IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 06, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017

or

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

For transition period from to .

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	04-3072298
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
167 Sidney Street	
Cambridge, Massachusetts	02139
(Address of principal executive offices)	(Zip code)

(617) 679-5500

(Registrant's telephone number, including area code)

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 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the 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
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.

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

Common Stock, par value $.001 per share	194,870,303
Class	Outstanding as of November 1, 2017

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “pr “will,” and “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the Securities and Exchange Commission, or the SEC, on March 15, 2017. These factors and the other cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements whenever they appear in this Quarterly Report on Form 10-Q. In addition, any forward-looking statements represent our estimates only as of the date that this Quarterly Report on Form 10-Q is filed with the SEC, and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except per share amounts)	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,941	$ 80,667
Short-term investments	1,400	28,347
Prepaid expenses and other current assets	3,669	2,030
Total current assets	69,010	111,044
Property and equipment, net	1,412	1,853
Restricted cash and other assets	327	334
Total assets	$ 70,749	$ 113,231
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 849	$ 556
Accrued expenses	6,119	7,394
Current portion of note payable	285	292
Current portion of deferred revenue	563	1,111
Total current liabilities	7,816	9,353
Deferred revenue, net of current portion	94	152
Note payable, net of current portion	—	209
Other liabilities	759	168
Total liabilities	8,669	9,882
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, $0.001 par value, Authorized — 280,000 shares; Issued and outstanding — 149,680 and 149,065 shares at September 30, 2017 and	150	149

December 31, 2016, respectively		
Additional paid-in capital	651,498	641,687
Accumulated deficit	(589,568)	(538,470)
Accumulated other comprehensive loss	—	(17)
Total stockholders' equity	62,080	103,349
Total liabilities and stockholders' equity	$ 70,749	$ 113,231

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	2017	2016	2017	2016
Alliance revenue	$ 164	$ 323	$ 729	$ 918
Operating expenses:				
Research and development	10,912	9,393	40,288	28,817
General and administrative	3,919	3,907	11,888	11,601
Total operating expenses	14,831	13,300	52,176	40,418
Loss from operations	(14,667)	(12,977)	(51,447)	(39,500)
Other income (expense):				
Interest income	159	90	456	320
Interest expense	(11)	(19)	(40)	(63)
Foreign currency exchange (loss) gain	(11)	3	(27)	32
Net loss	$ (14,530)	$ (12,903)	$ (51,058)	$ (39,211)
Basic and diluted net loss per common share (Note 14)	$ (0.10)	$ (0.10)	$ (0.34)	$ (0.32)
Shares used in computing basic and diluted net loss per common share	149,638	121,389	149,385	121,332
Net loss	$ (14,530)	$ (12,903)	$ (51,058)	$ (39,211)
Other comprehensive gain (loss):				
Unrealized (loss) gain on available-for-sale securities	(1)	13	17	133
Comprehensive loss	$ (14,531)	$ (12,890)	$ (51,041)	$ (39,078)

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)	Nine Months Ended September 30, 2017	2016
Cash Flows from Operating Activities:		
Net loss	$ (51,058)	$ (39,211)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,165	5,127
Issuance of common stock for services rendered	119	129
Accretion of discounts and premiums on investments	94	466
Depreciation and amortization expense	559	484
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,639)	(48)
Accounts payable, accrued expenses, and other liabilities	(393)	937
Deferred revenue	(606)	(833)
Net cash used in operating activities	(43,759)	(32,949)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	—	(2,946)
Proceeds from maturity of available-for-sale securities	26,870	29,946
Proceeds from sale of available-for-sale securities	—	1,974
Purchases of property and equipment	(100)	(369)
Net cash provided by investing activities	26,770	28,605
Cash Flows from Financing Activities:		
Proceeds from exercise of common stock warrants and options and employee stock purchases	488	111
Payments on note payable	(216)	(193)
Payments on capital lease	(9)	(6)
Net cash provided by (used in) financing activities	263	(88)
Net decrease in cash and cash equivalents	(16,726)	(4,432)
Cash and cash equivalents, beginning of period	80,667	26,586
Cash and cash equivalents, end of period	$ 63,941	$ 22,154

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2017

(UNAUDITED)

(1) Organization

Business Overview

Idera Pharmaceuticals, Inc. (“Idera” or the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel oligonucleotide therapeutics for oncology and rare diseases. The Company uses two distinct proprietary drug discovery technology platforms to design and develop drug candidates: its Toll-like receptor (“TLR”) targeting technology and its third-generation antisense (“3GA”) technology. The Company developed these platforms based on its scientific expertise and pioneering work with synthetic oligonucleotides as therapeutic agents. Using its TLR targeting technology, the Company designs synthetic oligonucleotide-based drug candidates to modulate the activity of specific TLRs. In addition, using its 3GA technology, the Company is developing drug candidates to turn off the messenger RNA (“mRNA”) associated with disease causing genes. The Company believes its 3GA technology may potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference (“RNAi”) technologies.

Idera is focused on the clinical development of drug candidates for oncology and rare diseases characterized by small, well-defined patient populations with serious unmet medical needs. The Company believes it can develop and commercialize these targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

The Company’s pipeline of drug candidates includes IMO-2125, IMO-8400 and IDRA-008.

Toll-Like Receptors

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, the Company believes TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using its chemistry-based platform, the Company has designed TLR agonists and antagonists to act by modulating the activity of targeted TLRs. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that inhibits an immune response by blocking the targeted TLR.

The Company's TLR agonist lead drug candidate IMO-2125 is an agonist of TLR9. The Company is developing IMO-2125 for the treatment by intra-tumoral injection of multiple oncology indications both in combination with checkpoint inhibitors and as monotherapy. The Company is currently developing IMO-2125 for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma and for administration as a single agent intra-tumorally in multiple tumor types.

The Company's TLR antagonist lead drug candidate is IMO-8400, which is an antagonist of TLR7, TLR8 and TLR9. The Company is developing IMO-8400 for the treatment of rare diseases and has selected dermatomyositis as its lead clinical target. The Company selected this indication for development based on the reported increase in TLR expression in this disease state, expression of cytokines indicative of key TLR-mediated pathways and the presence of auto-antibodies that can induce TLR-mediated immune responses.

Third-Generation Antisense

The Company is developing its 3GA technology to "turn off" the mRNA associated with disease causing genes. The Company has designed 3GA oligonucleotides to specifically address challenges associated with earlier generation antisense and RNAi technologies.

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The Company has selected IDRA-008 as its first 3GA candidate to enter clinical development. The Company is planning to develop IDRA-008 for a well-established liver target with available pre-clinical animal models and well-known clinical endpoints.

Liquidity and Financial Condition

At September 30, 2017, the Company had an accumulated deficit of $589.6 million. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company or its collaborators successfully complete development and obtain marketing approval for the Company's drug candidates, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

The Company believes, based on its current operating plan, that its existing cash, cash equivalents and investments, together with the net proceeds from its common stock offering and the exercise of common stock warrants in October 2017 as more fully described in Note 18, will enable the Company to fund its operations into the second quarter of 2019. The Company has and will continue to evaluate available alternatives to extend its operations beyond the second quarter of 2019.

(2) New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation (Topic 718), which is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years. As of January 1, 2017, the Company adopted this standard, which had the following impacts on its financial statements. (1) ASU 2016-09 requires organizations to recognize all income tax effects of awards in the statement of operations when the awards vest or are settled. The Company's net operating loss deferred tax assets increased by $1.4 million and were offset by a corresponding increase

in the valuation allowance given the Company's continued loss position. Accordingly, the adoption of this portion of ASU 2016-09 had no impact on the Company's Accumulated deficit. (2) ASU 2016-09 allows organizations to repurchase more shares from employees than they could previously purchase for tax withholding purposes without triggering liability accounting. The adoption of this portion of ASU 2016-09 had no impact on the Company's financial statements. (3) ASU 2016-09 allows companies to make a policy election to account for forfeitures as they occur. The Company has made the policy election to account for forfeitures as they occur and has used the modified retrospective transition method, resulting in less than a $0.1 million reduction in Additional paid-in capital and an increase in Accumulated deficit as of January 1, 2017, to reflect the cumulative effect of previously estimated forfeitures.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was amended by ASU No. 2015-14 (as amended, "ASU 2014-09"). ASU No. 2014-09 requires an entity to recognize revenue from the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In particular, this ASU addresses contracts with more than one performance obligation, as well as the accounting for some costs to obtain or fulfill a contract with a customer, and provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers. This ASU is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within that fiscal year. Early adoption of this ASU is permitted only for fiscal years beginning after December 15, 2016, including interim periods within that fiscal year. This guidance is applicable to the Company's fiscal year beginning January 1, 2018 and the Company expects to adopt ASU 2014-09 in the first quarter of 2018 using the modified retrospective transition method. To date, the Company has derived its revenues from a limited number of license and collaboration agreements. The consideration the Company is eligible to receive under these

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agreements includes upfront payments, research and development funding, contingent revenues in the form of commercial and development milestones and option payments and royalties. Each of the Company's license and collaboration agreements has unique terms that need to be evaluated separately under the new standard. The Company is substantially complete with its initial assessment of its two active license and collaboration agreements, and currently does not expect the adoption of the ASU to have a material impact on its financial statements but is expected to result in expanded footnote disclosures. The Company will continue to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact our current conclusion.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets, with lease terms of more than 12 months, to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with current U.S. Generally Accepted Accounting Principles ("U.S. GAAP"), the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current U.S. GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. This guidance is applicable to the Company's fiscal year beginning January 1, 2019. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. GAAP for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2017 are not necessarily indicative of results that may be expected for the year ending December 31, 2017. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on March 15, 2017.

(4) Financial Instruments

The fair value of the Company's financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 6, "Fair Value of Assets and Liabilities." The Company is required to disclose the estimated fair values of its financial instruments. The Company's financial instruments consist of cash, cash equivalents, available-for-sale investments and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of September 30, 2017 and December 31, 2016. As of September 30, 2017 and December 31, 2016, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the note issued under the Company's loan and security agreement, which is discussed in Note

5(a) to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, including put and call features which the Company determined are clearly and closely associated with the debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial.

(5) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2017 and December 31, 2016 consisted of cash and money market funds.

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(6) Fair Value of Assets and Liabilities

The Company applies the guidance in FASB Accounting Standards Codification (ASC) Topic 820, Fair Value Measurement, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using assumptions that market participants would use in pricing the asset or liability (the "inputs") into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company's estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management's interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2017 and December 31, 2016 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2017				
Assets				
Money market funds	$ 49,637	$ 49,637	$ —	$ —
Short-term investments – municipal bonds	1,400	—	1,400	—
Total Assets	$ 51,037	$ 49,637	$ 1,400	$ —
Total Liabilities	$ —	$ —	$ —	$ —
December 31, 2016				
Assets				
Money market funds	$ 67,580	$ 67,580	$ —	$ —
Short-term investments – corporate bonds	19,729	—	19,729	—
Short-term investments – municipal bonds	8,618	—	8,618	—
Total Assets	$ 95,927	$ 67,580	$ 28,347	$ —
Total Liabilities	$ —	$ —	$ —	$ —

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond and municipal bond investments, the fair value of which may not represent actual transactions of identical securities. The fair value of corporate and municipal bonds is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders' equity on the Company's balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value at September 30, 2017 or December 31, 2016.

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(7) Investments

The Company's available-for-sale investments at fair value consisted of the following at September 30, 2017 and December 31, 2016:

	September 30, 2017		
	Gross Unrealized	Gross Unrealized	Estimated Fair