IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 06, 2015
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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 September 30, 2015

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 incorporation or organization)	**(I.R.S. Employer 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 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 (§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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting 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 ¨

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

Common Stock, par value $.001 per share	**118,350,364**
Class	**Outstanding as of October 15, 2015**

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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. 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, 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 below under Part II, Item 1A Risk Factors. 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 Securities and Exchange Commission 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, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,996	$ 19,971
Short-term investments	38,028	21,256
Prepaid expenses and other current assets	2,358	1,203
Total current assets	68,382	42,430
Long-term investments	28,670	7,344
Property and equipment, net	1,685	1,306
Restricted cash and other assets	347	346
Total assets	$ 99,084	$ 51,426
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 881	$ 2,458
Accrued expenses	4,571	4,460
Current portion of note payable	254	128
Total current liabilities	5,706	7,046
Note payable, net of current portion	569	742
Other liabilities	151	236
Total liabilities	6,426	8,024
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, Authorized 5,000 shares		
Series E convertible preferred stock, Designated zero shares and 424 shares at September 30, 2015 and December 31, 2014, respectively; Issued and outstanding zero 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 118,340 and 94,829 shares at September 30, 2015 and	118	95

December 31, 2014, respectively		
Additional paid-in capital	580,658	494,850
Accumulated deficit	(488,091)	(451,526)
Accumulated other comprehensive loss	(27)	(17)
Total stockholders equity	92,658	43,402
Total liabilities and stockholders equity	$ 99,084	$ 51,426

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)

(In thousands, except per share amounts)	Three Months Ended September 30, 2015	2014	Nine Months Ended September 30, 2015	2014
Alliance revenue	$ 20	$ 30	$ 59	$ 71
Operating expenses:				
Research and development	7,454	6,678	25,134	19,248
General and administrative	4,030	2,873	11,688	7,646
Total operating expenses	11,484	9,551	36,822	26,894
Loss from operations	(11,464)	(9,521)	(36,763)	(26,823)
Other income (expense):				
Investment income	123	14	239	45
Interest expense	(27)		(81)	
Foreign currency exchange gain	3	52	40	54
Net loss	(11,365)	(9,455)	(36,565)	(26,724)
Preferred stock dividends		119		422
Net loss applicable to common stockholders	$ (11,365)	$ (9,574)	$ (36,565)	$ (27,146)
Basic and diluted net loss per common share applicable to common stockholders (Note 13)	$ (0.10)	$ (0.11)	$ (0.32)	$ (0.33)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	118,248	84,527	113,821	81,200
Net loss	$ (11,365)	$ (9,455)	$ (36,565)	$ (26,724)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	50	(5)	(10)	5
Comprehensive loss	$ (11,315)	$ (9,460)	$ (36,575)	$ (26,719)

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, 2015	2014
Cash Flows from Operating Activities:		
Net loss	$ (36,565)	$ (26,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,013	2,086
Depreciation and amortization expense	346	135
Amortization of investment premiums	397	149
Issuance of common stock for services rendered	90	62
Non-employee stock option expense	142	(8)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,163)	(228)
Accounts payable, accrued expenses, and other liabilities	(1,590)	2,718
Net cash used in operating activities	(34,330)	(21,810)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(63,106)	(2,619)
Maturities of available-for-sale securities	23,602	2,000
Sales of available-for-sale securities	999	
Purchases of property and equipment	(659)	(891)
Net cash used in investing activities	(39,164)	(1,510)
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	80,599	37,137
Proceeds from issuance of note payable		850
Dividends paid		(582)
Proceeds from exercise of common stock warrants and options and employee stock purchases	987	8,132
Payments on note payable	(59)	
Payments on capital lease	(8)	(4)
Net cash provided by financing activities	81,519	45,533
Net increase in cash and cash equivalents	8,025	22,213
Cash and cash equivalents, beginning of period	19,971	26,278
Cash and cash equivalents, end of period	$ 27,996	$ 48,491

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, 2015

(UNAUDITED)

(1) Organization

Idera Pharmaceuticals, Inc. (Idera or the Company) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel 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 program, which the Company previously referred to as its GSO program. 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 third-generation antisense technology, the Company is developing drug candidates to turn off the messenger RNA (mRNA) associated with disease causing genes. The Company believes that its third-generation antisense technology may potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference (RNAi) technologies.

Idera is currently conducting a Phase 1/2 clinical trial of IMO-8400, a novel synthetic oligonucleotide antagonist of TLR7, TLR8 and TLR9, in patients with Waldenström s macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma (DLBCL) who harbor the MYD88 L265P oncogenic mutation. The Company is also developing IMO-8400 for the treatment of rare diseases and has selected dermatomyositis and Duchenne muscular dystrophy (DMD) as the first non-cancer rare diseases for which it plans to develop IMO-8400. The Company believes it can develop and commercialize therapies on its own in these disease indications, which are characterized by small, well-defined patient populations with serious unmet medical needs.

The Company also evaluated a second novel synthetic oligonucleotide antagonist of TLR7, TLR8 and TLR9, IMO-9200, as a drug candidate for potential use in inflammatory bowel disease (IBD). The Company has also conducted a Phase 1 clinical trial of subcutaneously injected IMO-9200 in healthy subjects and preclinical studies using oral administration of IMO-9200 in mouse models of colitis. The Company is currently reviewing its strategic options in relation to the advancement of IMO-9200, as IBD falls outside of the core focus of oncology and rare diseases.

In the second quarter of 2015, the Company entered into a strategic clinical research alliance with MD Anderson Cancer Center (MD Anderson) to advance clinical development of a TLR9 agonist administered in combination with checkpoint inhibitors. The Company plans to initiate the first trial from the research alliance, a Phase 1/2 clinical trial of IMO-2125, one of the Company s clinical-stage TLR9 agonists, administered intra-tumorally in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma in the fourth quarter of 2015.

The Company is also developing its third-generation antisense drug candidates to specifically address challenges associated with earlier generation antisense. Although currently used technologies to silence RNA have demonstrated the ability to inhibit the expression of disease-associated proteins, the Company believes that to reach their full therapeutic potential, gene silencing technologies need to achieve an improved therapeutic index through reduced immunotoxicity and increased potency. The Company is conducting preclinical studies in the field of oncology and

rare diseases where there is an unmet medical need. The company has selected NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4) as gene targets to advance into IND-enabling activities. Potential disease indications include, but are not limited to interstitial cystitis, uveitis and facioscapulohumeral muscular dystrophy (FSHD), respectively. Concurrently, the Company is engaging in academic collaborations to further evaluate the application of this third-generation antisense technology platform in additional gene targets and exploring development opportunities with third parties for applications outside of the Company s current focus areas.

As of September 30, 2015, the Company had an accumulated deficit of $488,091,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, 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.

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(2) New Accounting Pronouncements - Recently Issued

In May 2014, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was amended by ASU No. 2015-14. ASU No. 2014-09, as amended by ASU No. 2015-14, 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 will be effective 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. The Company is currently evaluating the effect that the adoption of this ASU will have on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 amends FASB ASC 205-40, Presentation of Financial Statements Going Concern, by providing guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements, including requiring management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements and providing certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. ASU 2014-15 will be effective for fiscal years ending after December 15, 2016 and for interim periods thereafter. Early adoption of ASU 2014-15 is permitted. The Company is currently evaluating the effect that the adoption of ASU 2014-15 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 United States Generally Accepted Accounting Principles (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 nine months ended September 30, 2015 are not necessarily indicative of results that may be expected for the year ending December 31, 2015. 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, 2014, which was filed with the SEC on March 12, 2015.

(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, receivables and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of September 30, 2015 and December 31, 2014. As of September 30, 2015 and December 31, 2014, 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, 2014, 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, 2015 and December 31, 2014 consisted of cash, commercial paper and money market funds.

(6) Fair Value of Assets and Liabilities

The Company measures fair value 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

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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 Company applies ASU No. 2011-04, Fair Value Measurement (Topic 820), in its fair value measurements and disclosures.

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, 2015 and December 31, 2014 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, 2015					
Assets					
Money market funds		$ 27,890	$ 27,890	$	$
Short-term investments	commercial paper	6,470		6,470	
Short-term investments	corporate bonds	25,366		25,366	
Short-term investments	municipal bonds	6,192		6,192	
Long-term investments	corporate bonds	22,812		22,812	
Long-term investments	municipal bonds	5,858		5,858	
Total assets		$ 94,588	$ 27,890	$ 66,698	$
Total liabilities		$	$	$	$
December 31, 2014					
Assets					
Money market funds		$ 17,156	$ 17,156	$	$
Other cash equivalents	commercial paper	2,500		2,500	
Short-term investments	commercial paper	4,494		4,494	
Short-term investments	certificate of deposit	500		500	
Short-term investments	corporate bonds	14,357		14,357	
Short-term investments	municipal bonds	1,905		1,905	
Long-term investments	corporate bonds	7,344		7,344	
Total assets		$ 48,256	$ 17,156	&nb	