

IDERA PHARMACEUTICALS, INC.

Form 10-Q

November 01, 2016

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended September 30, 2016

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

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IDERA PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

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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)

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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	147,653,120
Class	Outstanding as of October 28, 2016

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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,” “prudent,” “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 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, or 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, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,154	\$ 26,586
Short-term investments	29,856	33,574
Prepaid expenses and other current assets	3,455	3,082
Total current assets	55,465	63,242
Long-term investments	1,408	26,997
Property and equipment, net	1,579	1,692
Restricted cash and other assets	26	345
Total assets	\$ 58,478	\$ 92,276
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 344	\$ 1,169
Accrued expenses	6,118	4,274
Current portion of note payable	284	261
Current portion of deferred revenue	1,111	1,111
Total current liabilities	7,857	6,815
Deferred revenue, net of current portion	429	1,262
Note payable, net of current portion	285	501
Other liabilities	35	116
Total liabilities	8,606	8,694
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares:	—	—

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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 — 121,411 and 121,265 shares at September 30, 2016 and December 31, 2015, respectively

Additional paid-in capital	121	121
Accumulated deficit	589,044	583,676
Accumulated other comprehensive income (loss)	(539,292)	(500,081)
Total stockholders' equity	(1)	(134)
Total liabilities and stockholders' equity	49,872	83,582
	\$ 58,478	\$ 92,276

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,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Alliance revenue	\$ 323	\$ 20	\$ 918	\$ 59
Operating expenses:				
Research and development	9,393	7,454	28,817	25,134
General and administrative	3,907	4,030	11,601	11,688
Total operating expenses	13,300	11,484	40,418	36,822
Loss from operations	(12,977)	(11,464)	(39,500)	(36,763)
Other income (expense):				
Interest income	90	123	320	239
Interest expense	(19)	(27)	(63)	(81)
Foreign currency exchange gain (loss)	3	3	32	40
Net loss	\$ (12,903)	(11,365)	(39,211)	(36,565)
Basic and diluted net loss per common share (Note 13)	\$ (0.10)	\$ (0.10)	\$ (0.32)	\$ (0.32)
Shares used in computing basic and diluted net loss per common share	121,389	118,248	121,332	113,821
Net loss	\$ (12,903)	\$ (11,365)	\$ (39,211)	\$ (36,565)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	13	50	133	(10)
Comprehensive loss	\$ (12,890)	\$ (11,315)	\$ (39,078)	\$ (36,575)

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, 2016	2015
Cash Flows from Operating Activities:		
Net loss	\$ (39,211)	\$ (36,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-employee stock option expense	—	142
Stock-based compensation	5,127	4,013
Issuance of common stock for services rendered	129	90
Accretion of premiums and discounts on investments	466	397
Depreciation and amortization expense	484	346
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(48)	(1,163)
Accounts payable, accrued expenses, and other liabilities	937	(1,590)
Deferred revenue	(833)	—
Net cash used in operating activities	(32,949)	(34,330)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(2,946)	(63,106)
Proceeds from maturity of available-for-sale securities	29,946	23,602
Proceeds from sale of available-for-sale securities	1,974	999
Purchases of property and equipment	(369)	(659)
Net cash provided by (used in) investing activities	28,605	(39,164)
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	—	80,599
Proceeds from exercise of common stock warrants and options and employee stock purchases	111	987
Payments on note payable	(193)	(59)
Payments on capital lease	(6)	(8)
Net cash (used in) provided by financing activities	(88)	81,519
Net (decrease) increase in cash and cash equivalents	(4,432)	8,025
Cash and cash equivalents, beginning of period	26,586	19,971
Cash and cash equivalents, end of period	\$ 22,154	\$ 27,996

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, 2016

(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 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. 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 that its 3GA technology may potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference (“RNAi”) technologies.

The Company’s business strategy 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 plans to execute early-stage development through proof-of-concept clinical trials and explore potential collaborative alliances to support late-stage development and commercialization.

The Company’s TLR-targeted clinical-stage drug candidates are IMO-2125 and IMO-8400. IMO-2125 is an agonist of TLR9 and IMO-8400 is an antagonist of TLR7, TLR8 and TLR9. The Company has also created compounds that are agonists of TLR3, TLR7, TLR8 and TLR9, as well as additional antagonist candidates.

At September 30, 2016, the Company had an accumulated deficit of \$539,292,000. 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 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.

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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 amends FASB Accounting Standards Codification ("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 ASU 2014-15 and has not yet adopted it. The Company believes that, based on its current operating plan, its existing cash, cash equivalents and investments, including the estimated \$48.9 million of net proceeds raised in its October 2016 offering, including the partial exercise by the underwriters of their option to purchase additional shares of the offering and after deducting underwriters' discounts and commissions and estimated offering expenses (see Note 18, "Subsequent Events"), will enable the Company to fund its operations into the first quarter of 2018. The Company has and will continue to evaluate available alternatives to extend its operations beyond the first quarter of 2018.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in ASU 2016-01 address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption of some of the amendments included in ASU 2016-01 for financial statements of fiscal years or interim periods that have not yet been issued is permitted as of the beginning of the fiscal year of adoption. The Company is currently evaluating the effect that the adoption of ASU 2016-01 will have on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The amendments in ASU 2016-02 will require 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 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the effect that the adoption of ASU 2016-02 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815) Contingent Put and Call Options in Debt Instruments. ASU 2016-06 amends FASB ASC 815-15 to clarify what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts, which is one of the criteria for bifurcating an embedded derivative. ASU 2016-06 will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. An entity should apply the amendments in ASU No. 2016-06 on a modified retrospective basis to existing debt instruments as of the beginning of the fiscal year for which the amendments are effective. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect that the adoption of ASU 2016-06 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718). ASU 2016-09 will require organizations to recognize all income tax effects of awards in the statement of operations when the awards vest or are settled. ASU 2016-09 will also allow organizations to repurchase more shares from employees than they could previously purchase for tax withholding purposes without triggering liability accounting and to make a policy election to account for forfeitures as they occur. ASU 2016-09 will be effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the effect that the adoption of ASU 2016-09 will have on its financial statements.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606). ASU 2016-10 amends ASC 606, Revenue from Contracts with Customers, to clarify two aspects of ASC 606, identifying performance obligations and the licensing implementation guidance, while retaining the related principles of those areas. The amendments in ASU 2016-10 do not change the core principle of the guidance in ASC 606. The amendments in ASU No. 2016-10 affect the guidance in ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which is not yet

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effective. The effective date and transition requirements for the amendments in ASU No. 2016-10 are the same as the effective date and transition requirements in ASC 606 and any other Topic amended by ASU 2014-09. ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, defers the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company is currently evaluating the effect that the adoption of ASU 2016-10 will have on its financial statements.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606). ASU 2016-12 amends ASC 606 to address certain issues in the guidance on assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. The amendments in ASU 2016-12 do not change the core principle of the guidance in ASC 606. The amendments in ASU No. 2016-12 affect the guidance in ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which is not yet effective. The effective date and transition requirements for the amendments in ASU No. 2016-12 are the same as the effective date and transition requirements in ASC 606 and any other Topic amended by ASU 2014-09. ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, defers the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company is currently evaluating the effect that the adoption of ASU 2016-12 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, 2016 are not necessarily indicative of results that may be expected for the year ending December 31, 2016. 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, 2015, which was filed with the SEC on March 10, 2016.

### (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, 2016 and December 31, 2015. As of September 30,

2016 and December 31, 2015, 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, 2015, 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, 2016 and December 31, 2015 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



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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 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, 2016 and December 31, 2015 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, 2016				
Assets				
Money market funds	\$ 21,647	\$ 21,647	\$ —	\$ —
Short-term investments – corporate bonds	22,591	—	22,591	—
Short-term investments – municipal bonds	7,265	—	7,265	—
Long-term investments – municipal bonds	1,408	—	1,408	—
Total Assets	\$ 52,911	\$ 21,647	\$ 31,264	\$ —
Total Liabilities	\$ —	\$ —	\$ —	\$ —
December 31, 2015				
Assets				
Money market funds	\$ 26,056	\$ 26,056	\$ —	\$ —
Short-term investments – commercial paper	3,974	—	3,974	—
Short-term investments – corporate bonds	24,575	—	24,575	—
Short-term investments – municipal bonds	5,025	—	5,025	—
Long-term investments – corporate bonds	21,186	—	21,186	—
Long-term investments – municipal bonds	5,811	—	5,811	—
Total Assets	\$ 86,627	\$ 26,056	\$ 60,571	\$ —
Total Liabilities	\$ —	\$ —	\$ —	\$ —

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond, commercial paper 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. 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 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 balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value at September 30, 2016 or December 31, 2015.

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## (7) Investments

The Company's available-for-sale investments at fair value consisted of the following at September 30, 2016 and December 31, 2015:

	September 30, 2016			Estimated
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gain	Fair Value
	(In thousands)			
Short-term investments – corporate bonds	22,603	(13)	1	22,591
Short-term investments – municipal bonds	7,257	—	8	7,265
Total short-term investments	29,860	(13)	9	29,856
Long-term investments – municipal bonds	1,405	—	3	1,408
Total long-term investments	1,405	—	3	1,408
Total investments	\$ 31,265	\$ (13)	\$ 12	\$ 31,264

	December 31, 2015			Estimated
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Fair Value
	(In thousands)			
Short-term investments – commercial paper	\$ 3,973	\$ —	\$ 1	\$ 3,974
Short-term investments – corporate bonds	24,600	(25)	—	24,575
Short-term investments – municipal bonds	5,025	—	—	5,025
Total short-term investments	33,598	(25)	1	33,574
Long-term investments – corporate bonds	21,289	(103)	—	21,186
Long-term investments – municipal bonds	5,818	(9)	2	5,811
Total long-term investments	27,107	(112)	2	26,997
Total investments	\$ 60,705	\$ (137)	\$ 3	\$ 60,571

The Company had no realized gains or losses from available-for-sale securities in the nine months ended September 30, 2016 and 2015. There were no losses or other-than-temporary declines in value included in “Interest income” on the Company's condensed statements of operations and comprehensive loss for any securities for the nine months ended September 30, 2016 and 2015. The Company had no auction rate securities as of September 30, 2016 and December 31, 2015. See Note 4, “Financial Instruments,” and Note 6, “Fair Value of Assets and Liabilities” for additional information related to the Company's investments.

## (8) Property and Equipment

At September 30, 2016 and December 31, 2015, net property and equipment at cost consisted of the following:

(In thousands)	September 30, 2016	December 31, 2015
Leasehold improvements	\$ 671	\$ 603
Laboratory equipment and other	4,786	4,543
Total property and equipment, at cost	5,457	5,146
Less: Accumulated depreciation and amortization	3,878	3,454
Property and equipment, net	\$ 1,579	\$ 1,692

Depreciation and amortization expense on property and equipment was approximately \$162,000 and \$126,000 in the three months ended September 30, 2016 and 2015, respectively, and \$469,000 and \$329,000 in the nine months ended September 30, 2016 and 2015, respectively. There were \$21,000 and \$48,000 in non-cash property returns and additions, respectively, in the nine months ended September 30, 2016 and 2015, respectively.

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## (9) Restricted Cash

As part of the Company's lease arrangement for its office and laboratory facility in Cambridge, Massachusetts, the Company is required to restrict cash held in a certificate of deposit securing a line of credit for the lessor. As of September 30, 2016 and December 31, 2015, the restricted cash amounted to \$311,000 held in certificates of deposit securing a line of credit for the lessor. The lease expires August 2017. As such, this amount is reported in Prepaid expenses and other current assets as of September 30, 2016 and in Restricted cash and other assets as of December 31, 2015.

## (10) Comprehensive Loss

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss for the nine months ended September 30, 2016 and 2015 is comprised of reported net loss and any change in net unrealized gains and losses on investments during each period, which is included in accumulated other comprehensive income (loss) on the accompanying balance sheets. The Company applies ASU No. 2011-05, Comprehensive Income, by presenting the components of net income and other comprehensive income as one continuous statement.

The following table includes the changes in the accumulated balance of the component of other comprehensive income (loss) for the nine months ended September 30, 2016 and 2015:

(In thousands)	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Accumulated unrealized loss on available-for-sale securities at beginning of period	\$ (134)	\$ (17)
Change during the period	133	(10)
Accumulated unrealized loss on available-for-sale securities at end of period	\$ (1)	\$ (27)

## (11) Collaboration with GlaxoSmithKline Intellectual Property Development Limited

In November 2015, the Company entered into a collaboration and license agreement with GlaxoSmithKline Intellectual Property Development Limited (“GSK”) to license, research, develop and commercialize pharmaceutical compounds from the Company’s 3GA technology for the treatment of selected targets in renal disease (the “GSK Agreement”). The initial collaboration term is currently anticipated to last between two and four years. In connection with the GSK Agreement, GSK identified an initial target for the Company to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan, currently estimated to take 27 months to complete. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. Once GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

At any time during the first two years of the GSK Agreement, GSK has the option to select up to two additional targets, for further research under mutually agreed upon research plans. GSK may then designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate.

In accordance with the GSK Agreement, a Joint Steering Committee (“JSC”) was formed with equal representation from Idera and GSK. The responsibilities of the JSC, include, but are not limited to monitoring the progress of the collaboration, reviewing research plans and dealing with disputes that may arise between the parties. If a dispute cannot be resolved by the JSC, GSK has final decision making authority.

Under the terms of the GSK Agreement, the Company received a \$2,500,000 upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. The Company is eligible to receive up to approximately \$100,000,000 in license, research, clinical development and commercialization milestone payments. Approximately \$9,000,000 of these milestone payments are payable by GSK upon the identification of the additional

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targets, the completion of current and future research plans and the designation of development candidates. Approximately \$89,000,000 is payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, the Company is eligible to receive royalty payments on sales upon commercialization at varying rates of up to five percent on annual net sales, as defined in the GSK Agreement.

## Accounting Analysis

The Company evaluated the GSK Agreement in accordance with the provisions of ASC 605-25. The GSK Agreement contains the following initial deliverables: (i) a collaboration license for Idera's proprietary technology related to the initial target (the "Collaboration License"), (ii) research services (the "Research Services"), and (iii) participation in the JSC (the "JSC Deliverable").

The Company has determined that GSK's options to choose up to two additional targets and to purchase additional collaboration licenses for the Company's proprietary technology related to each additional target are substantive options. GSK is not contractually obligated to exercise the options. Moreover, as a result of the uncertain outcome of the research activities, there is significant uncertainty as to whether GSK will decide to exercise its options for any additional targets. Consequently, the Company is at risk with regard to whether GSK will exercise the options. The Company has determined that GSK's options to choose up to two additional targets and to purchase additional collaboration licenses for the Company's proprietary technology related to each additional target are not priced at a significant and incremental discount.

The Company has concluded that the Collaboration License does not qualify for separation from the Research Services. As it relates to the assessment of standalone value, the Company has determined that GSK cannot fully exploit the value of the Collaboration License without receipt of the Research Services from the Company. The Research Services involve unique skills and specialized expertise, particularly as it relates to the Company's proprietary technology, which is not available in the marketplace. Accordingly, GSK must obtain the Research Services from the Company which significantly limits the ability for GSK to utilize the Collaboration License for its intended purpose on a standalone basis. Therefore, the Collaboration License does not have standalone value from the Research Services. As a result, the Collaboration License and the Research Services have been combined as a single unit of accounting (the R&D Services Unit of Accounting). The Company has concluded that the JSC Deliverable identified at the inception of the arrangement has standalone value from the other deliverables noted based on its nature. Factors considered in this determination included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement.

Therefore, the Company has identified two units of accounting in connection with its initial deliverables under the GSK Agreement as follows: (i) R&D Services Unit of Accounting, and (ii) JSC Deliverable.

Allocable arrangement consideration at inception of the GSK Agreement is comprised of the up-front payment of \$2,500,000, which was allocated to the R&D Services Unit of Accounting. No amount was allocated to the JSC Deliverable because the related best estimate of selling price was determined to be de minimus. The \$2,500,000 was recorded as deferred revenue in the Company's balance sheet and is being recognized as revenue on a straight line basis as the Research Services are delivered over the estimated 27 month research plan period.

Payments to be received in connection with GSK's identification of additional targets and designation of development candidates are considered substantive options as a result of the uncertainties related to the research, development and commercialization activities, and the uncertainty as to whether GSK will exercise the options. The substantive options are not priced at a significant incremental discount. Accordingly, the substantive options are not considered deliverables at the inception of the arrangement and the associated option exercise payments are not accounted for at inception of the agreement.

The clinical and commercial milestones provided for in the GSK Agreement are all performance obligations of GSK occurring after the Company has completed its obligations. As a result, they represent contingent revenue to the Company and will be accounted for at the time the contingencies are resolved.



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The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

The Company recognized as revenue approximately \$278,000 and \$833,000 of deferred revenue related to the GSK Agreement during the three and nine months ended September 30, 2016, respectively. This revenue is classified as alliance revenue in the accompanying statements of operations and comprehensive loss. There was approximately \$1,540,000 of deferred revenue related to the GSK Agreement at September 30, 2016, including approximately \$1,111,000 classified as current portion of deferred revenue in the accompanying balance sheet.

## (12) Stock-Based Compensation

The Company recognizes all stock-based payments to employees and directors as expense in the statements of operations and comprehensive loss based on their fair values. The Company records compensation expense over an award's requisite service period, or vesting period, based on the award's fair value at the date of grant. The Company's policy is to charge the fair value of stock options as an expense, adjusted for forfeitures, on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors.

The Company recorded charges in Total operating expense of \$1,630,000 and \$1,144,000 in its statements of operations and comprehensive loss for the three months ended September 30, 2016 and 2015, respectively, and \$5,127,000 and \$4,013,000 in its statements of operations and comprehensive loss for the nine months ended September 30, 2016 and 2015, respectively, for stock-based compensation expense attributable to stock-based payments made to employees and directors. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The following weighted average assumptions apply to the options to purchase 3,281,000 and 2,228,000 shares of common stock granted to employees and directors during the nine months ended September 30, 2016 and 2015, respectively:

	Nine Months Ended September 30,	
	2016	2015
Average risk free interest rate	1.4%	1.3%
Expected dividend yield	—	—
Expected lives (years)	4.2	4.3
Expected volatility	92.8%	92.0%
Weighted average grant date fair value of options granted during the period (per share)	\$ 1.77	\$ 2.57
Weighted average exercise price of options granted during the period (per share)	\$ 2.65	\$ 3.85

The expected lives and the expected volatility of the options granted during the nine months ended September 30, 2016 and 2015 are based on historical experience. All options granted during the nine months ended September 30, 2016 and 2015 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

(13) Net Loss per Common Share

For the three and nine months ended September 30, 2016 and 2015, basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were 73,115,102 and 73,444,753 for the nine months ended September 30, 2016 and 2015, respectively, and consist of stock options, preferred stock and warrants.

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## (14) Common Stock Warrant Exercises, Stock Option Exercises and Employee Stock Purchases

The Company issued common stock as a result of warrant exercises, stock option exercises and employee stock purchases as follows during the nine months ended September 30, 2016 and 2015:

(In thousands)	Nine Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	Shares	Proceeds	Shares	Proceeds
Warrant exercises	—	\$ —	136	\$ 503
Stock option exercises	—	—	332	431
Employee stock purchases	79	111	19	53
Total	79	\$ 111	487	\$ 987

## (15) Related Party Transactions

The Company issued 66,915 and 23,689 shares of common stock in lieu of director board and committee fees of approximately \$129,000 and \$90,000 pursuant to the Company's director compensation program during the nine months ended September 30, 2016 and 2015, respectively. The number of shares issued was calculated based on the market closing price of the Company's common stock on the issuance date.

See also Note 17, "Financing" and Note 18, "Subsequent Events" for additional information on related party transactions.

## (16) Deferred Tax Assets

The Company's deferred tax assets are determined based on temporary differences between the financial reporting and tax bases of assets and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized. For the nine months ended September 30, 2016 and 2015, the Company did not record any current or deferred income tax provisions or benefits. Due to the uncertainty surrounding the future realization of the deferred tax assets, the Company has recorded full valuation allowances against its otherwise recognizable deferred tax assets at September 30, 2016 and December 31, 2015.

## (17) Financing

On February 19, 2015, the Company closed a follow-on underwritten public offering, in which it sold 23,000,000 shares of common stock at a price to the public of \$3.75 per share for aggregate gross proceeds of \$86.3 million. The net proceeds to the Company from the offering, after deducting underwriters' discounts and commissions and other offering costs and expenses, were \$80.6 million. Investment funds affiliated with Baker Bros. Advisors LP, one of the Company's principal stockholders, and two members of the Company's board of directors purchased 5,333,333 shares in this offering at the \$3.75 per share purchase price.

(18) Subsequent Events

On October 13, 2016, the Company closed a follow-on underwritten public offering, in which it sold 25,000,000 shares of common stock at a price to the public of \$2.00 per share for aggregate gross proceeds of \$50.0 million. On October 28, 2016, the Company sold an additional 1,225,243 shares of common stock pursuant to the underwriters' 30-day option to purchase additional shares at the public offering price less the underwriting discount. The estimated net proceeds to the Company from the offering, including the exercise by the underwriters of their option to purchase additional shares and after deducting underwriters' discounts and commissions and other offering costs and expenses, were approximately \$48.9 million. Investment funds affiliated with Baker Bros. Advisors LP and Pillar Invest Corporation, two of the Company's principal stockholders, and certain members of the Company's board of directors, purchased 5,125,000 shares in this offering at the \$2.00 per share purchase price.

As of October 13, 2016, Baker Bros. Advisors LP, and certain of its affiliated funds held 10,272,314 shares of the Company's common stock, warrants to purchase up to 20,316,327 shares of the Company's common stock at an

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exercise price of \$0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of the Company's common stock at an exercise price of \$0.01 per share.

As of October 13, 2016, entities affiliated with Pillar Invest Corporation held 20,346,942 shares of the Company's common stock and warrants to purchase up to 11,962,731 shares of the Company's common stock at exercise prices ranging from \$0.47 per share to \$1.46 per share.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel oligonucleotide therapeutics for oncology and rare diseases. We use two distinct proprietary drug discovery technology platforms to design and develop drug candidates: our Toll-like receptor, or TLR, targeting technology and our third-generation antisense, or 3GA, technology. We developed these platforms based on our scientific expertise and pioneering work with synthetic oligonucleotides as therapeutic agents. Using our TLR targeting technology, we design synthetic oligonucleotide-based drug candidates to modulate the activity of specific TLRs. Using our 3GA technology, we are developing drug candidates to turn off the messenger RNA, or mRNA, associated with disease causing genes. We believe that our 3GA technology may potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference, or RNAi, technologies.

Our business strategy focuses on the clinical development of drug candidates for oncology and rare diseases characterized by small, well-defined patient populations with serious unmet medical needs. We believe we can develop and commercialize these targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we plan to execute early-stage development through proof-of-concept clinical trials and explore potential collaborative alliances to support late-stage development and commercialization.

Our TLR-targeted clinical-stage drug candidates are IMO-2125 and IMO-8400. IMO-2125 is an agonist of TLR9 and IMO-8400 is an antagonist of TLR7, TLR8 and TLR9.

TLR Modulation Technology Platform

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we have 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.

Our TLR agonist lead drug candidate IMO-2125 is an agonist of TLR9. Our TLR antagonist lead drug candidate is IMO-8400, which is an antagonist of TLR7, TLR8 and TLR9. We also have created compounds that are agonists of TLR3, TLR7, TLR8 and TLR9 as well as additional antagonist candidates.

We are evaluating IMO-2125 for the treatment by intra-tumoral injection of multiple oncology indications both in combination with checkpoint inhibitors and as monotherapy. In addition, we are developing IMO-8400 for the treatment of a rare disease called dermatomyositis.

#### Intra-tumoral IMO-2125 Development Program in Immuno-oncology

Recent advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system. Despite these advancements, many patients fail to respond to these therapies. For instance, approximately fifty percent of patients with melanoma fail to respond to therapy with approved checkpoint inhibitors. Current published data suggests that the lack of response to checkpoint inhibition is related to a non-immunogenic tumor micro environment. Because TLR9 agonists stimulate the immune system, we believe that there is a scientific rationale to evaluate the combination of intra-tumoral injection of our TLR9 agonists with checkpoint inhibitors. Specifically, we believe that intra-tumoral injection of our TLR9 agonists activates a local immune response in the injected tumor, which complements the effect of the systemically administered checkpoint inhibitors. In studies in preclinical cancer models conducted in our laboratories, intra-tumoral injection of TLR9 agonists has potentiated the anti-tumor activity of multiple checkpoint inhibitors in multiple tumor models. These data have been presented at a number of scientific conferences from 2014 through 2016. We believe that these data support evaluation of combination regimens including a TLR9 agonist and a checkpoint inhibitor for the treatment of cancer.

We are initially developing IMO-2125 for use in combination with checkpoint inhibitors for the treatment of anti-PD1 refractory metastatic melanoma. We believe, based on internal commercial research that we conducted, that in the

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United States, by 2025, approximately 20,000 people will have metastatic melanoma and approximately 13,000 of those people will have metastatic melanoma that is anti-PD1 refractory. We also believe that TLR9 agonists may be useful in other tumor types that are unaddressable with current immunotherapy due in part to low mutation load and low dendritic cell infiltration, which include non-small cell lung cancer, head and neck cancer, renal cell cancer and bladder cancer. We believe, based on internal commercial research that we conducted, that in the United States, by 2025, approximately 160,000 people will have tumor types that are addressable with current immunotherapy and approximately 70,000 of those people will have tumor types that are anti-PD1 refractory.

In June 2015, we entered into a strategic research alliance with the University of Texas, MD Anderson Cancer Center, or MD Anderson, to commence clinical development of IMO-2125 in combination with checkpoint inhibitors. In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory). We recently amended the trial protocol to enable an additional arm to study the combination of IMO-2125 with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co. in the same patient population. In the Phase 1 portion of this clinical trial, escalating doses of IMO-2125 ranging from 4 mg through 32 mg in the ipilimumab arm and ranging from 8 mg through 32 mg in the pembrolizumab arm are being administered intra-tumorally into a selected tumor lesion, together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the anti-tumor activity of IMO-2125 when administered intra-tumorally in combination with ipilimumab or pembrolizumab. The primary objectives of the Phase 2 portion of the trial will be to characterize the safety of the combinations and determine the activity of the combinations utilizing immune-related response criteria. Additionally, a secondary objective of the Phase 2 portion of the trial is to assess treatment response using traditional RECIST criteria. Serial biopsies will be taken of selected injected and non-injected tumor lesions to assess immune changes and response assessments. We anticipate that the trial may enroll approximately 60 patients.

In September 2016, we disclosed early clinical results from the 4 mg and 8 mg dosing cohorts of the Phase 1 ipilimumab combination portion of the trial in which three of six evaluable patients demonstrated clinical responses (one complete response and two partial responses). We also disclosed that the drug was well tolerated through the initial dosing of the 16 mg dosing cohort. We are currently enrolling the 32 mg dosing cohort in the ipilimumab arm of the trial as well as the 8 mg dosing cohort in the pembrolizumab arm of the trial. We will be presenting available translational, efficacy and safety data findings from the 4 mg, 8 mg and 16 mg dosing cohorts in the ipilimumab arm during an oral presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2016.

We plan to transition to the Phase 2 portion of the clinical trial upon completion of both the ipilimumab and pembrolizumab dose finding arms. In the Phase 2 portion of the trial, patients will be randomized to receive intra-tumoral IMO-2125 in combination with either ipilimumab or pembrolizumab at the recommended dose determined by the Phase 1 portion of the trial. The Phase 2 portion of the trial will be conducted at multiple clinical sites.

We expect to have data from each of the cohorts in the ipilimumab arm of the Phase 1 portion of the trial by the end of 2016 and plan to then request an End-of-Phase 1 meeting with the U.S. Food and Drug Administration, or the FDA, to discuss the regulatory pathway for IMO-2125 in the anti-PD1 refractory metastatic melanoma population.



Additionally, we are planning to initiate a Phase 1 trial with IMO-2125 administered as a single agent intra-tumorally in multiple tumor types during the first quarter of 2017. We are also planning to initiate a Phase 2 clinical trial with IMO-2125 administered intra-tumorally together with other checkpoint inhibitors in multiple tumor types in the second half of 2017.

#### IMO-8400 in Rare Diseases

We have initiated clinical development of IMO-8400 for the treatment of rare diseases. We have selected dermatomyositis as the first rare disease for which we are developing IMO-8400. We 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.

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We considered that multiple independent research studies across a broad range of autoimmune diseases, including both dermatomyositis and psoriasis, have demonstrated that the over-activation of TLRs plays a critical role in disease maintenance and progression. In autoimmune diseases, endogenous nucleic acids released from damaged or dying cells initiate signaling cascades through TLRs, leading to the induction of multiple pro-inflammatory cytokines. This inflammation causes further damage to the body's own tissues and organs and the release of more self-nucleic acids, creating a self-sustaining autoinflammatory cycle that contributes to chronic inflammation in the affected tissue, promoting disease progression.

We believe that we demonstrated proof of concept for our approach of using TLRs to inhibit the over-activation of specific TLRs for the treatment of psoriasis and potentially other autoimmune diseases in a randomized, double-blind, placebo-controlled Phase 2 clinical trial of IMO-8400 that we conducted in patients with moderate to severe plaque psoriasis, a well-characterized autoimmune disease. In this trial, we evaluated IMO-8400 at four subcutaneous dose levels of 0.075 mg/kg, 0.15 mg/kg, 0.3 mg/kg, and 0.6 mg/kg, versus placebo, administered once weekly for 12 weeks in 46 patients. The trial met its primary objective as IMO-8400 was well tolerated at all dose levels with no treatment-related discontinuations, treatment-related serious adverse events or dose reductions. The trial also met its secondary objective of demonstrating clinical activity in psoriasis patients, as assessed by the Psoriasis Area Severity Index.

Dermatomyositis is a rare, debilitating, inflammatory muscle and skin disease associated with significant morbidity, decreased quality of life and an increased risk of premature death. While the cause of dermatomyositis is not well understood, the disease process involves immune system attacks against muscle and skin that lead to inflammation and tissue damage. Major symptoms can include progressive muscle weakness, severe skin rash, calcium deposits under the skin (calcinosis), difficulty swallowing (dysphagia) and interstitial lung disease. We believe, based on internal commercial research that we conducted, that dermatomyositis affects approximately 25,000 people in the United States, and is about twice as common in women as men, with a typical age of onset between 45 and 65 years in adults. Dermatomyositis represents one form of myositis, a spectrum of inflammatory muscle diseases that also includes juvenile dermatomyositis, polymyositis and inclusion body myositis.

In August 2014, we initiated a collaboration with The Myositis Association, or TMA, a leading U.S. patient advocacy organization focused on myositis, to advance the clinical development of IMO-8400 for the treatment of dermatomyositis. Under the collaboration, we and TMA agreed to develop educational programs for patients and healthcare providers on TLR antagonism and opportunities to participate in clinical research. In addition, we formed an advisory committee of leading independent experts in the treatment of dermatomyositis to advise us on the development of IMO-8400 in dermatomyositis.

In December 2015, we initiated a Phase 2, randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability and treatment effect of IMO-8400 in adult patients with dermatomyositis. Eligibility criteria include evidence of active skin and muscle involvement. Patients in the trial are randomized to one of three groups to receive once weekly subcutaneous injections of: placebo, 0.6 mg/kg or 1.8 mg/kg of IMO-8400 for a period of 24 weeks. The trial is expected to enroll approximately 36 patients and is being conducted at approximately 22 centers in the United States, the United Kingdom and Sweden. The primary efficacy endpoint is the change from baseline in the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI), a validated outcome measure of skin disease. Additional exploratory endpoints include muscle strength and function (which are among the International Myositis Assessment & Clinical Studies Group (IMACS) core set measures), patient-reported quality of life and biochemical markers of disease activity. We expect to complete enrollment of this trial in the second half of 2017 with data available in early 2018.

Third-generation Antisense (3GA)

Third-generation Antisense (3GA) Technology to Target mRNA

We are developing our 3GA technology to "turn off" the mRNA associated with disease causing genes. We have designed 3GA oligonucleotides to specifically address challenges associated with earlier generation antisense and RNAi technologies.

Our focus is on creating 3GA candidates targeted to specific genes to treat cancer and rare diseases. Our key considerations in identifying disease indications and gene targets in our 3GA program include: strong evidence that the disease is caused by a specific protein; clear criteria to identify a target patient population; biomarkers for early assessment of clinical proof of concept; a targeted therapeutic mechanism of action; unmet medical need to allow for a rapid

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development path to approval and commercial opportunity. Based on these criteria, we are developing 3GA compounds against multiple gene targets, including NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4). Potential disease indications include, but are not limited to, interstitial cystitis, lupus nephritis, uveitis and facioscapulohumeral muscular dystrophy (FSHD).

We are currently conducting clinical, regulatory and commercial analysis activities of these compounds, including IND-enabling studies of a compound against NLRP3, and plan to submit an investigational new drug application, or IND, for one of these compounds in 2017 and initiate a Phase 1 human clinical proof-of-concept trial in the second half of 2017. We plan to announce the first disease indication for which we plan to develop one of our 3GA compounds in January 2017. During the first half of 2016, we generated 3GA compounds for a series of additional gene targets. We expect that these will enable us to continue to expand our pipeline opportunities for both internal development as well as collaborations in areas outside of our focus. We have recently presented several pre-clinical data updates at significant oligonucleotide medical and scientific conferences.

### Collaboration with GlaxoSmithKline Intellectual Property Development Limited

In November 2015, we entered into a collaboration and license agreement with GlaxoSmithKline Intellectual Property Development Limited, or GSK, to license, research, develop and commercialize pharmaceutical compounds from our 3GA technology for the treatment of selected targets in renal disease, which we refer to as the GSK Agreement. The initial collaboration term is currently anticipated to last between two and four years. In connection with the GSK Agreement, GSK identified an initial target for us to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan, currently estimated to take 27 months to complete. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. Once GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

At any time during the first two years of the GSK Agreement, GSK has the option to select up to two additional targets, for further research under mutually agreed upon research plans. GSK may then designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate.

Under the terms of the GSK Agreement, we received a \$2,500,000 upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. We are eligible to receive up to approximately \$100,000,000 in license, research, clinical development and commercialization milestone payments, including the \$2,500,000 upfront payment. Approximately \$9,000,000 of these milestone payments are payable by GSK upon the identification of additional targets, the completion of current and future research plans and the designation of development candidates. Approximately \$89,000,000 is payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, we are eligible to receive royalty payments based on net sales of licensed products following

commercialization at varying rates of up to five percent on annual net sales, as defined in the GSK Agreement.

#### Additional Programs

IMO-9200 for Autoimmune Disease. We have developed a second novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. In 2015, we completed a Phase 1 clinical trial of IMO-9200 in healthy subjects as well as additional preclinical studies of IMO-9200 for autoimmune diseases. In 2015, we determined not to proceed with the development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of our company. We continue to explore and pursue strategic alternatives for IMO-9200.

IMO-8400 for B-Cell Lymphomas. In December 2013, we initiated a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia, and in March 2014, we initiated a Phase 1/2 clinical trial of IMO-8400 in diffuse large B-cell lymphoma, or DLBCL, harboring the MYD88 L265P oncogenic mutation.

In December 2015, we presented interim clinical data from the Phase 1/2 clinical trial of IMO-8400 in Waldenström's macroglobulinemia, which showed signals of positive clinical activity as well as safety in the first three dosing cohorts of the trial. For much of 2016, we continued dose escalation to a higher dose level to determine if stronger activity would be observed.

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In September 2016, we announced that we had suspended the clinical development of IMO-8400 for B-cell lymphomas, including our ongoing trials in Waldenström's macroglobulinemia and DLBCL, and plan to explore strategic alternatives for IMO-8400 in these indications. This decision was based upon our prioritization of the clinical development plans for IMO-2125 and our assessment that the level of clinical activity seen in the Waldenström's macroglobulinemia trial would not support the development of IMO-8400 for these indications as a monotherapy, the very slow enrollment rate in DLBCL and our commercial assessment. No patients are currently enrolled in the trial of IMO-8400 in DLBCL, and we will not enroll any additional patients in that trial. We plan to finish treating patients in the trial of IMO-8400 in Waldenström's macroglobulinemia but enrollment of new patients has been suspended. In these trials under our B-cell lymphoma program, IMO-8400 was generally well tolerated at all dose levels evaluated, with only one treatment-related discontinuation due to adverse events and no dose reductions. The treatment-related discontinuation involved a single patient who experienced a serious adverse event that was possibly related to IMO-8400.

### Accumulated Deficit

As of September 30, 2016, we had an accumulated deficit of \$539,292,000. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue, sales-based milestones or royalties from our development programs until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical development and comply with comprehensive regulatory requirements.

### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to stock-based compensation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the notes to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2015. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, stock-based compensation and research and development prepayments, accruals and related expenses, as described under the caption “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2015, fit the description of critical accounting estimates and judgments. There were no changes in these policies during the nine months ended September 30, 2016.

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## RESULTS OF OPERATIONS

## Three and Nine Months Ended September 30, 2016 and 2015

## Alliance Revenue

Alliance revenue increase by approximately \$303,000 from \$20,000 in the three months ended September 30, 2015 to \$323,000 in the three months ended September 30, 2016 and by approximately \$859,000 from \$59,000 in the nine months ended September 30, 2015 to \$918,000 in the nine months ended September 30, 2016 as a result of revenue recognized under the GSK Agreement. In November 2015, in connection with the execution of the GSK Agreement, we received a \$2,500,000 upfront payment that we recorded as deferred revenue. We are recognizing this deferred revenue as revenue on a straight line basis over the anticipated 27-month performance period under the GSK Agreement. Accordingly, we recognized approximately \$278,000 and \$833,000 of alliance revenue related to the GSK Agreement during the three and nine months ended September 30, 2016, respectively. We also recognized revenue from the reimbursement by licensees of costs associated with patent maintenance as alliance revenue in the three and nine months ended September 30, 2016 and 2015.

## Research and Development Expenses

Research and development expenses increased by \$1,939,000, or 26%, from \$7,454,000 for the three months ended September 30, 2015, to \$9,393,000 for the three months ended September 30, 2016 and by \$3,683,000, or 15%, from \$25,134,000 for the nine months ended September 30, 2015, to \$28,817,000 for the nine months ended September 30, 2016. In the following table, research and development expenses are set forth in the following six categories which are discussed beneath the table:

	Three months ended		Percentage Increase (Decrease)	Nine months ended		Percentage Increase (Decrease)
	September 30, 2016	September 30, 2015		September 30, 2016	September 30, 2015	
IMO-8400 external development expense	\$ 2,771	\$ 2,426	14%	\$ 8,814	\$ 6,952	27%
IMO-2125 external development expense	723	597	21%	2,330	597	290%
IMO-9200 external development expense	185	139	33%	471	2,404	(80%)



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Other drug development expense	3,246	1,962	65%	9,668	8,673	11%
Basic discovery expense	2,468	2,330	6%	7,534	6,508	16%
	\$ 9,393	\$ 7,454	26%	\$ 28,817	\$ 25,134	15%

IMO-8400 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately \$31,940,000 in IMO-8400 external development expenses through September 30, 2016, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis; preparation for and conduct of our Phase 1/2 clinical trial in patients with Waldenström’s macroglobulinemia and our Phase 1/2 clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation, which we announced plans to discontinue; the preparation for and conduct of our ongoing Phase 2 clinical trial in patients with dermatomyositis; the manufacture of additional drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with B-cell lymphoma harboring the MYD88 L265P oncogenic mutation.

The increases in our IMO-8400 external development expenses in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, were primarily due to increases in costs associated with our ongoing Phase 2 clinical trial in patients with dermatomyositis and costs incurred in connection with the manufacture of additional drug substance for use in our clinical trials in the three and nine months ended September 30, 2016. An increase in the cost of conducting our Phase 1/2 clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation also contributed to the increase in IMO-8400 external development expenses in the three months ended September 30, 2016. These increases were partially offset by a decrease in the cost of developing a companion diagnostic for identification of patients with B-cell lymphoma harboring the MYD88 L265P oncogenic mutation.

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We expect our IMO-8400 external development expenses to increase during 2016, as compared to 2015. In September 2016, we announced that we had suspended the clinical development of IMO-8400 for B-cell lymphomas, including our trials in Waldenström's macroglobulinemia and DLBCL, and plan to explore strategic alternatives for IMO-8400 in these indications. We expect to continue to incur costs associated with IMO-8400 as we continue our ongoing Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis, finish treating enrolled patients in our clinical trial of IMO-8400 in Waldenström's macroglobulinemia and wind down our clinical development of IMO-8400 in Waldenström's macroglobulinemia and DLBCL.

**IMO-2125 External Development Expenses.** These expenses include external expenses that we have incurred in connection with the development of IMO-2125 as part of our immuno-oncology program. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2125 clinical development in immuno-oncology, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of IMO-2125 as part of our immuno-oncology program in July 2015 and from July 2015 through September 30, 2016 we incurred approximately \$3,513,000 in IMO-2125 external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of the ongoing Phase 1/2 clinical trial being conducted under our research alliance with MD Anderson to assess the safety and efficacy of IMO-2125 in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma, the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies. The \$3,513,000 in IMO-2125 external development expenses excludes costs incurred prior to July 2015 with respect to IMO-2125, including costs incurred for the development of IMO-2125 for the treatment of patients with chronic hepatitis C virus which we discontinued in the third quarter of 2011.

We expect our IMO-2125 external development expenses to increase during 2016, as compared to 2015, as we plan to continue our Phase 1/2 clinical trial being conducted under our research alliance with MD Anderson to assess the safety and efficacy of IMO-2125 in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma, work on the design and planning for additional clinical trials of IMO-2125 and develop our strategy to optimize IMO-2125, and continue manufacturing activities and nonclinical studies.

**IMO-9200 External Development Expenses.** These expenses include external expenses that we have incurred in connection with IMO-9200 since October 2014, when we commenced clinical development of IMO-9200. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-9200 clinical development but exclude internal costs such as payroll and overhead expenses. We have incurred approximately \$4,632,000 in IMO-9200 external development expenses from October 2014 through September 30, 2016, including costs associated with our Phase 1 clinical trial in healthy subjects, the manufacture of additional drug substance for use in our clinical and nonclinical trials and additional nonclinical studies. We classified the IMO-9200 external development expenses incurred prior to October 2014 in other drug development expenses.

The decrease in IMO-9200 external development expenses in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, reflects decreases in clinical and nonclinical trial costs, drug manufacturing and nonclinical study costs incurred during the nine months ended September 30, 2016, as compared to the corresponding 2015 period. The increase in IMO-9200 external development expenses in the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, resulted from the manufacture of drug substance for stability testing. We expect our IMO-9200 external development expenses to decrease during 2016, as compared to 2015, as we determined not to proceed with the development of IMO-9200 but continue to explore and pursue strategic alternatives for IMO-9200.

Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified