## CONTACTS:

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