

# Inovio Pharmaceuticals Reports 2019 Second Quarter Financial Results

8/8/2019

PLYMOUTH MEETING, Pa., Aug. 8, 2019 /PRNewswire/ -- Inovio Pharmaceuticals, Inc. (NASDAQ: INO), an innovative biotechnology company focused on the discovery, development and commercialization of synthetic DNA technology targeted against cancers and infectious diseases, today reported financial results for the second quarter ended June 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/HPV-Related Diseases

Inovio completed enrollment of 198 participants for its primary Phase 3 registration trial (REVEAL 1) of VGX-3100 for the treatment of high-grade cervical dysplasia (cervical HSIL) caused by human papillomavirus (HPV). Inovio is currently enrolling its confirmatory Phase 3 trial (REVEAL 2).

VGX-3100 was granted an Advanced Therapy Medicinal Product Certificate for quality and non-clinical data by the European Medicines Agency (EMA), which confirms that Inovio's chemistry, manufacturing and controls (CMC) data and nonclinical results available to date overall comply with the scientific and technical standards for evaluating an EU Marketing Authorization.

Inovio and QIAGEN announced a collaboration to co-develop a liquid biopsy-based companion diagnostic to identify patients who could benefit from VGX-3100.

Inovio completed enrollment for its Phase 2 trial of VGX-3100 for the treatment of high-grade vulvar dysplasia (vulvar HSIL) in July. Inovio intends to report interim clinical data from this study, along with interim results from the Phase 2 study for high-grade anal dysplasia (anal HSIL), before the year end.

In July, Inovio executed a strategic refinement to focus on the commercial development of its late-stage HPV assets, which includes VGX-3100, and reallocate capital to develop fast-to-market product candidates, such as INO-3107 (previously called INO-3106) to treat RRP (recurrent respiratory papillomatosis). RRP is a rare, orphan disease caused by HPV 6 and 11 infections, for which clinical benefit was recently demonstrated in a

pilot study. Inovio plans to initiate the next clinical trial of INO-3107 within the next 12 months.

- **Cancer Combination Trials**

Inovio received a third Phase 2 milestone payment from AstraZeneca for MEDI0457 in combination with durvalumab for dosing patients in the third HPV-related cancer indication; two previous milestone payments resulted from initiating Phase 2 combination trials targeting head and neck and cervical cancers.

AstraZeneca continues to expand and evaluate MEDI0457 in three different Phase 2 trials that target HPV caused cancers. Subsequent to the quarter, AstraZeneca completed planned enrollment of its Phase 2 study in head and neck cancer ([ClinicalTrials.gov Identifier: NCT03162224](https://clinicaltrials.gov/ct2/show/study/NCT03162224)).

Inovio completed enrollment of its Phase 1/2 immuno-oncology trial in 52 patients with newly diagnosed glioblastoma three months ahead of schedule. Interim results evaluating safety, immunological impact, progression-free survival and overall survival from this study are expected by the end of 2019.

As part of the strategic organizational restructuring announcement in July, Inovio discontinued its Phase 1/2 clinical trial of INO-5401 in patients with advanced bladder cancer. The decision to discontinue the trial was made because of the recognition that several new therapeutic alternatives have been approved, or are likely to be approved, for study patients since the trial's design and inception, and because of the high expense of the trial.

INO-5151, Inovio's prostate cancer immunotherapy, will be combined with an immune modulator (CDX-301, FLT3 ligand, a dendritic cell mobilizer) and a PD-1 checkpoint inhibitor (nivolumab) targeting metastatic castration-resistant prostate cancer in a Parker Institute for Cancer Immunotherapy (PICI) sponsored platform study. As part of Inovio's clinical collaboration agreement with PICI and in collaboration with the Cancer Research Institute, INO-5151 is one arm (Cohort C) of this broad PICI-supported study which is a multi-arm, multi-stage platform design (PORTER Study: [ClinicalTrials.gov Identifier: NCT03835533](https://clinicaltrials.gov/ct2/show/study/NCT03835533)).

- **DNA-encoded Bi-specific T Cell Engagers (dBTEs)**

Preclinical data results for Inovio's transformative dBTE technology were published in JCI Insight. The current bi-specific T cell engager product has only a few hours of half-life and requires several weeks of continuous intravenous infusion. Inovio developed a novel dBTE targeting the HER2 molecule which was tested successfully in therapeutic models for the treatment of ovarian and breast cancers. A single injection of the HER2 dBTE candidate produced bi-specific antibodies that lasted for several weeks and effectively killed HER2-expressing tumor cells resulting in a near-complete tumor clearance. Inovio plans to rapidly advance its dBTE technology.

- **Infectious Diseases**

Inovio dosed its first patients in its Phase 1 clinical study evaluating safety, tolerability and immune responses to INO-4500 in patients with Lassa fever. INO-4500 is the world's first Lassa fever virus vaccine candidate. The INO-4500 program is fully funded through a global partnership with the Coalition for

Epidemic Preparedness Innovations (CEPI).

In July, positive clinical trial results from the world's first clinical testing of a vaccine against the Middle East Respiratory Syndrome Coronavirus (MERS) were published in *The Lancet Infectious Diseases*. Inovio's MERS DNA vaccine INO-4700 was well-tolerated and 94% of patients demonstrated overall high levels of antibody responses, while 88% of study participants demonstrated broad-based T cell responses. A Phase 2 field trial is being planned in the Middle East through the partnership with CEPI.

- Cash Position

As of June 30, 2019, cash and cash equivalents and short-term investments were \$106.0 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.

Dr. J. Joseph Kim, Inovio's President & CEO said, "Inovio is well-positioned to advance its later-stage HPV programs while devoting more resources to develop fast-to-market product candidates. Through its recent strategic organizational restructuring the company has sharpened its focus to create a more efficient organization with greater financial flexibility and a longer runway. We continue to make excellent progress on expanding our treatment capabilities within the areas of HPV related diseases and we're excited that before year-end we plan to have interim data from our Phase 2 studies involving VGX-3100 targeting vulvar HSIL and anal HSIL, and plan to initiate the next clinical trial of INO-3107 targeting RRP within 12 months."

## Second Quarter 2019 Financial Results

Total revenue was \$136,000 for the three months ended June 30, 2019, compared to \$24.4 million for the same period in 2018. Total operating expenses were \$28.3 million for the three months ended June 30, 2019, compared to \$29.7 million for the same period in 2018.

Inovio's net loss for the quarter ended June 30, 2019 was \$29.4 million, or \$0.30 per basic and diluted share, compared to \$6.6 million, or \$0.07 per basic and \$0.08 per diluted share, for the quarter ended June 30, 2018.

## Revenue

The year over year decrease in revenue under collaborative research and development arrangements was primarily due to the recognition of the gross up-front payment from ApolloBio of \$23.0 million during the second quarter of

2018 (approximately \$19.4 million was received after payment of required taxes).

## Operating Expenses

Research and development (R&D) expenses were \$22.5 million for the three months ended June 30, 2019 and June 30, 2018.

Contributions received from current grant agreements and recorded as contra-research and development expense were \$2.6 million for the three months ended June 30, 2019 compared to \$1.9 million for the same period in 2018.

General and administrative (G&A) expenses were \$5.9 million for the three months ended June 30, 2019 versus \$7.2 million for the same period in 2018. The decrease in G&A expenses was primarily related to the foreign non-income taxes and advisory fees incurred in connection with the ApolloBio upfront payment Inovio received in 2018.

## Capital Resources

As of June 30, 2019, cash and cash equivalents and short-term investments were \$106.0 million compared to \$81.2 million as of December 31, 2018. As of June 30, 2019, Inovio had 98.6 million common shares outstanding and 125.5 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 notes.

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 June 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 10133668.

## 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 glioblastoma, as well as externally funded platform development programs in Zika, MERS, Lassa and HIV. Partners and collaborators include AstraZeneca, Regeneron, Roche/Genentech, ApolloBio Corporation, GeneOne Life Science, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Defense Advanced Research Projects Agency, National Institutes of Health, National Institute of Allergy and Infectious Diseases, National Cancer Institute, HIV Vaccines Trial Network, Walter Reed Army Institute of Research, Medical CBRN Defense Consortium (MCDC), The Wistar Institute, and the University of Pennsylvania. For more information, visit [www.inovio.com](http://www.inovio.com).

This press release contains certain forward-looking statements relating to our business, including our expectations related to our strategic organizational restructuring, our plans to develop electroporation-based drug and gene delivery technologies, dBTE platforms and DNA vaccines, 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 and the expectation that VGX-3100's Advanced Therapy Medicinal Product certificate will facilitate the preparation, filing, and review of a future European market application. 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 June 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

	June 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,735,943	\$ 23,693,633
Short-term investments	86,235,815	57,538,852
Accounts receivable	130,230	3,316,361
Accounts receivable from affiliated entities	996,936	738,583
Prepaid expenses and other current assets	2,309,362	1,406,590
Prepaid expenses and other current assets from affiliated entities	1,100,746	1,120,805
Total current assets	<u>110,509,032</u>	<u>87,814,824</u>
Fixed assets, net	14,265,951	15,949,014
Investment in affiliated entity - GeneOne	6,324,766	6,381,926
Investment in affiliated entity - PLS	2,157,832	3,023,987
Intangible assets, net	4,227,019	4,760,145
Goodwill	10,513,371	10,513,371
Operating lease right-of-use assets	14,222,236	—
Other assets	2,853,089	2,669,998
Total assets	<u>\$ 165,073,296</u>	<u>\$ 131,113,265</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 13,388,013	\$ 23,134,733
Accounts payable and accrued expenses due to affiliated entities	653,568	977,792
Accrued clinical trial expenses	4,638,397	5,671,764
Deferred revenue	120,694	223,577
Deferred revenue from affiliated entities	96,075	33,575
Deferred rent	—	1,065,387

Operating lease liability	1,948,716	—
Deferred grant funding	2,470,657	4,165,848
Deferred grant funding from affiliated entities	763,208	27,083
Total current liabilities	<u>24,079,328</u>	<u>35,299,759</u>
Deferred revenue, net of current portion	116,630	150,793
Convertible senior notes	62,757,286	—
Deferred rent, net of current portion	—	8,518,207
Operating lease liability, net of current portion	21,483,568	—
Deferred tax liabilities	26,649	24,766
Deferred grant funding from affiliated entities	81,000	—
Other liabilities	50,762	87,333
Total liabilities	<u>108,595,223</u>	<u>44,080,858</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	98,584	97,226
Additional paid-in capital	731,819,389	707,794,215
Accumulated deficit	(679,032,924)	(620,426,436)
Accumulated other comprehensive income (loss)	731,855	(528,867)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	<u>53,616,904</u>	<u>86,936,138</u>
Non-controlling interest	2,861,169	96,269
Total stockholders' equity	<u>56,478,073</u>	<u>87,032,407</u>
Total liabilities and stockholders' equity	<u>\$ 165,073,296</u>	<u>\$ 131,113,265</u>

Inovio Pharmaceuticals, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

Three Months Ended June 30,

Six Months Ended June 30,

	2019	2018	2019	2018
Revenues:				
Revenue under collaborative research and development arrangements	\$ 64,283	\$ 24,385,852	\$ 2,834,995	\$ 25,674,898
Revenue under collaborative research and development arrangements with affiliated entities	71,390	60,319	126,970	208,327
Miscellaneous revenue	—	2,590	3,614	95,180
Total revenues	135,673	24,448,761	2,965,579	25,978,405
Operating expenses:				
Research and development	22,486,266	22,462,620	46,876,155	47,040,371
General and administrative	5,850,101	7,189,310	12,825,129	16,887,325
Total operating expenses	28,336,367	29,651,930	59,701,284	63,927,696
Loss from operations	(28,200,694)	(5,203,169)	(56,735,705)	(37,949,291)
Other income (expense):				
Interest income	755,330	518,525	1,380,864	1,083,948
Interest expense	(2,194,783)	—	(2,851,031)	—
Change in fair value of common stock warrants	—	259,971	—	132,130
Gain (loss) on investment in affiliated entities	(173,212)	(2,092,608)	(923,315)	287,815
Other income (expense), net	127,512	(121,844)	91,673	(374,744)
Net loss before income tax benefit/(provision for income tax)	(29,685,847)	(6,639,125)	(59,037,514)	(36,820,142)
Income tax benefit/(provision for income taxes)	106,771	—	169,571	(2,169,811)
Net loss	(29,579,076)	(6,639,125)	(58,867,943)	(38,989,953)
Net loss attributable to non-controlling interest	191,850	—	261,455	—
Net loss attributable to Inovio Pharmaceuticals, Inc.	\$ (29,387,226)	\$ (6,639,125)	\$ (58,606,488)	\$ (38,989,953)
Net loss per share attributable to Inovio Pharmaceuticals, Inc. stockholders				
Basic	\$ (0.30)	\$ (0.07)	\$ (0.60)	\$ (0.43)
Diluted	\$ (0.30)	\$ (0.08)	\$ (0.60)	\$ (0.43)
Weighted average number of common shares outstanding				
Basic	98,083,896	91,153,776	97,795,910	90,804,722
Diluted	98,083,896	91,241,660	97,795,910	90,890,792

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