

Inovio Pharmaceuticals Reports 2019 Third Quarter Financial Results

11/12/2019

PLYMOUTH MEETING, Pa., Nov. 12, 2019 /PRNewswire/ -- Inovio Pharmaceuticals, Inc. (NASDAQ: INO), an innovative biotechnology company focused on the discovery, development, and commercialization of synthetic DNA products for treating cancers and infectious diseases, today reported financial results for the third quarter ended September 30, 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/MEDI0457/INO-3107/HPV-Related Diseases

REVEAL 1 Phase 3 trial of VGX-3100 for HPV-related high-grade cervical dysplasia, which completed enrollment of 198 patients in the second quarter of 2019, is on schedule to read out top-line efficacy data by the fourth quarter of 2020. Enrollment for the second Phase 3 trial for this program, REVEAL 2, remains on track, with expanded sites both within the United States and globally, including new sites recently opened in Argentina, Lithuania, and Spain.

Inovio completed enrollment of 33 patients for its Phase 2 trial of VGX-3100 for HPV-related high-grade vulvar dysplasia (vulvar HSIL).

In addition, the company completed enrollment in its open-label, 24 patient, Phase 2 trial of VGX-3100 in patients with HPV-related high-grade anal dysplasia (anal HSIL).

Inovio plans to present interim results for both vulvar HSIL and anal HSIL clinical trials at a medical conference in the first quarter of 2020.

In a global partnership with AstraZeneca, MEDI0457 (formerly INO-3112) in combination with durvalumab, an anti-PD-L1 checkpoint inhibitor, continues to be evaluated in multiple Phase 2 studies in patients with HPV-related head and neck, cervical, anal, penile, and vulvar cancers. Inovio is eligible to receive future milestone payments and double-digit tiered royalties on MEDI0457 product sales.

Inovio continues to prepare to initiate a pivotal clinical trial of INO-3107 for HPV-caused recurrent respiratory papillomatosis (RRP), which the company plans to advance as a rare, orphan product, within the first half of 2020.

- INO-5401/Glioblastoma Multiforme (GBM) Phase 2 Trial

Inovio reported positive interim data from its ongoing Phase 2 trial of newly diagnosed glioblastoma multiforme (GBM), which combines Inovio's INO-5401, a T cell-activating immunotherapy 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 (PFS6) 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). The data was presented at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting. Inovio will report 12- and 18-month overall survival data next year.

- **INO-5151/Prostate Cancer Combination Trial**

INO-5151 was featured in a trial-in-progress poster at SITC 2019. INO-5151, which is a combined formulation of INO-5150 (with SynCon® antigens encoding for PSA and PSMA) and INO-9012, is being tested in one arm (Cohort C) of this exploratory platform study along with nivolumab, a PD-1 inhibitor (Bristol-Myers Squibb), and CDX-301 (Celldex). This study is being conducted and funded by the Parker Institute for Cancer Immunotherapy (PICl) and the Cancer Research Institute (CRI), as part of Inovio's previously established clinical collaboration agreement ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03835533) Identifier: NCT03835533).

- **DNA-encoded monoclonal antibodies (dMAb®)/DNA-encoded Bi-specific T Cell Engagers (dBTE)**

Inovio and its collaborator, The Wistar Institute, received a \$4.6 million grant from the National Institutes of Health (NIH) in support of innovative research of antimicrobial resistance (AMR) and continued development of Inovio's DNA-encoded monoclonal antibodies (dMAb®) platform.

Using direct local delivery into the body by the CELLECTRA® platform, the synthetic genetic codes provided by the dMAbs instruct the body's cells to become a customized patient-specific factory that manufactures its own therapeutic antibody products, enabling a major leap in antibody technology. Traditional monoclonal antibodies represent the largest segment of pharmaceutical markets today, accounting for more than \$100 billion in pharmaceutical sales each year, with treatments spanning cancer, infectious diseases, inflammation, and cardiovascular diseases. With its synthetic design and in-patient production, dMAb products represent a disruptive and innovative entrant to this important class of pharmaceuticals. Collectively, dMAb and dBTE offer the opportunity to provide improved yet cost-effective therapeutic options across cancer and infectious diseases.

Earlier this year, Inovio advanced its first dMAb candidate INO-A002 (for preventing or treating Zika virus infection) to a Phase 1 dose-escalation trial to assess safety and tolerability and expression of dMAb-produced antibodies with full funding from the Bill & Melinda Gates Foundation.

- **Cash Position**

As of September 30, 2019, cash and cash equivalents and short-term investments were \$93.8 million compared to \$81.2 million as of December 31, 2018.

In August, Inovio closed a private placement of 1.0% convertible bonds due 2024 with an aggregate principal amount of 18 billion Korean Won (KRW) (approximately USD \$15.0 million based on the exchange rate on the date of issuance) issued to a group of institutional investors led by Korea Investment Partners (KIP), a global venture capital and private equity firm. These bonds are convertible into Inovio's Korean Depositary Receipts (KDRs) assuming Inovio has completed a secondary listing of its securities on the KOSDAQ Market of the Korea Exchange in the form of KDRs, or otherwise shares of common stock if KDRs are not listed at the time of conversion. Net proceeds from the offering were approximately \$14.5 million after deducting offering expenses payable by Inovio.

In July, Inovio implemented a strategic cost-reduction plan (including a 28% staff reduction and cessation of several R&D and clinical programs), which resulted in an approximately 25% reduction in annual burn. The reallocation of resources focuses the company's commercialization efforts for its lead asset, VGX-3100, while also developing high-value, fast-to-market product candidates, such as INO-3107 to treat RRP and INO-5401 for GBM.

Dr. J. Joseph Kim, Inovio's President & CEO, said, "Our recently presented INO-5401 data demonstrated promising efficacy results, in terms of progression-free survival rates, against a very difficult to treat cancer in GBM and highlighted the potential of our immunotherapies utilizing tumor-associated antigens in cancer treatments. Looking ahead, the next 12 months should be a transformational period for Inovio, as we expect to have data readouts from multiple Phase 3 and Phase 2 programs. With our sharpened focus on advancing and commercializing products for HPV-related diseases and fast-to-market opportunities, the company is uniquely positioned to bring multiple products to the market."

Dr. Kim further stated, "We continue to advance our HPV treatment capabilities, where we will have efficacy results from our Phase 3 VGX-3100 REVEAL 1 trial and Phase 2 VIN/AIN programs next year. Additionally, we plan to initiate a pivotal clinical trial of INO-3107 for HPV-caused RRP, which we expect to move forward rapidly as a rare, orphan product. In cancer, you can expect overall survival data from our INO-5401 cancer combination trial with Regeneron for GBM, building upon the promising PFS6 data. Finally, the fully enrolled head and neck cancer Phase 2 trial sponsored by our partner AstraZeneca, combining MEDI0457 with AstraZeneca's checkpoint inhibitor should be completed by the third quarter. Collectively, these anticipated data readouts in 2020 all point to great promise for Inovio's product pipeline, and further solidify Inovio as the leader in synthetic DNA immunotherapy."

Third Quarter 2019 Financial Results

Inovio's total revenue was \$867,000 for the three months ended September 30, 2019, compared to \$2.0 million for the same period in 2018. Inovio's total operating expenses were \$24.8 million for the three months ended September 30, 2019, compared to \$28.6 million for the same period in 2018.

Inovio's net loss for the quarter ended September 30, 2019 was \$23.1 million, or \$0.23 per basic and \$0.25 per diluted share, compared to \$25.0 million, or \$0.27 per basic and diluted share, for the same period in 2018.

Revenue

The year-over-year decrease in revenue under collaborative research and development arrangements was primarily due to a decrease in reimbursed drug manufacturing activities related to our partnership with AstraZeneca.

Operating Expenses

R&D expenses were \$19.1 million for the three months ended September 30, 2019, as compared to \$21.9 million for the same period in 2018. The decrease in R&D expenses was primarily related to decreases in employee compensation expense, drug manufacturing expense related to our partnership with AstraZeneca and engineering and lab supplies, among other variances. These decreases were offset by a personnel-related restructuring charge in connection with the one-time employee termination costs incurred during the third quarter of 2019.

Contributions received from current grant agreements and recorded as contra-R&D expense were \$2.8 million for the three months ended September 30, 2019, compared to \$2.6 million for the same period in 2018.

General and administrative (G&A) expenses were \$5.7 million for the three months ended September 30, 2019, versus \$6.8 million for the same period in 2018. The decrease in G&A expenses was primarily related to decreases in employee compensation, allocated depreciation expense, and legal expenses, among other variances.

Capital Resources

As of September 30, 2019, cash and cash equivalents and short-term investments were \$93.8 million compared to \$81.2 million as of December 31, 2018. As of September 30, 2019, Inovio had 99.0 million common shares outstanding and 129.5 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 condensed consolidated 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, 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 10136605.

About Inovio Pharmaceuticals, Inc.

Inovio is an innovative biotechnology company focused on the discovery, development, and commercialization of its synthetic DNA technology targeted against cancers and infectious diseases. Inovio's proprietary technology platform applies antigen sequencing and delivery to enable in vivo protein expression, which can activate potent immune responses to targeted diseases. The technology has 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 and GBM, as well as

externally funded platform development programs in Zika, MERS, Lassa, and HIV. Partners and collaborators include 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, Regeneron, Roche/Genentech, University of Pennsylvania, Walter Reed Army Institute of Research, and The Wistar Institute. For more information, visit 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-based immunotherapies, 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 and product development programs, 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 vaccines, our ability to support our pipeline of SynCon® active immunotherapy and vaccine 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, 2018, our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Inovio Pharmaceuticals, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS

September 30,
2019

December 31,
2018

(Unaudited)

ASSETS

Current assets:

Cash and cash equivalents	\$ 15,853,236	\$ 23,693,633
Short-term investments	77,945,753	57,538,852
Accounts receivable	776,295	3,316,361
Accounts receivable from affiliated entities	978,544	738,583
Prepaid expenses and other current assets	1,677,602	1,406,590
Prepaid expenses and other current assets from affiliated entities	1,581,111	1,120,805
Total current assets	98,812,541	87,814,824
Fixed assets, net	13,516,389	15,949,014
Investment in affiliated entity - GeneOne	5,707,256	6,381,926
Investment in affiliated entity - PLS	2,289,501	3,023,987
Intangible assets, net	3,960,457	4,760,145
Goodwill	10,513,371	10,513,371
Operating lease right-of-use assets	14,002,860	—
Other assets	2,731,055	2,669,998
Total assets	\$ 151,533,430	\$ 131,113,265

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable and accrued expenses	\$ 9,783,964	\$ 23,134,733
Accounts payable and accrued expenses due to affiliated entities	462,596	977,792
Accrued clinical trial expenses	4,500,898	5,671,764
Deferred revenue	106,111	223,577
Deferred revenue from affiliated entities	64,825	33,575
Deferred rent	—	1,065,387
Operating lease liability	2,011,008	—
Deferred grant funding	1,896,526	4,165,848
Deferred grant funding from affiliated entities	720,925	27,083
Total current liabilities	19,546,853	35,299,759
Deferred revenue, net of current portion	124,105	150,793
Convertible senior notes	62,119,671	—
Convertible bonds	7,954,851	—
Derivative liability	4,503,918	—
Deferred rent, net of current portion	—	8,518,207
Operating lease liability, net of current portion	20,953,308	—

Deferred tax liabilities	26,649	24,766
Deferred grant funding from affiliated entities	135,000	—
Other liabilities	50,343	87,333
Total liabilities	<u>115,414,698</u>	<u>44,080,858</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	99,046	97,226
Additional paid-in capital	735,017,743	707,794,215
Accumulated deficit	(702,123,617)	(620,426,436)
Accumulated other comprehensive income (loss)	700,398	(528,867)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	<u>33,693,570</u>	<u>86,936,138</u>
Non-controlling interest	2,425,162	96,269
Total stockholders' equity	<u>36,118,732</u>	<u>87,032,407</u>
Total liabilities and stockholders' equity	<u>\$ 151,533,430</u>	<u>\$ 131,113,265</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Revenue under collaborative research and development arrangements	\$ 617,427	\$ 1,813,287	\$ 3,452,422	\$ 27,488,185
Revenue under collaborative research and development arrangements with affiliated entities	53,014	184,990	179,984	393,317
Miscellaneous revenue	196,422	2,591	200,036	97,771
Total revenues	<u>866,863</u>	<u>2,000,868</u>	<u>3,832,442</u>	<u>27,979,273</u>
Operating expenses:				
Research and development	19,137,209	21,851,858	66,013,364	68,892,229
General and administrative	5,681,441	6,791,693	18,506,570	23,679,018
Total operating expenses	<u>24,818,650</u>	<u>28,643,551</u>	<u>84,519,934</u>	<u>92,571,247</u>
Loss from operations	<u>(23,951,787)</u>	<u>(26,642,683)</u>	<u>(80,687,492)</u>	<u>(64,591,974)</u>
Other income (expense):				

Interest income	637,438	565,039	2,018,302	1,648,987
Interest expense	(2,428,671)	—	(5,279,702)	—
Change in fair value of common stock warrants	—	228,665	—	360,795
Change in fair value of derivative liability	2,551,453	—	2,551,453	—
Gain (loss) on investment in affiliated entities	(485,841)	1,017,359	(1,409,156)	1,305,174
Other income (expense), net	140,956	(184,052)	232,629	(558,796)
Net loss before income tax benefit/(provision for income tax)	(23,536,452)	(25,015,672)	(82,573,966)	(61,835,814)
Income tax benefit/(provision for income taxes)	—	—	169,571	(2,169,811)
Net loss	(23,536,452)	(25,015,672)	(82,404,395)	(64,005,625)
Net loss attributable to non-controlling interest	445,759	—	707,214	—
Net loss attributable to Inovio Pharmaceuticals, Inc.	\$ (23,090,693)	\$ (25,015,672)	\$ (81,697,181)	\$ (64,005,625)
Net loss per share attributable to Inovio Pharmaceuticals, Inc. stockholders				
Basic	\$ (0.23)	\$ (0.27)	\$ (0.83)	\$ (0.70)
Diluted	\$ (0.25)	\$ (0.27)	\$ (0.83)	\$ (0.70)
Weighted average number of common shares outstanding				
Basic	99,007,985	92,423,122	98,204,375	91,350,117
Diluted	102,807,056	92,423,122	98,204,375	91,350,117

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