

IDERA PHARMACEUTICALS, INC.

Form 10-Q

August 12, 2014

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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 June 30, 2014

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
(State or other jurisdiction of
incorporation or organization)

04-3072298
(I.R.S. Employer
Identification No.)

167 Sidney Street

Cambridge, Massachusetts
(Address of principal executive offices)

02139
(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, 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

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

Common Stock, par value \$.001 per share
Class

83,767,193
Outstanding as of July 15, 2014

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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, 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, projects, 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.

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****IDERA PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS****(UNAUDITED)**

(In thousands, except per share amounts)	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,886	\$ 26,278
Short-term investments	8,844	3,125
Prepaid expenses and other current assets	836	874
Total current assets	64,566	30,277
Long-term investments	1,004	6,189
Property and equipment, net	686	90
Restricted cash	311	311
Total assets	\$ 66,567	\$ 36,867
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,026	\$ 904
Accrued expenses	4,221	3,506
Total current liabilities	6,247	4,410
Other liabilities	59	5
Total liabilities	6,306	4,415
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.01 par value, Authorized 5,000 shares		
Series E convertible preferred stock, Designated, issued and outstanding 424 shares	5,528	5,528
Series D convertible preferred stock, Designated, issued and outstanding zero shares and 1,124 shares at June 30, 2014 and December 31, 2013, respectively		5,464
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 83,758 and 66,252 shares at June 30, 2014 and December 31,	84	66

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2013, respectively

Additional paid-in capital	484,799	434,285
Accumulated deficit	(430,153)	(412,884)
Accumulated other comprehensive gain (loss)	3	(7)
Total stockholders' equity	60,261	32,452
Total liabilities and stockholders' equity	\$ 66,567	\$ 36,867

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

Table of Contents**IDERA PHARMACEUTICALS, INC.****CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(UNAUDITED)**

(In thousands, except per share amounts)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Alliance revenue	\$ 38	\$ 29	\$ 41	\$ 36
Operating expenses:				
Research and development	5,637	1,997	12,570	4,325
General and administrative	2,730	1,599	4,773	3,126
Total operating expenses	8,367	3,596	17,343	7,451
Loss from operations	(8,329)	(3,567)	(17,302)	(7,415)
Other income (expense):				
Investment income, net	16	2	31	4
Foreign currency exchange gain (loss)	5	(26)	2	13
Net loss	(8,308)	(3,591)	(17,269)	(7,398)
Loss on extinguishment of convertible preferred stock and preferred stock dividends	118	2,030	303	2,309
Net loss applicable to common stockholders	\$ (8,426)	\$ (5,621)	\$ (17,572)	\$ (9,707)
Basic and diluted net loss per common share applicable to common stockholders (Note 13)	\$ (0.10)	\$ (0.15)	\$ (0.22)	\$ (0.30)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	82,961	38,048	79,509	32,875
Net loss	\$ (8,308)	\$ (3,591)	\$ (17,269)	\$ (7,398)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale securities	(1)		10	
Comprehensive loss	\$ (8,309)	\$ (3,591)	\$ (17,259)	\$ (7,398)

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)	Six Months Ended June 30,	
	2014	2013
Cash Flows from Operating Activities:		
Net loss	\$ (17,269)	\$ (7,398)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,320	518
Depreciation and amortization expense	78	75
Amortization of investment premiums	96	
Issuance of common stock for services rendered	36	9
Other	(3)	8
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	38	(4)
Accounts payable, accrued expenses, and other liabilities	1,947	(1,214)
Net cash used in operating activities	(13,757)	(8,006)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(2,619)	
Maturities of available-for-sale securities	2,000	
Purchases of property and equipment	(533)	(1)
Net cash used in investing activities	(1,152)	(1)
Cash Flows from Financing Activities:		
Proceeds from equity financings	37,202	14,721
Dividends paid	(463)	(509)
Proceeds from exercise of common stock warrants and options and employee stock purchases	6,780	2
Payments on capital lease	(2)	(2)
Net cash provided by financing activities	43,517	14,212
Net increase in cash and cash equivalents	28,608	6,205
Cash and cash equivalents, beginning of period	26,278	10,096
Cash and cash equivalents, end of period	\$ 54,886	\$ 16,301

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

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IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

June 30, 2014

(UNAUDITED)

(1) Organization

Idera Pharmaceuticals, Inc. (Idera or the Company) is a clinical stage biotechnology company advancing drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of orphan autoimmune diseases. These drug candidates are designed to inhibit over-activation of specific Toll-like receptors (TLRs). In addition to Idera s TLR program, the Company has initiated a research program to develop its gene silencing oligonucleotides (GSOs) to inhibit the production of disease-associated proteins by targeting RNA.

The Company s lead drug candidate in its TLR program is IMO-8400, an antagonist of TLR7, TLR8, and TLR9. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. IMO-8400 is in development for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of selected orphan autoimmune diseases. The Company has completed a Phase 1 trial of IMO-8400 in healthy subjects and a Phase 2 randomized, placebo-controlled trial in patients with moderate to severe plaque psoriasis. The Company is currently conducting a Phase 1/2 trial of IMO-8400 in patients with Waldenström s macroglobulinemia and a Phase 1/2 trial of IMO-8400 in patients with diffuse large B-cell lymphoma, or DLBCL, who harbor the MYD88 L265P oncogenic mutation. The Company is also advancing a second novel antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. The Company has completed preclinical studies of IMO-9200 to support initiation of clinical development.

Idera s business strategy is to develop IMO-8400, IMO-9200, and other TLR antagonist drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of orphan autoimmune diseases. In addition, the Company may seek to enter into collaborative alliances with pharmaceutical companies to advance its TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus, and arthritis.

At June 30, 2014, the Company had an accumulated deficit of \$430,153,000. 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.

(2) New Accounting Pronouncements - Recently Issued

In April 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-08 Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360):

Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this ASU require that a disposal representing a strategic shift that has (or will have) a major effect on an entity's operations and financial results or a business activity classified as held for sale should be reported as discontinued operations. The amendments also expand the disclosure requirements for discontinued operations and add new disclosure requirements for individually significant components that do not qualify as discontinued operations. This ASU will be effective prospectively for fiscal years beginning on or after December 15, 2014. Early adoption is permitted, but only for disposals that have not been previously reported in financial statements previously issued. The Company does not expect the adoption of this ASU to have a material effect on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606). This ASU 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, 2016. Early adoption of this ASU is not permitted. The Company is currently evaluating the effect that the adoption of this ASU will have on its financial statements.

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(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 six months ended June 30, 2014 are not necessarily indicative of results that may be expected for the year ended December 31, 2014. 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, 2013, which was filed with the SEC on March 13, 2014.

(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 receivables. The estimated fair values of these financial instruments approximate their carrying values as of June 30, 2014 and December 31, 2013. As of June 30, 2014 and December 31, 2013, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the Company s Series E convertible preferred stock (the Series E preferred stock), the embedded features of which are discussed in Note 8(g) to the financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2013.

(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 June 30, 2014 and December 31, 2013 consisted of cash 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 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 Accounting Standards Update (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 June 30, 2014 and December 31, 2013 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)
June 30, 2014					
Assets					
Money market funds		\$ 54,814	\$ 54,814	\$	\$
Short-term investments	commercial paper	998		998	
Short-term investments	corporate bonds	7,846		7,846	
Long-term investments	corporate bonds	1,004		1,004	
Total Assets		\$ 64,662	\$ 54,814	\$ 9,848	\$

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(In thousands)		Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Total			
December 31, 2013				
Assets				
Money market funds	\$ 25,201	\$ 25,201	\$	\$
Short-term investments commercial paper	1,997		1,997	
Short-term investments corporate bonds	1,128		1,128	
Long-term investments corporate bonds	6,189		6,189	
Total Assets	\$ 34,515	\$ 25,201	\$ 9,314	\$

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond and commercial paper investments whose fair value may not represent actual transactions of identical securities. The fair value of corporate 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. The fair value of commercial paper is generally determined based on the relationship between the investment's discount rate and the discount rates of the same issuer's commercial paper available in the market which may not be actively traded daily. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2. Since any investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive gain (loss) or within stockholders' equity on the balance sheets. The Company did not elect to measure any other financial assets or liabilities at fair value at June 30, 2014 or December 31, 2013.

(7) Investments

The Company's available-for-sale investments at fair value consisted of the following at June 30, 2014 and December 31, 2013:

	Cost	June 30, 2014		Estimated Fair Value
		Gross Unrealized (Losses)	Gross Unrealized Gains	
		(In thousands)		
Commercial paper due in one year or less	\$ 998	\$	\$	\$ 998
Corporate bonds due in one year or less	7,842			