INOVIO PHARMACEUTICALS, INC.
Form 10-Q
August 08, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

OR

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 001-14888

INOVIO PHARMACEUTICALS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	33-0969592
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

660 W. GERMANTOWN PIKE, SUITE 110
PLYMOUTH MEETING, PA 19462

(Address of principal executive offices) (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (267) 440-4200

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

COMMON STOCK, $0.001 PAR VALUE	NASDAQ
(Title of Class)	(Name of Each Exchange on Which Registered)

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The number of shares outstanding of the Registrant's Common Stock, $0.001 par value, was 90,227,174 as of August 4, 2017.

INOVIO PHARMACEUTICALS, INC.
FORM 10-Q

For the Quarterly Period Ended June 30, 2017

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Part I. Financial Information

Item 1. Financial Statements

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$23,860,637	$19,136,472
Short-term investments	68,138,619	85,629,412
Accounts receivable	7,522,548	15,821,511
Accounts receivable from affiliated entity	1,189,300	748,355
Prepaid expenses and other current assets	4,914,764	1,749,059
Prepaid expenses and other current assets from affiliated entity	1,251,730	1,512,424
Total current assets	106,877,598	124,597,233
Fixed assets, net	15,017,992	9,025,446
Investment in affiliated entity - GeneOne	14,612,344	16,052,065
Investment in affiliated entity - PLS	3,339,802	3,777,510
Intangible assets, net	6,817,855	7,628,394
Goodwill	10,513,371	10,513,371
Other assets	1,674,251	2,113,147
Total assets	$158,853,213	$173,707,166
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$16,477,761	$19,597,787
Accounts payable and accrued expenses due to affiliated entity	847,421	1,072,579
Accrued clinical trial expenses	7,188,751	6,368,389
Common stock warrants	1,363,637	1,167,614
Deferred revenue	548,690	14,762,720
Deferred revenue from affiliated entity	274,194	407,292
Deferred rent	681,544	446,646
Total current liabilities	27,381,998	43,823,027
Deferred revenue, net of current portion	205,938	317,808
Deferred revenue from affiliated entity, net of current portion	—	86,694
Deferred rent, net of current portion	7,560,867	5,926,424
Deferred tax liabilities	174,793	174,793
Total liabilities	35,323,596	50,328,746
Inovio Pharmaceuticals, Inc. stockholders' equity:		
Preferred stock	—	—
Common stock	77,634	74,062
Additional paid-in capital	589,890,620	556,718,356
Accumulated deficit	(467,715,568)	(434,838,235)
Accumulated other comprehensive income	1,180,662	1,327,968
Total Inovio Pharmaceuticals, Inc. stockholders' equity	123,433,348	123,282,151
Non-controlling interest	96,269	96,269
Total stockholders' equity	123,529,617	123,378,420
Total liabilities and stockholders' equity	$158,853,213	$173,707,166

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Revenue under collaborative research and development arrangements	$16,358,316	$1,889,988	$20,646,902	$3,686,845
Revenue under collaborative research and development arrangements with affiliated entity	176,879	499,720	410,209	636,720
Grants and miscellaneous revenue	2,797,647	3,814,083	8,037,880	9,990,381
Grants and miscellaneous revenue from affiliated entity	1,079,282	—	1,693,318	—
Total revenues	20,412,124	6,203,791	30,788,309	14,313,946
Operating expenses:				
Research and development	23,878,751	19,630,801	48,421,255	37,819,961
General and administrative	6,169,106	5,799,530	13,936,695	11,171,143
Gain on sale of assets	—	(1,000,000)	—	(1,000,000)
Total operating expenses	30,047,857	24,430,331	62,357,950	47,991,104
Loss from operations	(9,635,733)	(18,226,540)	(31,569,641)	(33,677,158)
Other income (expense):				
Interest and other income, net	300,021	341,131	640,362	674,201
Change in fair value of common stock warrants, net	(312,500)	(113,775)	(196,023)	(520,024)
Gain (loss) on investment in affiliated entity	169,096	(705,527)	(1,439,721)	6,775,450
Net loss attributable to Inovio Pharmaceuticals, Inc.	$(9,479,116)	$(18,704,711)	$(32,565,023)	$(26,747,531)
Loss per common share—basic and diluted:				
Net loss per share attributable to Inovio Pharmaceuticals, Inc. stockholders	$(0.13)	$(0.26)	$(0.44)	$(0.37)
Weighted average number of common shares outstanding—basic and diluted	75,409,702	72,957,159	74,783,791	72,591,986

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$(9,479,116)	$(18,704,711)	$(32,565,023)	$(26,747,531)
Other comprehensive income (loss):				
Unrealized gain (loss) on investment in affiliated entity	312,253	282,572	(437,708)	263,575
Unrealized gain on short-term investments	86,862	322,767	290,402	542,448
Comprehensive loss attributable to Inovio Pharmaceuticals, Inc.	$(9,080,001)	$(18,099,372)	$(32,712,329)	$(25,941,508)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(32,565,023)	$(26,747,531)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,020,679	827,327
Amortization of intangible assets	810,539	556,554
Change in value of common stock warrants	196,023	520,025
Stock-based compensation	7,937,473	5,251,166
Amortization of premiums on investments	140,599	139,659
Loss on short-term investments	67,366	—
Deferred rent	1,869,341	(31,783)
Loss (gain) on investment in affiliated entity	1,439,721	(6,775,450)
Gain on sale of intangible assets	—	(1,000,000)
Changes in operating assets and liabilities:		
Accounts receivable	8,298,963	(3,032,891)
Accounts receivable from affiliated entity	(440,945)	—
Prepaid expenses and other current assets	(3,165,705)	(270,785)
Prepaid expenses and other current assets from affiliated entity	260,694	(1,271,605)
Other assets	438,896	(655,334)
Accounts payable and accrued expenses	(4,305,114)	(247,009)
Accrued clinical trial expenses	820,362	2,405,804
Accounts payable and accrued expenses due to affiliated entity	(225,158)	435,922
Deferred revenue	(14,325,900)	1,323,827
Deferred revenue from affiliated entity	(219,792)	(437,827)
Net cash used in operating activities	(31,946,981)	(29,009,931)
Cash flows from investing activities:		
Purchases of investments	(14,600,112)	(27,985,410)
Maturities of investments	32,173,342	27,662,695
Purchases of capital assets	(5,828,137)	(2,196,896)
Proceeds from sale of intangible assets	—	1,000,000
Purchase of intangible assets and other assets	—	(1,200,000)
Net cash provided by (used in) investing activities	11,745,093	(2,719,611)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	24,060,196	1,301,435
Proceeds from stock option and warrant exercises, net of tax payments	865,857	1,395,346
Expenses from other financing activities	—	(149,559)
Net cash provided by financing activities	24,926,053	2,547,222
Increase (decrease) in cash and cash equivalents	4,724,165	(29,182,320)
Cash and cash equivalents, beginning of period	19,136,472	57,632,693
Cash and cash equivalents, end of period	$23,860,637	$28,450,373
Supplemental disclosure of non-cash activities		
Common stock issued for purchase of intangible and other assets of Bioject	$—	$4,300,000
Change in amounts accrued for purchases of property and equipment	$1,185,087	$(110,136)
Lease incentive recorded as fixed assets and deferred rent	$—	$134,500

See accompanying notes to unaudited condensed consolidated financial statements.

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INOVIO PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Operations

Inovio Pharmaceuticals, Inc. (the “Company” or “Inovio”), a clinical stage biopharmaceutical company, develops active DNA immunotherapies and vaccines focused on preventing and treating cancers and infectious diseases. Inovio’s DNA-based immunotherapies, in combination with proprietary electroporation delivery devices are intended to generate robust immune responses, in particular T cells, to fight target diseases. Inovio’s synthetic products are based on its SynCon® immunotherapy design. The Company and its collaborators are currently conducting or planning clinical programs of its proprietary SynCon® immunotherapies for HPV-caused pre-cancers and cancers, influenza, prostate cancer, breast/lung/pancreatic cancer, hepatitis C virus ("HCV"), hepatitis B virus ("HBV"), HIV, Ebola, Middle East Respiratory Syndrome ("MERS") and Zika virus. The Company's partners and collaborators include MedImmune, LLC, The Wistar Institute, University of Pennsylvania, GeneOne Life Science Inc. ("GeneOne"), Regeneron Pharmaceuticals, Inc., Genentech, Inc., Plumbline Life Sciences, Inc., Drexel University, National Microbiology Laboratory of the Public Health Agency of Canada, National Institute of Allergy and Infectious Diseases (“NIAID”), United States Military HIV Research Program (“USMHRP”), U.S. Army Medical Research Institute of Infectious Diseases (“USAMRIID”), HIV Vaccines Trial Network (“HVTN”), and Defense Advanced Research Projects Agency (“DARPA”). Inovio was incorporated in Delaware in June 2001 and has its principal executive offices in Plymouth Meeting, Pennsylvania.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Inovio have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) as contained in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of June 30, 2017 and the condensed consolidated statements of operations, condensed consolidated statements of comprehensive loss and the condensed consolidated statements of cash flows for the three and six months ended June 30, 2017 and 2016, are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three and six months ended June 30, 2017 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2017, or for any other period. These unaudited financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2016, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 15, 2017. The balance sheet at December 31, 2016 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The Company has evaluated subsequent events after the balance sheet date of June 30, 2017 through the date it filed these unaudited condensed consolidated financial statements with the SEC.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

3. Critical Accounting Policies

Revenue Recognition.

The Company recognizes revenues when all four of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

Grant revenue

The Company receives non-refundable grants under available government programs. Government grants towards current expenditures are recorded as revenue when there is reasonable assurance that the Company has complied with all conditions necessary to receive the grants, collectability is reasonably assured, and as the expenditures are incurred.
License fee and milestone revenue

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The Company has adopted a strategy of co-developing or licensing its gene delivery technology for specific genes or specific medical indications. Accordingly, the Company has entered into collaborative research and development agreements and has received third-party funding for pre-clinical research and clinical trials. Agreements that contain multiple elements are analyzed to determine whether the deliverables within the agreement can be separated or whether they must be accounted for as a single unit of accounting in accordance with the FASB's Accounting Standards Update (“ASU”) No. 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The delivered item(s) were considered a separate unit of accounting if all of the following criteria were met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. If these criteria were not met, the deliverable was combined with other deliverables in the arrangement and accounted for as a combined unit of accounting.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (“VSOE”) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the price to the collaborator is fixed or determinable, and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The Company applies ASU No. 2010-17, Revenue Recognition (Topic 605): Milestone Method of Revenue Recognition (“Milestone Method”). Under the Milestone Method, the Company will recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone,
2. The consideration relates solely to past performance, and
3. The consideration is reasonable r