IDERA PHARMACEUTICALS, INC.
Form 10-Q
August 06, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2015

or

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

For transition period from _____ to _____.

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(617) 679-5500

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

Common Stock, par value $.001 per share	118,122,662
Class	Outstanding as of July 15, 2015

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FORWARD-LOOKING STATEMENTS

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

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except per share amounts)	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,369	$ 19,971
Short-term investments	39,368	21,256
Prepaid expenses and other current assets	1,602	1,203
Total current assets	77,339	42,430
Long-term investments	30,567	7,344
Property and equipment, net	1,575	1,306
Restricted cash and other assets	350	346
Total assets	$ 109,831	$ 51,426
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,845	$ 2,458
Accrued expenses	3,411	4,460
Current portion of note payable	247	128
Total current liabilities	6,503	7,046
Note payable, net of current portion	636	742
Other liabilities	183	236
Total liabilities	7,322	8,024
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, Authorized 5,000 shares		
Series E convertible preferred stock, Designated zero shares and 424 shares at June 30, 2015 and December 31, 2014, respectively; Issued and outstanding zero shares		
Series A convertible preferred stock, Designated 1,500 shares; Issued and outstanding 1 share		
Common stock, $0.001 par value, Authorized 280,000 shares; Issued and outstanding 118,110 and 94,829 shares at June 30, 2015 and December 31, 2014,	118	95

respectively		
Additional paid-in capital	579,194	494,850
Accumulated deficit	(476,726)	(451,526)
Accumulated other comprehensive loss	(77)	(17)
Total stockholders equity	102,509	43,402
Total liabilities and stockholders equity	$ 109,831	$ 51,426

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

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Alliance revenue	$ 5	$ 38	$ 39	$ 41
Operating expenses:				
Research and development	8,960	5,637	17,680	12,570
General and administrative	3,821	2,730	7,658	4,773
Total operating expenses	12,781	8,367	25,338	17,343
Loss from operations	(12,776)	(8,329)	(25,299)	(17,302)
Other income (expense):				
Investment income, net	48	16	62	31
Foreign currency exchange gain	9	5	37	2
Net loss	(12,719)	(8,308)	(25,200)	(17,269)
Preferred stock dividends		118		303
Net loss applicable to common stockholders	$ (12,719)	$ (8,426)	$ (25,200)	$ (17,572)
Basic and diluted net loss per common share applicable to common stockholders (Note 13)	$ (0.11)	$ (0.10)	$ (0.23)	$ (0.22)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	118,002	82,961	111,570	79,509
Net loss	$ (12,719)	$ (8,308)	$ (25,200)	$ (17,269)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale securities	(78)	(1)	(60)	10
Comprehensive loss	$ (12,797)	$ (8,309)	$ (25,260)	$ (17,259)

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, 2015	2014
Cash Flows from Operating Activities:		
Net loss	$ (25,200)	$ (17,269)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,869	1,320
Depreciation and amortization expense	213	78
Amortization of investment premiums	199	96
Issuance of common stock for services rendered	60	36
Non-employee stock option expense	495	(3)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(399)	38
Accounts payable, accrued expenses, and other liabilities	(806)	1,947
Net cash used in operating activities	(22,569)	(13,757)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(56,196)	(2,619)
Maturities of available-for-sale securities	13,602	2,000
Sales of available-for-sale securities	999	
Purchases of property and equipment	(376)	(533)
Net cash used in investing activities	(41,971)	(1,152)
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	80,599	37,202
Dividends paid		(463)
Proceeds from exercise of common stock warrants and options and employee stock purchases	343	6,780
Payments on capital lease	(4)	(2)
Net cash provided by financing activities	80,938	43,517
Net increase in cash and cash equivalents	16,398	28,608
Cash and cash equivalents, beginning of period	19,971	26,278
Cash and cash equivalents, end of period	$ 36,369	$ 54,886

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, 2015

(UNAUDITED)

(1) Organization

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

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

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

The Company is also planning to initiate a clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma, and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target. IMO-2125 and IMO-2055 are novel synthetic oligonucleotide agonists of TLR-9.

The Company is also developing its third-generation antisense drug candidates to specifically address challenges associated with earlier generation antisense and RNAi technologies. Although currently used technologies to silence RNA have demonstrated the ability to inhibit the expression of disease-associated proteins, the Company believes that to reach their full therapeutic potential, gene silencing technologies need to achieve an improved therapeutic index with efficient systemic delivery without using a delivery technology, reduced immunotoxicity and increased potency. The Company is currently undertaking an analysis of oncology and rare disease indications for development of drug candidates generated from its third-generation antisense technology. The Company is currently conducting disease

model studies and plans to begin investigational new drug application (IND)-enabling development programs in each of the first two disease indications selected for further development in its third-generation antisense program in the second half of 2015.

As of June 30, 2015, the Company had an accumulated deficit of $476,726,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

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

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(2) New Accounting Pronouncements - Recently Issued

In May 2014, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2014-09 Revenue from Contracts with Customers (Topic 606). 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.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern (ASU 2014-15). ASU 2014-15 amends FASB ASC 205-40 Presentation of Financial Statements Going Concern, by providing guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements, including requiring management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements and providing certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. ASU 2014-15 will be effective for fiscal years beginning after December 15, 2016 and for interim periods thereafter. Early adoption of ASU 2014-15 is permitted. The Company is currently evaluating the effect that the adoption of ASU 2014-15 will have on its financial statements.

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with United States Generally Accepted Accounting Principles (U.S. GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the six months ended June 30, 2015 are not necessarily indicative of results that may be expected for the year ending December 31, 2015. For further information, refer to the financial statements and footnotes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the SEC on March 12, 2015.

(4) Financial Instruments

The fair value of the Company s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 6, Fair Value of Assets and Liabilities. The Company is required to disclose the estimated fair values of its financial instruments. The Company s financial instruments consist of cash, cash equivalents, available-for-sale investments, receivables and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of June 30, 2015 and December 31, 2014. As of June 30, 2015 and December 31, 2014, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the note issued under the Company s loan and security agreement, which is discussed in Note 5(a) to the financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014, including put and call features which the Company determined are clearly and closely associated with the debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial.

(5) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at June 30, 2015 and December 31, 2014 consisted of cash, commercial paper and money market funds. As of June 30, 2015, the Company had an unsettled investment purchase trade amounting to approximately $938,000 included in long-term investments and accounts payable because the cash was not deducted from the Company s account until July 2015.

(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

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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 June 30, 2015 and December 31, 2014 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)		Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2015					
Assets					
Money market funds		$ 29,773	$ 29,773	$	$
Other cash equivalents	commercial paper	5,498		5,498	
Short-term investments	commercial paper	13,957		13,957	
Short-term investments	corporate bonds	19,097		19,097	
Short-term investments	municipal bonds	6,314		6,314	
Long-term investments	corporate bonds	28,161		28,161	
Long-term investments	municipal bonds	2,406		2,406	
Total Assets		$ 105,206	$ 29,773	$ 75,433	$
Total Liabilities		$	$	$	$
December 31, 2014					
Assets					
Money market funds		$ 17,156	$ 17,156	$	$
Other cash equivalents	commercial paper	2,500		2,500	
Short-term investments	commercial paper	4,494		4,494	
Short-term investments	certificate of deposit	500		500	
Short-term investments	corporate bonds	14,357		14,357	
Short-term investments	municipal bonds	1,905		1,905	
Long-term investments	corporate bonds	7,344		7,344	
Total Assets		$ 48,256	$ 17,156	$ 31,100	$
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, certificate of deposit and municipal bond investments whose fair value 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. The fair value of certificates of deposit approximates carrying value. 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 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 June 30, 2015 or December 31, 2014.

(7) Investments

The Company s available-for-sale investments at fair value consisted of the following at June 30, 2015 and December 31, 2014:

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		June 30, 2015			
		Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
		(In thousands)			
Short-term investments	commercial paper	$ 13,949	$	$ 8	$ 13,957
Short-term investments	corporate bonds	19,102	(9)	4	19,097
Short-term investments	municipal bonds	6,317	(3)		6,314
Total short-term investments		39,368	(12)	12	39,368
Long-term investments	corporate bonds	28,238	(77)		28,161
Long-term investments	municipal bonds	2,406			2,406
Total long-term investments		30,644	(77)		30,567
Total investments		$ 70,012	$ (89)	$ 12	$ 69,935

		December 31, 2014			
		Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
		(In thousands)			
Short-term investments	commercial paper	$ 4,493	$	$ 1	$ 4,494
Short-term investments	certificate of deposit	500			500
Short-term investments	corporate bonds	14,364	(7)		14,357
Short-term investments	municipal bonds	1,906	(1)		1,905
Total short-term investments		21,263	(8)	1	21,256
Long-term investments	corporate bonds	7,354	(10)		7,344
Total long-term investments		7,354	(10)		7,344
Total investments		$ 28,617	$ (18)	$ 1	$ 28,600

The Company had no realized gains or losses from available-for-sale securities in the three months ended June 30, 2015 and 2014. There were no losses or other-than-temporary declines in value included in Investment income, net on the Company s condensed statements of operations and comprehensive loss for any securities for the six months ended June 30, 2015 and 2014. The Company had no auction rate securities as of June 30, 2015 and December 31, 2014. 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 June 30, 2015 and December 31, 2014, net property and equipment at cost consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Leasehold improvements	$ 581	$ 525
Laboratory equipment and other	4,197	3,884
Total property and equipment, at cost	4,778	4,409
Less: accumulated depreciation	3,203	3,103
Property and equipment, net	$ 1,575	$ 1,306

Depreciation and amortization expense on property and equipment was approximately $110,000 and $47,000 in the three months ended June 30, 2015 and 2014, respectively, and approximately $203,000 and $78,000 in the six months ended June 30, 2015 and 2014, 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 June 30, 2015 and December 31, 2014, the restricted cash amounted to $311,000 held in certificates of deposit securing a line of credit for the lessor.

(10) Exton Office Lease

On April 1, 2015, the Company entered into a lease of approximately 4,300 square feet of office space in Exton, Pennsylvania. The term of the lease ends on April 30, 2020, with one five-year renewal option exercisable by the Company. The Company classifies the lease as an operating lease. Future minimum commitments as of June 30, 2015 under the Company s Exton office lease agreement are approximately:

December 31,	Operating Lease (In thousands)
2015	$ 50
2016	76
2017	78
2018	81
2019	83
2020	28
	$ 396

(11) 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 six months ended June 30, 2015 and 2014 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 gain (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 gain (loss) for the six months ended June 30, 2015 and 2014:

(In thousands)	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Accumulated unrealized loss on available-for-sale securities at beginning of period	$ (17)	$ (7)
Change during the period	(60)	10

Accumulated unrealized (loss) gain on available-for-sale securities at end of period	$ (77)	$ 3

(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 of $1,523,000 and $785,000 in its statements of operations and comprehensive loss for the three months ended June 30, 2015 and 2014, respectively, and $2,869,000 and $1,320,000 in its statements of operations and comprehensive loss for the six months ended June 30, 2015 and 2014, respectively, for stock-based compensation expense attributable to stock-based payments made to employees and directors. The stock-based compensation for the three and six months ended June 30, 2015 includes approximately $329,000 for the recognition of additional cost associated with the acceleration of vesting and extension of the exercise period of a retiring director s stock options due to a modification. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions apply to the options to purchase 2,034,000 and 2,116,000 shares of common stock granted to employees and directors during the six months ended June 30, 2015 and 2014, respectively:

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	Six Months Ended June 30,	
	2015	2014
Average risk free interest rate	1.3%	1.6%
Expected dividend yield		
Expected lives (years)	4.3	4.8
Expected volatility	92.0%	83.0%
Weighted average grant date fair value of options granted during the period (per share)	$ 2.61	$ 2.61
Weighted average exercise price of options granted during the period (per share)	$ 3.92	$ 4.01

The expected lives and the expected volatility of the options granted during the six months ended June 30, 2015 and 2014 are based on historical experience. All options granted during the six months ended June 30, 2015 and 2014 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 Applicable to Common Stockholders

For the three and six months ended June 30, 2015 and 2014, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 74,628,647 and 80,016,676 for the six months ended June 30, 2015 and 2014, respectively, and consist of stock options, preferred stock and warrants.

For the three months ended June 30, 2014, net loss per common share applicable to common stockholders reflects $118,000 in dividends accrued on shares of the Series E convertible preferred stock (Series E preferred stock). For the six months ended June 30, 2014, net loss per common share applicable to common stockholders reflects $303,000 in dividends accrued on shares of the Company s Series D convertible preferred stock (Series D preferred stock) and the Series E preferred stock. There were no dividends accrued on the Series D preferred stock and Series E preferred stock during the three and six months ended June 30, 2015 because the Series D preferred stock and Series E preferred stock were converted to common stock during February 2014 and December 2014, respectively.

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

The Company issued 265,558 and 3,364,033 shares of common stock and received total proceeds of $343,000 and $6,780,000 for warrant and stock option exercises and employee stock purchases under the Company s 1995 Employee Stock Purchase Plan during the six months ended June 30, 2015 and June 30, 2014, respectively, as follows:

	Six Months Ended June 30, 2015		Six Months Ended June 30, 2014	
(In thousands)	Shares	Proceeds	Shares	Proceeds
Warrant exercises		$	3,044	$ 5,990
Stock option exercises	255	311	315	780
Employee stock purchases	11	32	5	10
Total	266	$ 343	3,364	$ 6,780

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(15) Related Party Transactions

February 2014 Conversion of Series D Preferred Stock

On January 10, 2014, the Company notified Pillar Pharmaceuticals I, L.P. (Pillar I), an investment partnership managed by one of the Company s directors and significant stockholders and the holder of all 1,124,260 shares of the Company s issued and outstanding Series D preferred stock, of its intention to redeem the Series D preferred stock on February 10, 2014 in accordance with the terms of the Certificate of Designations, Preferences and Rights of Series D Preferred Stock (the Series D Certificate of Designations). Following this notice, Pillar I had the right to convert its Series D preferred stock into shares of the Company s common stock at any time prior to the close of business on February 9, 2014. On February 6, 2014, Pillar I converted such shares into 6,266,175 shares of the Company s common stock in accordance with the terms of the Series D Certificate of Designations. As a result of the conversion, no shares of the Company s Series D preferred stock remain outstanding.

On March 28, 2014, the Company filed a Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Convertible Preferred Stock with the State of Delaware Secretary of State which eliminated the designation of the shares of Series D preferred stock.

December 2014 Conversion of Series E Preferred Stock

In December 2014, the holders of Series E preferred stock converted such shares into 8,484,840 shares of common stock in accordance with the terms of the Certificate of Designations, Preferences and Rights of Series E Preferred Stock. As a result of this conversion, no shares of Series E preferred stock remain outstanding.

On March 12, 2015, the Company filed a Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series E Convertible Preferred Stock with the State of Delaware Secretary of State which eliminated the designation of the shares of Series E preferred stock.

Director Stock Purchases

The Company issued 15,472 and 8,546 shares of common stock in lieu of director board and committee fees of approximately $60,000 and $36,000 pursuant to the Company s director compensation program during the six months ended June 30, 2015 and 2014, respectively.

See also Note 16, Registration Rights Agreement, and Note 17, Financing for additional information on related party transactions.

(16) Registration Rights Agreement

On February 9, 2015, the Company entered into a registration rights agreement with investment funds (the Selling Stockholders) affiliated with Baker Bros. Advisors LP and two members of the Company s board of directors, relating to the registration for resale of the shares of the Company s common stock held by the Selling Stockholders, including the shares of the Company s common stock that may be issued upon the exercise of warrants held by the Selling Stockholders (collectively, the Registrable Shares).

Under the registration rights agreement, the Company has agreed to file a registration statement on Form S-3 with the SEC within 60 days after demand by any of the Selling Stockholders, to register for resale the Registrable Shares. The Company has agreed to use its reasonable best efforts to cause the registration statement to become effective as

promptly as practicable after filing, and to remain effective until the shares being registered thereunder have been sold or may be sold freely without limitations or restrictions as to volume or manner of sale pursuant to Rule 144. The registration rights agreement contains customary covenants and agreements by the Company and customary indemnification obligations of the Company and the Selling Stockholders.

(17) Financing

February 19, 2015 Follow-on Underwritten Public Offering

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 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.

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On February 19, 2015, Baker Bros. Advisors LP and certain of its affiliated funds (which include the Selling Stockholders) (collectively, Baker Brothers) held 6,965,432 shares of the Company s common stock, warrants to purchase up to 20,316,327 shares of the Company s common stock at an 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.

February 10, 2014 Follow-on Underwritten Public Offering

On February 10, 2014, the Company closed a follow-on underwritten public offering, in which it sold 7,867,438 shares of common stock at a price to the public of $4.00 per share and pre-funded warrants to purchase up to 2,158,750 shares of common stock at a price to the public of $3.99 per share for aggregate gross proceeds of $40.1 million. The pre-funded warrants have an exercise price of $0.01 per share and will expire if not exercised by February 10, 2021. The net proceeds to the Company from the offering, after deducting underwriters discounts and commissions and other offering costs and expenses and excluding the proceeds of the exercise of the pre-funded warrants, if any, were approximately $37.2 million.

(18) Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

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 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 technology, which was previously referred to as our GSO 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 act by modulating the activity of specific TLRs. In addition, using our third-generation antisense technology, we are developing drug candidates to turn off the messenger RNA, or mRNA, associated with disease causing genes. We believe that our third-generation antisense 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 development of drug candidates for oncology and rare diseases, as we believe we can develop and commercialize targeted therapies on our own in disease indications characterized by small, well-defined patient populations with serious unmet medical needs. To the extent we seek to develop drug candidates for broader disease indications, we plan to explore potential collaborative alliances to support late-stage development and commercialization.

TLR Modulation Technology Platform

TLRs play a central role in the innate immune system by regulating signaling cascades that stimulate inflammation. 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 antagonists and agonists to act by modulating the activity of targeted TLRs. A TLR antagonist is a compound that inhibits an immune response by downregulating the activity of the targeted TLR. A TLR agonist is a compound that stimulates an immune response by increasing the activity of the targeted TLR.

Our TLR antagonist lead drug candidates are IMO-8400 and IMO-9200, which are both antagonists of TLR7, TLR8 and TLR9. We also have created compounds that are agonists of TLR3, TLR7, TLR8 or TLR9. Our TLR agonist lead drug candidates are IMO-2055 and IMO-2125, which are both agonists of TLR9.

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We are evaluating IMO-8400, a novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of rare diseases. We are also evaluating IMO-9200, a novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, for the treatment of inflammatory bowel disease, or IBD. In addition, we are planning to advance our TLR9 agonist, IMO-2125, into clinical development for intratumoral injection in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target.

IMO-8400 Development Program in Genetically Defined Forms of B-cell Lymphoma

We are developing IMO-8400 for the treatment of certain B-cell lymphomas in which the MYD88 L265P oncogenic mutation is present. Oncogenic mutations are changes in the DNA of tumor cells that promote the survival and proliferation of tumor cells. MYD88 is an adaptor protein in the TLR signaling pathway that mediates TLR signaling.

We believe, based on independent research and our own preclinical research, that the inhibition of specific TLRs may be a useful approach in the treatment of certain B-cell lymphomas in which the MYD88 L265P oncogenic mutation is present. In independent research reported by investigators from the National Cancer Institute at the American Association for Cancer Research Annual Meeting in 2013, it was shown that the MYD88 L265P oncogenic mutation over-activated TLR7 and TLR9-mediated signaling and that inhibition of TLR7 and TLR9 promoted tumor cell death in preclinical models.

In December 2014, we announced that the U.S. Food and Drug Administration, or the FDA, had granted orphan drug designation for IMO-8400 for the treatment of Waldenström s macroglobulinemia. In April 2015, we announced that the FDA had granted orphan drug designation for IMO-8400 for the treatment of diffuse large B-cell lymphoma, or DLBCL. Orphan drug designation is granted by the FDA Office of Orphan Products Development to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals annually in the United States. This designation provides certain incentives, including eligibility for federal grants, research and development tax credits, a waiver of Prescription Drug User Fee Act filing fees and a seven-year marketing exclusivity period, once the product is approved and as long as orphan drug designation is maintained.

Phase 1/2 Clinical Trial of IMO-8400 in Waldenström s Macroglobulinemia. In 2014, we initiated patient treatment in our ongoing open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia who have relapsed after or were refractory to prior therapy. Objectives of the trial include evaluation of safety and tolerability of escalating IMO-8400 dose levels and assessment of IMO-8400 clinical activity using disease-specific international guidelines for classifying clinical response. In this trial, we are evaluating doses of 0.6, 1.2 and 2.4 mg/kg per week administered as subcutaneous injections for 24 weeks. For the 2.4 mg/kg dose level, we are administering IMO-8400 in two doses of 1.2 mg/kg per week. We expected to enroll up to approximately 30 patients in this trial. Patients who complete 24 weeks of IMO-8400 treatment are eligible to enroll in an on-going open-ended extension protocol to evaluate the long-term safety, tolerability, and clinical activity of IMO-8400 in patients with Waldenström s macroglobulinemia. We have enrolled the targeted number of patients at each of the three dose levels to fulfill the requirements for dose escalation. We currently expect to have data from this trial in the fourth quarter of 2015.

Phase 1/2 Clinical Trial of IMO-8400 in Diffuse Large B-cell Lymphoma. We are also conducting an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL who have relapsed after or were refractory to prior therapy. With the concurrence of the FDA Center for Devices and Radiological Health, we plan to enroll in this trial only those patients with tumors that are positive for the presence of the MYD88 L265P oncogenic mutation. Objectives of the trial include evaluation of safety and tolerability of escalating IMO-8400 dose levels and

assessment of IMO-8400 clinical activity using disease-specific international guidelines for classifying clinical response. In this trial, we plan to evaluate escalating doses of 0.6, 1.2 and 2.4 mg/kg per week, administered as subcutaneous injections for as long as the patient may be deriving clinical benefit from the treatment. For each dose level, we plan to administer IMO-8400 subcutaneously in equally divided doses given twice per week. We may enroll up to 30 patients in this dose-ranging trial. We have activated all 13 planned clinical sites and initiated screening of potential trial participants for the MYD88 L265P oncogenic mutation. The initial patient enrolled in the trial began IMO-8400 treatment in April 2015. We plan to complete this trial and have the data available during 2016. In this trial, we plan to use a prototype companion diagnostic we developed under our collaboration agreement with Abbott Molecular, Inc., or Abbott Molecular, to identify patients with the MYD88 L265P oncogenic mutation.

We believe that Waldenström s macroglobulinemia and DLBCL in patients with the MYD88 L265P oncogenic mutation are rare diseases with serious unmet medical needs, based on prevalence of the indications and our understanding of the current treatment paradigms. If we observe sufficient tolerability and a therapeutic effect in either or both of our Phase 1/2 clinical trials, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory path for the applicable

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program. We cannot predict whether or when any of our drug candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval.

Application of TLR Agonists in Immuno-Oncology

We have completed and are conducting additional preclinical studies to characterize potential combination regimens with various checkpoint inhibitors and our TLR9 agonists. In June 2015, we entered into a strategic clinical research alliance with MD Anderson Cancer Center to advance clinical development of intratumoral TLR9 agonists in combination with checkpoint inhibitors. We intend to initiate the first trial of the research alliance to assess the safety and efficacy of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma. We expect to initiate this first clinical trial in the fourth quarter of 2015. We are also planning a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target.

IMO-8400 Development Program in Rare Diseases

We are planning to initiate clinical development of IMO-8400 for the treatment of rare diseases by the end of 2015. We have selected dermatomyositis and Duchenne muscular dystrophy, or DMD, as the first non-cancer rare diseases for which we plan to develop IMO-8400. We selected these indications for development based on the reported role of TLRs in the pathogenesis of the disease states, clinical feasibility including ease of patient identification, availability of endpoints for regulatory approval and commercial potential. We anticipate commencing clinical development in these two indications by initiating a Phase 2 clinical trial in dermatomyositis by the end of 2015 and a Phase 2 clinical trial in DMD in 2016.

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 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, 0.15, 0.3, 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. In March 2015, we presented the complete data from the Phase 2 trial of IMO-8400 in patients with moderate to severe plaque psoriasis at the annual meeting of the American Academy of Dermatology. With our focus on rare diseases, we do not currently plan to conduct further clinical development of IMO-8400 for the treatment of psoriasis.

IMO-8400 Development Program for Dermatomyositis. We are finalizing our clinical trial plan for a Phase 2 clinical trial of IMO-8400 in dermatomyositis and anticipate initiating this trial in the fourth quarter of 2015. If this clinical trial is successful, we may evaluate the potential of IMO-8400 to treat additional forms of myositis.

IMO-8400 Development Program for Duchenne Muscular Dystrophy. We are conducting additional preclinical studies of TLR antagonist drug candidates in DMD models and are working in collaboration with Parent Project Muscular Dystrophy, a leading U.S. patient advocacy organization, on the design of a clinical development program for IMO-8400 in DMD. We anticipate initiating a Phase 2 clinical trial of IMO-8400 in DMD in 2016.

Program in Autoimmune Diseases

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 May 2015, we completed and reported top-line data from a Phase 1 clinical trial of subcutaneously administered IMO-9200 in healthy subjects. We have also completed and presented data during the 2015 Digestive Disease Week Conference from preclinical studies of orally administered IMO-9200 in models of IBD, including Crohn s Disease and ulcerative colitis. In these preclinical studies, the results demonstrated the potential for orally dosed IMO-9200 as a treatment for IBD. As our company is focused on drug development specifically in oncology and rare diseases, we are currently reviewing our various strategic options related to the future development of IMO-9200.

Third-generation Antisense Technology to Target RNA

We are currently undertaking an analysis of oncology and rare disease indications for development of drug candidates generated from our third-generation antisense technology. Our key considerations in identifying disease indications in our third-generation antisense program include: strong evidence that the disease is caused by a specific protein; clear criteria to identify a target patient

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population; biomarkers for early assessment of clinical proof of concept; a targeted therapeutic mechanism for action; and unmet medical need to allow for a rapid development path to approval. We are currently conducting disease model studies and plan to begin investigational new drug application, or IND, enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program in the second half of 2015.

Accumulated Deficit

As of June 30, 2015, we had an accumulated deficit of $476,726,000. We expect to incur substantial operating losses in future periods. We do not expect to generate 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, 2014. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policy relating to stock-based compensation, 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, 2014, fits the description of critical accounting estimates and judgments. There were no changes in this policy during the six months ended June 30, 2015.

RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2015 and 2014

Research and Development Expenses

Research and development expenses increased by $3,323,000, or 59%, from $5,637,000 for the three months ended June 30, 2014, to $8,960,000 for the three months ended June 30, 2015. Research and development expenses increased by $5,110,000, or 41%, from $12,570,000 for the six months ended June 30, 2014 to $17,680,000 for the six months ended June 30, 2015. In the following table, research and development expenses are set forth in the following five categories which are discussed beneath the table:

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	Three Months Ended June 30, (in thousands)		Percentage Increase	Six Months Ended June 30, (in thousands)		Percentage Increase
	2015	2014	(Decrease)	2015	2014	(Decrease)
IMO-8400 external development expense	$ 1,851	$ 1,407	32%	$ 3,938	$ 3,840	3%
IMO-9200 external development expense	599			2,265		%
Companion diagnostic external development expense	252	500	(50)%	588	1,300	(55)%
Other drug development expense	4,139	1,885	120%	6,711	4,409	52%
Basic discovery expense	2,119	1,845	15%	4,178	3,021	38%
	$ 8,960	$ 5,637	59%	$ 17,680	$ 12,570	41%

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 $15,276,000 in IMO-8400 external development expenses through June 30, 2015, 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 ongoing Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial in patients with DLBCL, the manufacture of additional drug substance for use in our ongoing and planned clinical trials, as well as additional nonclinical studies and associated costs incurred in connection with our dermatomyositis program.

IMO-8400 external development expenses increased in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014. The increases in IMO-8400 external development expenses during the 2015 periods were primarily due to higher costs incurred in connection with 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, higher costs incurred in connection with the manufacture of additional drug substance for use in our ongoing and planned clinical trials, and associated costs incurred in connection with our dermatomyositis program which was initiated after the corresponding 2014 periods. The increases in IMO-8400 external development expenses during the three and six months ended June 30, 2015 were partially offset by lower costs associated with long-term nonclinical safety studies conducted during the 2014 periods.

We expect our IMO-8400 external development expenses to increase during the remainder of 2015, as compared to the corresponding 2014 periods, as we plan to continue 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, initiate a Phase 2 clinical trial in patients with dermatomyositis, prepare for a Phase 2 clinical trial in patients with DMD, and continue manufacturing activities and nonclinical safety 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 $3,928,000 in IMO-9200 external development expenses from October 2014 through June 30, 2015, including costs associated with our Phase 1 clinical trial in healthy subjects, the manufacture of additional drug substance for use in our ongoing and planned clinical trials and additional nonclinical

studies. We classified the IMO-9200 external development expenses incurred prior to October 2014 in other drug development expenses.

Companion Diagnostic External Development Expenses. These expenses include external 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 incurred since January 2014 when development of the companion diagnostic commenced. We have incurred approximately $2,816,000 in companion diagnostic external development expenses from January 2014 through June 30, 2015, including costs associated with start-up activities, the development of an assay as the prototype of the companion diagnostic, introduction and use of the assay in our ongoing Phase 1/2 clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation, and the expected submission by Abbott Molecular of an Investigational Device Exemption with the FDA Center for Devices and Radiological Health.

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During the three and six months ended June 30, 2015, our companion diagnostic external development expenses reflect costs associated with the continued development of the assay and use of the assay in our ongoing Phase 1/2 clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation. During the three and six months ended June 30, 2014, our companion diagnostic external development expenses reflect costs associated with start-up activities and the initiation of development of an assay as the prototype of the companion diagnostic.

Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed.

The increase in other drug development expenses in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to additional headcount associated with our expanded drug development programs, higher stock-based compensation costs, higher consulting costs, the manufacture of IMO-2055 drug supplies and costs associated with IMO-2125, which we plan to use in our immuno-oncology program, during the three and six months ended June 30, 2015. The increase in other drug development expenses during the three and six months ended June 30, 2015 was partially offset by higher costs of preclinical studies and manufacturing activities that were incurred during the three and six months ended June 30, 2014 to support the IND submission for IMO-9200. Costs associated with the clinical development of IMO-9200 since October 2014 are included in IMO-9200 external development expenses.

Basic Discovery Expenses. These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, and our third-generation antisense program. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses.

The increase in basic discovery expenses in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to increases in stock-based compensation and external research. The increase in basic discovery expenses in the six-month period is also attributable to an increase in cash compensation. The increase in basic discovery expenses during the three and six months ended June 30, 2015 was partially offset by a decrease in the cost of laboratory supplies.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, and without knowing the results from our ongoing and planned clinical trials of IMO-8400, our planned clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma, a planned Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target and our planned IND-enabling development programs in each of the first two disease indications selected for development in our third-generation antisense program, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate from our research and development programs. Moreover, the clinical development of any drug candidate from our research and development programs is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

In addition to the expected increase in IMO-8400 external development expenses in 2015, we expect additional external development expenses as a result of our planned initiation of a clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, during the fourth quarter of 2015.

General and Administrative Expenses

General and administrative expenses increased by $1,091,000, or 40%, from $2,730,000 in the three months ended June 30, 2014, to $3,821,000 in the three months ended June 30, 2015 and increased by $2,885,000, or 60%, from $4,773,000 in the six months ended June 30, 2014 to $7,658,000 in the six months ended June 30, 2015. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

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The increase in general and administrative expenses during the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to higher stock-based compensation costs primarily attributable to options granted after May 31, 2014, higher cash compensation costs, including additional headcount to support our drug development programs, the hiring of a new Chief Executive Officer in December 2014, the accrual of incentive compensation, and higher insurance costs. The increase in general and administrative expenses during the three and six months ended June 30, 2015 was partially offset by a decrease in recruiting expenses. We expect general and administrative expenses to increase during the remainder of 2015, as compared to 2014, due to additional headcount to support our drug development programs.

Investment Income, Net

Investment income, net increased by $32,000, from $16,000 in the three months ended June 30, 2014 to $48,000 in the three months ended June 30, 2015, and increased by $31,000, from $31,000 in the six months ended June 30, 2014 to $62,000 in the six months ended June 30, 2015, in each case primarily due to an increase in interest income resulting from an increase in investment balances, including corporate debt securities, in 2015 resulting from our follow-on underwritten public offering in February 2015 and warrant and option exercises since June 30, 2014. The increase in interest income during the three and six months ended June 30, 2015, as compared to the corresponding 2014 periods, was partially offset by an increase in interest expense on our note payable which we incurred pursuant to our loan and security agreement with Oxford Finance LLC executed on September 30, 2014.

Preferred Stock Dividends

The $118,000 in preferred stock dividends in the three months ended June 30, 2014 reflects dividends accrued on shares of our Series E convertible preferred stock, or Series E preferred stock. The $303,000 in preferred stock dividends in the six months ended June 30, 2014 reflects dividends accrued on shares of our Series D convertible preferred stock, or Series D preferred stock, and our Series E preferred stock. There were no dividends accrued on our Series D preferred stock and Series E preferred stock during the three and six months ended June 30, 2015 because the Series D preferred stock and Series E preferred stock were converted to common stock during February 2014 and December 2014, respectively.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was $12,719,000 for the three months ended June 30, 2015, compared to $8,426,000 for the three months ended June 30, 2014 and $25,200,000 for the six months ended June 30, 2015 compared to $17,572,000 for the six months ended June 30, 2014. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through June 30, 2015, we incurred losses of $216,533,000. We also incurred net losses of $260,193,000 prior to December 31, 2000 during which time we were primarily involved in the development of antisense technology. Since our inception, we had an accumulated deficit of $476,726,000 through June 30, 2015. We expect to continue to incur substantial operating losses in the future.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We require cash to fund our operating expenses and to make capital expenditures. Historically, we have funded our cash requirements primarily through the following:

sale of common stock, preferred stock and warrants and warrant exercises;

debt financing, including capital leases;

license fees, research funding and milestone payments under collaborative and license agreements; and

interest income.

February 19, 2015 Follow-on Underwritten Public Offering

On February 19, 2015, we closed a follow-on underwritten public offering, in which we 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 us from the offering, after deducting underwriters discounts and commissions and other offering costs and expenses were $80.6 million.

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Cash Flows

Six Months Ended June 30, 2015

As of June 30, 2015, we had approximately $106,304,000 in cash, cash equivalents and investments, a net increase of approximately $57,733,000 from December 31, 2014. Net cash used in operating activities totaled $22,569,000 during the six months ended June 30, 2015, reflecting our $25,200,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and amortization. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The $41,971,000 net cash used in investing activities during the six months ended June 30, 2015 reflects the purchase of $56,196,000 of available-for-sale securities, which are investments that we do not have the positive intent to hold to maturity at the time of purchase, the maturity of $13,602,000 of available-for-sale securities, the sale of $999,000 of available-for-sale securities, and payments for the purchase of $376,000 in property and equipment.

The $80,938,000 net cash provided by financing activities during the six months ended June 30, 2015 primarily reflects $80,599,000 in net proceeds from our follow-on underwritten public offering of our common stock in February 2015 and $343,000 in net proceeds from employee stock purchases under our 1995 Employee Stock Purchase Plan, or ESPP, and the exercise of common stock options.

Six Months Ended June 30, 2014

As of June 30, 2014, we had approximately $64,734,000 in cash, cash equivalents and investments, a net increase of approximately $29,142,000 from December 31, 2013. Net cash used in operating activities totaled $13,757,000 during the six months ended June 30, 2014, reflecting our $17,269,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation and depreciation and amortization. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during the six months ended June 30, 2014 reflects the purchase of $2,619,000 of available-for-sale securities, the maturity of $2,000,000 of available-for-sale securities, and payments for the purchase of $533,000 in property and equipment.

The $43,517,000 net cash provided by financing activities during the six months ended June 30, 2014 primarily reflects $37,302,000 in net proceeds from our follow-on underwritten public offering of our securities in February 2014, which were partially offset by $100,000 in payments related to our 2013 financings, and $6,780,000 in net proceeds from the exercise of common stock options and warrants and employee stock purchases under our 1995 ESPP which were partially offset by dividends paid on our Series D preferred stock and our Series E preferred stock.

Funding Requirements

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009, and we had an accumulated deficit of $476,726,000 at June 30, 2015. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital. We have received no revenues from the sale of drugs. As of July 15, 2015, substantially all of our revenues have been from collaboration and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available or when we

will become profitable, if at all.

We do not expect to generate significant additional funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaboration with third parties, which we expect will take a number of years. In addition, we have no committed external sources of funds.

We had cash, cash equivalents and investments of approximately $106,304,000 at June 30, 2015. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments will enable us to fund our operations into the first quarter of 2017. Specifically, we believe that our available funds will be sufficient to enable us to:

- complete our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;

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initiate a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target and complete at least one of these trials;

initiate a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 2 clinical trial of IMO-8400 in patients with DMD;

review our strategic options for the development of IMO-9200; and

conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program.

We expect that we will require substantial additional funds to complete the clinical trials that we plan to initiate and to conduct any additional research and development of our TLR drug candidates or third-generation antisense technology, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

the results of our clinical and preclinical development activities in our genetically defined forms of B-cell lymphoma and rare disease programs, our immuno-oncology program, and our third-generation antisense program and our ability to advance our drug candidates and third-generation antisense technology on the timelines anticipated;

the cost, timing, and outcome of regulatory reviews;

competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;

the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and

our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our

own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 10 to the financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 that was filed with the Securities and Exchange Commission on March 12, 2015, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

Contractual Obligations

During the six months ended June 30, 2015, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, except for a lease of approximately 4,300 square feet of office space in Exton, Pennsylvania that we entered into on April 1, 2015. The Exton office lease term continues through April 30, 2020, with one five-year renewal option exercisable by us. We classify the lease as an operating lease. Future minimum commitments as of June 30, 2015 under our Exton office lease agreement are approximately:

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December 31,	Operating Lease (In thousands)
2015	$ 50
2016	76
2017	78
2018	81
2019	83
2020	28
	$ 396

As of June 30, 2015, we had no off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As of June 30, 2015, all material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. We do not own auction rate securities or derivative financial investment instruments in our investment portfolio. At June 30, 2015, all of our invested funds were invested in two money market funds and commercial paper, classified in cash and cash equivalents on the accompanying balance sheet, corporate bonds, municipal bonds and commercial paper classified in short-term investments, and corporate bonds and municipal bonds classified in long-term investments.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

ITEM 4. CONTROLS AND PROCEDURES.

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2015. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of June 30, 2015, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) *Changes in Internal Controls*. No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1A. RISK FACTORS.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our common stock. Our business, financial condition and results of operations could be materially and adversely affected by any of these and currently unknown risks or uncertainties. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our securities.

Risks Relating to Our Financial Results and Need for Financing

We will need additional financing, which may be difficult to obtain. Our failure to obtain necessary financing or doing so on unattractive terms could result in the termination of our operations and the sale and license of our assets or otherwise adversely affect our research and development programs and other operations.

We had cash, cash equivalents and investments of approximately $106.3 million at June 30, 2015. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments will enable us to fund our operations into the first quarter of 2017. Specifically, we believe that our available funds will be sufficient to enable us to:

- complete our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;
- initiate a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target and complete at least one of these trials;
- initiate a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 2 clinical trial of IMO-8400 in patients with DMD;
- review our strategic options for the development of IMO-9200; and
- conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program.

We expect that we will require substantial additional funds to complete the clinical trials that we plan to initiate and to conduct any additional research and development of our TLR drug candidates or third-generation antisense technology, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We are

seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

- the results of our clinical and preclinical development activities in our genetically defined forms of B-cell lymphoma and rare disease programs, our immuno-oncology program, and our third-generation antisense program and our ability to advance our drug candidates and third-generation antisense technology on the timelines anticipated;

- the cost, timing, and outcome of regulatory reviews;

- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;

- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and

- our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely

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affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 10 to the financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 that was filed with the Securities and Exchange Commission on March 12, 2015, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

We have incurred substantial losses and expect to continue to incur losses. We will not be successful unless we reverse this trend.

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of June 30, 2015, we had an accumulated deficit of $476.7 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to June 30, 2015, we incurred losses of $216.5 million. We incurred losses of $260.2 million prior to December 31, 2000, during which time we were primarily involved in the development of non-TLR-targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of June 30, 2015, substantially all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

Risks Relating to Our Business, Strategy and Industry

We are depending heavily on the development of TLR-targeted drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program and on the development of our third-generation antisense technology. If we terminate the development of any of our programs or any of our drug candidates in such programs, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our time and financial resources in the development of TLR-targeted clinical stage lead drug candidates as part of our rare disease program. In the future, we intend to invest a significant portion of our time and financial resources in the development of our TLR-targeted candidates for the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program. We also plan to invest substantial time and resources to further advance the development of drug candidates under our

third-generation antisense program. For instance:

- we are conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;

- we are planning to conduct a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target;

- we are planning to conduct a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 2 clinical trial of IMO-8400 in patients with DMD;

- we conducted a Phase 1 clinical trial of IMO-9200 in healthy subjects and are reviewing our strategic options related to the future development of IMO-9200; and

- we are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program.

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We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our TLR drug candidates in our genetically defined forms of B-cell lymphoma, rare disease and immuno-oncology programs, and the successful identification, development and commercialization of drug candidates in our third-generation antisense program.

Our ability to generate product revenues under our collaboration with Merck & Co. and under any other collaboration that we enter into with respect to our other programs, will depend on the development and commercialization of the drug candidates being developed.

Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-2055, including:

- In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 hepatitis C virus, or HCV, patients based on observations of lymphoproliferative malignancies in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which there were no similar observations.

- In July 2011, Merck KGaA, Darmstadt, Germany, or Merck KGaA, a former collaborator, informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 clinical trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line squamous cell carcinoma of the head and neck, or SCCHN, and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In May 2012, we announced that in a Phase 2 clinical trial of IMO-2055 in combination with cetuximab in patients with second-line SCCHN, the combination of IMO-2055 and cetuximab did not meet the primary endpoint of the trial.

We are conducting multiple clinical trials of IMO-8400 in different indications. If patients in any of these trials experience adverse safety events, we may be required to delay, discontinue or modify all of our clinical trials of IMO-8400.

We are seeking and expect to continue to seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications and with respect to applications of our third-generation antisense technology program. Our previous setbacks with respect to our programs for IMO-2125, and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

Our ability to successfully develop and commercialize these drug candidates, or other potential candidates, will depend on our ability to overcome these recent challenges and on several factors, including the following:

- the drug candidates demonstrating activity in clinical trials;

- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;

timely enrollment in clinical trials of IMO-8400 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;

satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;

the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;

timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;

the ability to combine our drug candidates and the drug candidates being developed by Merck & Co. and any other collaborators safely and successfully with other therapeutic agents;

achieving and maintaining compliance with all regulatory requirements applicable to the products;

establishment of commercial manufacturing arrangements with third-party manufacturers;

the successful commercial launch of the drug candidates, assuming FDA approval is obtained, whether alone or in combination with other products;

acceptance of the products as safe and effective by patients, the medical community, and third-party payors;

competition from other companies and their therapies;

changes in treatment regimens;

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the strength of our intellectual property portfolio in the United States and abroad; and

a continued acceptable safety and efficacy profile of the drug candidates following marketing approval.

We are developing drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma. Our approach for the treatment of these genetically defined B-cell lymphomas is novel and may not result in any approved and marketable products.

We are in the early stages of developing our program in genetically defined forms of B-cell lymphoma, an area in which we have little experience. In connection with this program, we are focusing our efforts on the research and development of TLR antagonist drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma. The scientific evidence to support the feasibility of developing drug candidates for this use is both preliminary and limited. We have conducted preclinical studies in human lymphoma cell lines that carry the MYD88 L265P oncogenic mutation to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined forms of B-cell lymphoma. Although the preliminary results of our preclinical studies have been promising, it is unknown whether these results are indicative of results that may be obtained in our clinical trials. Therefore, we do not know if our approach of inhibiting TLRs to treat patients with genetically defined forms of B-cell lymphoma will be successful or if we will ever succeed in obtaining regulatory approval to market any product for this purpose. In addition, in the event that our development efforts for such a drug candidate progress towards commercialization, we likely will need to develop companion diagnostics for such drug candidate. We have no experience in developing companion diagnostics and will be dependent on the efforts of third-party collaborators to successfully develop and commercialize these companion diagnostics on our behalf. In May 2014, we entered into an agreement with Abbott Molecular to develop a companion diagnostic for identification of patients with B-cell lymphoma harboring the MYD88 L265P oncogenic mutation. We cannot assume that the program under this agreement will be successful.

We are in the early stages of developing our third-generation antisense program, which is a novel technology, and our efforts may not be successful or result in any approved and marketable products.

We are in the early stages of developing our third-generation antisense technology program, and the scientific evidence to support the feasibility of developing drugs based on this technology is preliminary. Further, neither we nor any other company has received regulatory approval to market therapeutics utilizing third-generation antisense drug candidates.

The future success of our third-generation antisense technology program depends on our success in identifying and developing marketable products based on such technology. Although the results of our preclinical studies to date have been supportive of the viability of this technology, it is unknown whether these results are indicative of results that may be obtained in any future clinical trials that we may conduct. We are currently undertaking an analysis of priority oncology and rare disease indications and development strategies to determine next steps in developing our third-generation antisense technology, and are currently conducting disease model studies and plan to begin IND-enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program in the second half of 2015. However, many steps must be successfully achieved prior to the declaration of a third-generation antisense drug candidate and the initiation of clinical development. Given the level of uncertainty of our ability to successfully achieve these many steps and the uncertainty of the drug discovery and clinical development processes in general, there can be no assurance that we will succeed in developing any marketable product as a result of our efforts with respect to our third-generation antisense technology program.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because there are a limited number of patients with Waldenström s macroglobulinemia or patients with DLBCL harboring the MYD88 L265P oncogenic mutation, and a limited number of patients with dermatomyositis, DMD, or other rare diseases having indications for which we may determine to develop our TLR antagonists, our ability to enroll eligible patients in any clinical trials for these indications may be limited or may result in slower enrollment than we anticipate. In addition, the relapsed or refractory DLBCL patients that we are seeking to enroll in our Phase 1/2 clinical trial of IMO-8400 typically have late stage disease, which confers a very poor prognosis. As a result, some patients, who screen positive for the MYD88 L265P based on tumor tissue testing, may experience rapid deterioration that precludes them from meeting study eligibility criteria and they are unable to enroll into the trial. If enrolled, the disease in these patients may be too advanced for them to derive any clinically meaningful benefit from treatment or for their participation in the study to contribute meaningful data to the clinical trial. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors drug candidates.

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Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the TLR antagonist drug candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the availability of competing clinical trials or other therapies;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If our clinical trials are unsuccessful, or if they are delayed or terminated, we may not be able to develop and commercialize our drug candidates.

In order to obtain regulatory approvals for the commercial sale of our drug candidates, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. Clinical trials are lengthy, complex, and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and efficacious. The FDA or other equivalent foreign regulatory agencies may not allow us to complete these trials or commence and complete any other clinical trials.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks in clinical trials, even after demonstrating promising results in earlier trials. Moreover, effects seen in nonclinical studies, even if not observed in

clinical trials, may result in limitations or restrictions on clinical trials. Numerous unforeseen events may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

Only one TLR-targeted drug, imiquimod, which is marketed as Aldara® and Zyclara® by Meda AB, Graceway Pharmaceuticals LLC, and iNova Pharmaceuticals (Australia) Pty Limited has been approved by the FDA. Other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of Actilon®, a TLR9 agonist, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis discontinued the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, an investigational vaccine which contained a TLR9 agonist adjuvant, and in February 2013 Dynavax announced receipt of a Complete Response Letter from FDA regarding its Biological License Application for HEPLISAV®, which is an investigational hepatitis B vaccine that contains a TLR9 agonist adjuvant. These setbacks may result in enhanced scrutiny by regulators or institutional review boards, or IRBs, of clinical trials of our drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of our drug candidates.

Other events that could delay or inhibit conduct of our clinical trials include:

- regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- nonclinical or clinical data may not be readily interpreted, which may lead to delays and/or misinterpretation;

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our nonclinical tests, including toxicology studies, or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect may not be promising;

the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;

we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;

regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;

we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA s or foreign equivalent s review or approval of our drug candidates, or the rejection of data developed with the involvement of such person(s);

we or our contract manufacturers may be unable to manufacture sufficient quantities of our drug candidates for use in clinical trials;

the cost of our clinical trials may be greater than we currently anticipate; and

our drug candidates may not cause the desired effects or may cause undesirable side effects or our drug candidates may have other unexpected characteristics.

We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our drug candidates.

Delays in commencing clinical trials of potential products could increase our costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

Our drug candidates and our collaborators drug candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. In conducting clinical

trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our drug candidate development costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

Commencing clinical trials may be delayed for a number of reasons, including delays in:

- manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;
- demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;
- reaching an agreement with any collaborators on all aspects of the clinical trial;
- reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;
- resolving any objections from the FDA or any regulatory authority on an IND or proposed clinical trial design;
- obtaining IRB approval for conducting a clinical trial at a prospective site; and
- enrolling patients in order to commence the clinical trial.

The technologies on which we rely are unproven and may not result in any approved and marketable products.

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds, or oligonucleotides, targeted to TLRs and on third-generation antisense drug candidates. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. The results of preclinical studies with TLR-targeted compounds may not be indicative of results that may be obtained in clinical trials, and results we have obtained in the clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs or of third-generation antisense drug candidates may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective or harmful ways that we have not yet identified.

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Moreover, only one oligonucleotide drug, Kynamro®, has been approved by the FDA for marketing in the United States since 1998. As such, oligonucleotides as a chemical class of drug candidates have limited precedence for successful late-stage development and regulatory approval. As we progress our oligonucleotide drug candidates into Phase 2 clinical trials involving patients with severe disease and as we conduct long-term nonclinical toxicology studies, we expect to encounter an increased risk of generating clinical adverse events and nonclinical toxicology study results that will require careful interpretation. In animal toxicology studies, we have observed adverse treatment-related effects on serum complement as well as evidence of adverse kidney, vascular, and heart pathology in longer term dosing of animals with our oligonucleotide compounds, which we believe are consistent with data previously generated with other third party oligonucleotides. Given the limited experience in assessing the relevance of oligonucleotide-related adverse animal toxicology findings to humans, the clinical and regulatory context for interpreting the significance of such events and results is not well established.

As a result of these factors, we may never succeed in obtaining regulatory approval to market any product. Furthermore, the commercial success of any of our drug candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by patients, the medical community, and third-party payors as clinically useful, safe, and cost-effective. In addition, if products being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our technologies and market acceptance of our drug candidates could be impacted negatively.

Our setbacks with respect to our TLR-targeted compounds, together with the setbacks experienced by other companies developing TLR-targeted compounds, may result in a negative perception of our technology and our TLR-targeted compounds, impact our ability to obtain marketing approval of these drug candidates and adversely affect acceptance of our technology and our TLR-targeted compounds by patients, the medical community and third-party payors.

Our efforts to educate the medical community on our potentially unique approaches may require greater resources than would be typically required for products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience, and cost-effectiveness of our drug candidates as compared to competitive products will also affect market acceptance.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than us.

We are developing our TLR-targeted drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program. One of our drug candidates, IMO-8400, is in clinical development for the treatment of certain genetically defined forms of B-cell lymphoma, including Waldenström s macroglobulinemia and DLBCL harboring the MYD88 L265P oncogenic mutation. We plan to initiate clinical trials of IMO-8400 in dermatomyositis and DMD. We are also planning to conduct Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial of either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target in our immuno-oncology program. Finally, we are seeking and expect to continue to seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

We are developing IMO-8400 for the treatment of certain genetically defined forms of B-cell lymphoma. There are currently no drugs specifically approved for the treatment of Waldenström s macroglobulinemia or DLBCL harboring the MYD88 L265P oncogenic mutation other than ibrutinib, which is marketed as Imbruvica® by Pharmacyclics, Inc. and was approved in January 2015 for the treatment of Waldenström s macroglobulinemia in the United States. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with the monoclonal antibody rituximab and/or with one or more chemotherapeutic agents. Rituximab is co-marketed in the United States by Biogen Idec Inc. and Genentech Inc. and Hoffmann-La Roche, and Chugai Pharmaceutical Co., Ltd. in territories outside the United States. We are aware of additional compounds in development for the treatment of genetically defined forms of B-cell lymphoma, including an inhibitor of interleukin-1 receptor-associated kinase 4, which is being developed by Nimbus Discovery, Inc.

Our principal competitor developing TLR antagonist targeted compounds for rare diseases is Dynavax. In addition, we are aware that other companies including Dynavax, InDex Pharmaceuticals AB, Mologen AG, BioLineRx Ltd., Innate Immunotherapeutics Ltd., VentiRx Pharmaceuticals Inc., Telormedix S.A., Gilead Sciences Inc., GlaxoSmithKline plc, AstraZeneca plc and Hoffmann-La Roche are developing TLR agonists for various indications, some of which are in the field of oncology.

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Many of the drug development programs in dermatomyositis are focusing on expanding the use of drugs approved in different indications through investigator sponsored studies such as the ongoing studies of the monoclonal antibodies, belimumab and tocilizumab. In addition, Novartis is developing a competitive anti-inflammatory approach with its new investigational drug, BAF312, a sphingosine-1-phosphate receptor modulator aimed at inhibiting the migration of lymphocytes to the location of inflammation. We are not aware of other new chemical or molecular entities being developed for the treatment of dermatomyositis.

Competitors with respect to our DMD program include ReveraGen and Catabasis, both whom are pursuing novel anti-inflammatory approaches for the treatment of DMD. ReveraGen is conducting a Phase 1 healthy volunteer study and Catabasis initiated a Phase 2 clinical trial in DMD patients in June 2015. In addition, Sarepta Therapeutics Inc. and BioMarin Pharmaceuticals Inc. (following its acquisition of Prosensa Holding N.V.), each have RNA-based drug candidates targeted at treating genetically defined subsets of DMD in late stage development. PTC Therapeutics, Inc. also has a drug candidate targeted at treating a genetically defined subset of DMD that is conditionally approved for the treatment of DMD in Europe, and is currently being evaluated in a Phase 3 clinical trial. We believe that these dystrophin replacement therapeutic approaches, as well as other therapeutic approaches being pursued for the treatment of DMD, including anti-inflammatory, muscle blood flow, reducing fibrosis, increasing muscle mass, supporting muscle integrity and cardioprotective approaches being pursued by multiple companies, have the potential to be complementary to our TLR antagonist approach.

Immuno-oncology, which utilizes a patient s own immune system to combat cancer, is currently an active area of research for biotechnology and pharmaceutical companies. Interest in immuno-oncology is driven by recent efficacy data in cancers with historically bleak outcomes and the potential to achieve a cure or functional cure for some patients. As such, our efforts in this field will be competitive with a wide variety of different approaches. Any one of these competitive approaches may result in the development of novel technologies that are more effective, safer or less costly than any that we are developing. In addition, Dynavax is conducting a Phase 1/2 clinical trial of an investigational TLR9 agonist in combination with checkpoint inhibitors.

We are also developing third-generation antisense drug candidates that we have created using our proprietary technology, to inhibit the production of disease-associated proteins by targeting RNA. We also face competition from other companies working to develop novel drugs using technologies that may compete with our third-generation antisense technology. We are aware of multiple companies that are developing technologies that use oligonucleotide-based compounds to inhibit the production of disease associated proteins. These technologies include, but are not limited to, antisense technology as well as RNAi. In the field of antisense technologies, we compete with multiple companies, including Isis and its partners. Isis is currently marketing an antisense drug, Kynamro, and has several antisense drug candidates in clinical trials. In the field of RNAi, our primary competition is with Alnylam and its partners. Alnylam is currently developing multiple RNAi-based technologies and has several drug candidates in clinical trials. Any of the competing companies may develop gene-silencing technologies more rapidly and more effectively than us, and antisense technology and RNAi may become the preferred technology for drugs that target RNA in order to inhibit the production of disease-associated proteins.

Some of these potentially competitive products have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed products have been accepted by the medical community, patients, and third-party payors. Our ability to compete may be affected by the previous adoption of such products by the medical community, patients, and third-party payors. Additionally, in some instances, insurers and other third-party payors seek to encourage the use of generic products, which makes branded products, such as our drug candidates, potentially less attractive, from a cost perspective, to buyers.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our drug candidates and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our drug candidates and competitive products will also affect competition among products. We expect the relative speed with which we can develop products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

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Competition for technical and management personnel is intense in our industry, and we may not be able to sustain our operations or grow if we are unable to attract and retain key personnel.

Our success is highly dependent on the retention of principal members of our technical and management staff, including Mr. Vincent Milano and Dr. Sudhir Agrawal. Mr. Milano serves as our President and Chief Executive Officer, and Dr. Agrawal serves as our President of Research.

We are a party to employment agreements with Mr. Milano and Dr. Agrawal. Mr. Milano s employment agreement is terminable upon 15 days prior written notice at the election of either party and immediately in the event of a termination for cause (as defined therein). Dr. Agrawal s employment agreement expires on October 19, 2017, but automatically extends annually for additional one-year periods. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Mr. Milano or Dr. Agrawal.

Furthermore, our future growth will require hiring a number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

Regulatory Risks

We are subject to comprehensive regulatory requirements, which are costly and time consuming to comply with; if we fail to comply with these requirements, we could be subject to adverse consequences and penalties.

The testing, manufacturing, labeling, advertising, promotion, export, and marketing of our drug candidates are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

In general, submission of materials requesting permission to conduct clinical trials may not result in authorization by the FDA or any equivalent foreign regulatory agency to commence clinical trials. Further, permission to continue ongoing trials may be withdrawn by the FDA or other regulatory agencies at any time after initiation, based on new information available after the initial authorization to commence clinical trials or for other reasons. In addition, submission of an application for marketing approval to the relevant regulatory agency following completion of clinical trials may not result in the regulatory agency approving the application if applicable regulatory criteria are not satisfied, and may result in the regulatory agency requiring additional testing or information.

Even if we obtain regulatory approval for any of our drug candidates, we will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current Good Manufacturing Practices, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians, advertising and promotion, and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product. For example, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.

Both before and after approval is obtained, failure to comply with regulatory requirements, or discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in:

the regulatory agency s delay in approving, or refusal to approve, an application for marketing of a product or a supplement to an approved application;

total or partial suspension of any ongoing clinical trials;

restrictions on our drug candidates or the marketing or manufacturing of our drug candidates;

withdrawal of our drug candidates from the market;

warning letters;

voluntary or mandatory product recalls;

fines;

suspension or withdrawal of regulatory approvals;

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product seizure or detention;

refusal to permit the import or export of our drug candidates;

injunctions or the imposition of civil penalties; and

criminal penalties.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any current or future collaborator are not able to maintain regulatory compliance, we or such collaborator, as applicable, will not be permitted to market our future products and our business will suffer.

We may not be able to obtain marketing approval for products resulting from our development efforts.

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds and are planning to initiate clinical trials for a number of additional disease indications. Specifically, we are currently:

conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;

planning to conduct a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and a Phase 1/2 clinical trial involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for a selected oncology target;

planning to conduct a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 2 clinical trial of IMO-8400 in patients with DMD;

reviewing our strategic options for the development of IMO-9200; and

planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our third-generation antisense program.

The FDA and other regulatory authorities may not approve any of our potential products for any indication.

We may need to address a number of technological challenges in order to complete development of our drug candidates. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, unintended alteration of the immune system over time, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. If we do not obtain necessary regulatory approvals, our business will be adversely affected.

We may not be able to obtain orphan drug exclusivity for applications of our TLR antagonist drug candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency, or EMA, or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The FDA has granted us orphan drug designation for IMO-8400 for the treatment of Waldenström s macroglobulinemia and the treatment of DLBCL. However, there can be no assurance that we will obtain orphan drug exclusivity for Waldenström s macroglobulinemia, DLBCL or any other disease indications for which we develop IMO-8400 or our other drug candidates. Even if

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we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We intend to seek fast track designation for some applications of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy designation by the FDA for any application of our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those drug candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some applications of our drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe an application of one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If we are unable to successfully develop companion diagnostics for our drug candidates intended for the treatment of genetically defined forms of B-cell lymphoma, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of these drug candidates.

We plan to develop companion diagnostics for our TLR antagonist drug candidates in our genetically defined forms of B-cell lymphoma program. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our TLR antagonist drug candidates specifically for the treatment of patients with a genetically defined form of B-cell lymphoma. We do not have experience or capabilities in developing or commercializing diagnostics

and plan to rely on third parties or collaborators to perform these functions. In May 2014, we entered into an agreement with Abbott Molecular for the development and potential commercialization of a companion diagnostic for use with IMO-8400 with respect to our identification of patients with B-cell lymphoma harboring the MYD88 L265P oncogenic mutation in our genetically defined forms of B-cell lymphoma program. We may enter into similar agreements for our other drug candidates and possible expansion indications for IMO-8400. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

If we, any third parties that we engage to assist us or any of our collaborators are unable to successfully develop companion diagnostics for our TLR antagonist drug candidates, or experience delays in doing so:

- the development of our TLR antagonist drug candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;

- our TLR antagonist drug candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and

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we may not realize the full commercial potential of any TLR antagonist drug candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific oncogenic mutation targeted by our TLR antagonist drug candidates.

If any of these events were to occur, our business would be harmed, possibly materially.

We have only limited experience in regulatory affairs and our drug candidates are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing the applications necessary to obtain regulatory approvals. Moreover, the products that result from our research and development programs will likely be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional drugs. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any product that we develop.

Failure to obtain regulatory approval in jurisdictions outside the United States will prevent us from marketing our products abroad.

We intend to market our products, if approved, in markets outside the United States, which will require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among such markets and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

Risks Relating to Collaborators

Our existing collaborations and any collaborations we enter into in the future may not be successful.

Historically, an important element of our business strategy has included entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2006, we entered into an exclusive license and research collaboration with Merck & Co. to research, develop, and commercialize vaccine products containing our TLR7, TLR8 and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines. Additionally, in May 2014, we entered into a development and commercialization agreement with Abbott Molecular for the development of an in vitro companion diagnostic for use in our clinical development programs to treat certain genetically defined forms of B-cell lymphoma with IMO-8400.

Any collaboration that we enter into may not be successful. For instance, in July 2011, Merck KGaA informed us that it had determined not to conduct further clinical development of IMO-2055, and in November 2011, we entered into an agreement with Merck KGaA terminating our collaboration with them. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations and any potential future collaborations have risks, including the following:

our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;

our collaborators may control the development of the companion diagnostic to be developed for use in conjunction with our drug candidates including the timing of development;

our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;

disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;

disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;

we may have difficulty enforcing the contracts if any of our collaborators fail to perform;

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- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;

- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;

- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators acts or omissions;

- our collaborators may challenge our intellectual property rights or utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;

- our collaborators may not comply with all applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements;

- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. For example, we have a strategic partnership with Merck & Co., which merged with Schering-Plough Corporation, which has been involved with certain TLR-targeted research and development programs. Although the merger has not affected our partnership with Merck & Co. to date, management of the combined company could determine to reduce the efforts and resources that the combined company will apply to its strategic partnership with us or terminate the strategic partnership. The ability of our drug candidates to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such drug candidates;

- our collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or development of our drug candidates; and

- our collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely affect their willingness or ability to fulfill their obligations to us.

Given these risks, it is possible that any collaborative alliance into which we enter may not be successful. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, effective as of February 2010, Novartis terminated the research collaboration and option agreement that we entered into with it in May 2005, and in November 2011, we entered into an agreement with Merck KGaA terminating our collaboration with them. In addition, Merck & Co. may terminate its license and research collaboration agreement by giving us 90 days advance notice. The termination or expiration of our agreement with Merck & Co. or Abbott Molecular or any other collaboration agreement that we enter into in the future may adversely affect us financially and could harm our business reputation.

If we are unable to establish additional collaborative alliances, our business may be materially harmed.

Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. We are seeking and expect to continue to seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications. We are also seeking and expect to continue to seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our third-generation antisense technology program.

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of certain genetically defined forms of B-cell lymphoma and autoimmune diseases and on third-generation antisense drug candidates. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional collaborative alliances, particularly with respect to our TLR-targeted drug candidates and technology and our third-generation antisense technology. For example, potential partners may note that our TLR collaborations with Novartis and with Merck KGaA have been terminated. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-2055, and our other TLR-targeted drug candidates, given our setbacks with respect to these drug candidates. Additionally, in the event we seek collaborations for our third-generation antisense program, any potential collaborators may not be willing to enter into a collaboration with us due to the early stage of this technology. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

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Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology or our third-generation antisense technology, the terms of such a collaborative alliance may not be on terms that are favorable to us. Moreover, collaborations are complex and time consuming to negotiate, document, and implement. We may not be successful in our efforts to establish and implement collaborations on a timely basis.

Risks Relating to Intellectual Property

If we are unable to obtain and maintain patent protection for our discoveries, the value of our technology and products will be adversely affected.

Our patent positions, and those of other drug discovery companies, are generally uncertain and involve complex legal, scientific, and factual questions. Our ability to develop and commercialize drugs depends in significant part on our ability to:

- obtain and maintain valid and enforceable patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect our trade secrets.

We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, held unenforceable, narrowed in the course of a post-issuance proceeding or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Moreover, intellectual property laws may change and negatively impact our ability to obtain issued patents covering our technologies or to enforce any patents that issue. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

As of July 15, 2015, we owned more than 45 U.S. patents and patent applications and more than 80 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents

and patent applications include claims covering the chemical compositions of matter and methods of use of our IMO compounds, such as IMO-8400, IMO-9200, IMO-2055 and IMO-2125, as well as other compounds. As of July 15, 2015, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and certain methods of its use that has a statutory expiration date in 2031. With respect to IMO-9200, we have a U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which we would expect to expire, if issued, at the earliest in 2034. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and certain methods of its use, including in combination with marketed cancer products, with the composition claims expiring in 2023. With respect to IMO-2125, we have an issued U.S. patent that covers the chemical composition of matter of IMO-2125 and methods of its use that will expire in 2026.

As of July 15, 2015, we owned two issued U.S. patents, four pending U.S. patent applications and nine foreign patent applications related to our third-generation antisense compounds and methods of their use. The issued patents covering our third-generation antisense technologies have a statutory expiration date in 2030.

In addition to our TLR-targeted and third-generation antisense patent portfolios, we are the owner of or hold licenses to patents and patent applications related to antisense technology. As of July 15, 2015, our antisense patent portfolio included more than 15 U.S. patents and more than 55 patents throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates through 2021.

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Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our development and commercialization costs, or prevent us from developing or marketing products.

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third-party patents or patent applications related to our compounds under development. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of certain third-party U.S. patents that contain claims related to TLR modulation as well as antisense technology. Although we do not believe any of our TLR or antisense compounds under development infringe any valid claim of these patents, we cannot be assured that the holder of such patents would not seek to assert such patents against us or, if the holder did, that the courts would not interpret the claims of such patents more broadly than we believe appropriate and determine that we are in infringement of such patents. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from U.S. and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

We may become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages, require us to stop our development and commercialization efforts or result in our patents being invalidated, interpreted narrowly or limited.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not practicing and do not intend to practice any of the intellectual property involved in the proceedings.

Other patent office proceedings include oppositions, reexaminations, supplemental examinations and *inter partes* reviews involving our patents or the patents of third parties. We may initiate such proceedings or have such proceedings brought against us. An adverse determination in any such proceeding, or in litigation, could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. An adverse determination in a proceeding involving a patent in our portfolio could result in the loss of protection or a narrowing in the scope of protection provided by that patent.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all. In a patent office proceeding, such as an opposition, reexamination or *inter partes* review, our patents may be narrowed or invalidated.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Relating to Product Manufacturing, Marketing and Sales, and Reliance on Third Parties

Because we have limited manufacturing experience, and no manufacturing facilities or infrastructure, we are dependent on third-party manufacturers to manufacture drug candidates for us. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.

We have limited manufacturing experience and no manufacturing facilities, infrastructure or clinical or commercial scale manufacturing capabilities. In order to continue to develop our drug candidates, apply for regulatory approvals, and ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for nonclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties to produce materials that may be required for the commercial production of our drug candidates, if approved. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any drug candidates on a timely and competitive basis. We currently do not have any long term supply contracts.

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There are a limited number of manufacturers that operate under the FDA s cGMP regulations capable of manufacturing our drug candidates. As a result, we may have difficulty finding manufacturers for our drug candidates with adequate capacity for our needs. If we are unable to arrange for third-party manufacturing of our drug candidates on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third party in connection with the production of our drug candidates that becomes necessary for the manufacture of our drug candidates; and
- reliance upon third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. For example, one of our contract manufacturers notified us that it had received a cGMP warning letter from the FDA in February 2011. This contract manufacturer no longer manufactures drug product for us. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in the conduct of our clinical trials, or a delay in, or failure to obtain, regulatory approval of any of our drug candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, product seizures or recalls, imposition of operating restrictions, total or partial suspension of production or distribution, or criminal prosecution.

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of July 15, 2015, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA s cGMP and New Drug Application/biologics license application regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also

implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

We have no experience selling, marketing or distributing products and no internal capability to do so.

If we receive regulatory approval to commence commercial sales of any of our drug candidates, we will face competition with respect to commercial sales, marketing, and distribution. These are areas in which we have no experience. To market any of our drug candidates directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. In particular, we would need to recruit experienced marketing and sales personnel. Alternatively, we could engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. However, to the extent we entered into such arrangements, we would be dependent on the efforts of third parties. If we are unable to establish sales and distribution capabilities, whether internally or in reliance on third parties, our business would suffer materially.

If third parties on whom we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business may suffer.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We have contracted with contract research organizations to manage our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia, our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation, and our planned clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for

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successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. If these third parties fail to carry out their obligations, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, or to commercialize such drug candidate being tested in such studies or trials. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our research, clinical, quality and corporate infrastructure.

Failure of our third-party collaborators to successfully commercialize companion diagnostics developed for use with any TLR antagonist drug candidates that we develop with respect to our genetically defined forms of B-cell lymphoma program could harm our ability to commercialize these TLR antagonist drug candidates.

Some of the TLR antagonist drug candidates that we develop with respect to our genetically defined forms of B-cell lymphoma program will necessitate the use of companion diagnostics. We do not plan to develop companion diagnostics internally and, as a result, we will be dependent on the efforts of our third-party collaborators to successfully commercialize these companion diagnostics. Our collaborators:

- may not perform their obligations as expected;
- may encounter production difficulties that could constrain the supply of the companion diagnostics;
- may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community;
- may not pursue commercialization of any companion diagnostics that achieve regulatory approval;
- may elect not to continue or renew commercialization programs based on changes in the collaborators strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of such companion diagnostics; and
- may terminate their relationship with us.

If companion diagnostics for use with our genetically defined forms of B-cell lymphoma TLR antagonist drug candidates fail to gain market acceptance, our ability to derive revenues from sales of these TLR antagonist drug candidates could be harmed. If our collaborators fail to commercialize these companion diagnostics, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with genetically defined forms of B-cell lymphoma TLR antagonist drug candidates or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of these TLR antagonist drug candidates.

The commercial success of any drug candidates that we may develop will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our products do not achieve an adequate level of acceptance, we may not generate product revenue and we may not become profitable. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects, including any limitations or warnings contained in the product s approved labeling;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our drug candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and

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publicity concerning our products or competing products and treatments.

Even if a potential product displays a favorable efficacy and safety profile, market acceptance of the product will not be known until after it is launched. Our efforts to educate patients, the medical community, and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors.

If we are unable to obtain adequate reimbursement from third-party payors for any products that we may develop or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Most patients rely on Medicare, Medicaid, private health insurers, and other third-party payors to pay for their medical needs, including any drugs we may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While the program established by this statute may increase demand for our products if we were to participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries or may otherwise negotiate the price they are willing to pay.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our drug candidates. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act became law. These health care reform laws are intended to broaden access to health insurance; reduce or constrain the growth of health care spending, especially Medicare spending; enhance remedies against fraud and abuse; add new transparency requirements for health care and health insurance industries; impose new taxes and fees on certain sectors of the health industry; and impose additional health policy reforms. Among the new fees is an annual assessment on makers of branded pharmaceuticals and biologics, under which a company s assessment is based primarily on its share of branded drug sales to federal health care programs. Such fees could affect our future profitability. Although it is too early to determine the effect of the new health care legislation on our future profitability and financial condition, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. In particular, third-party payors may limit the indications for

which they will reimburse patients who use any products that we may develop. Cost control initiatives could limit the price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

We face a risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing, and marketing of human therapeutic drugs. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products. Regardless of merit or eventual outcome, liability claims and product recalls may result in:

decreased demand for our drug candidates and products;

damage to our reputation;

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

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costs to defend related litigation;

substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;

loss of revenue;

the diversion of management s attention away from managing our business; and

the inability to commercialize any products that we may develop.

Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

Risks Relating to Ownership of Our Common Stock

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that stockholders may consider desirable.

Section 203 of the Delaware General Corporation Law and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

the inability of stockholders to act by written consent or to call special meetings; and

the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law imposes restrictions on our ability to engage in business combinations and other specified transactions with significant stockholders. These provisions could have the

effect of delaying, deferring or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

We have two significant securityholders. If these securityholders choose to act together, they could exert substantial influence over our business. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, they would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock.

As of April 15, 2015, Baker Bros. Advisors LP, and certain of its affiliated funds, which we refer to collectively as Baker Brothers, held 6,970,902 shares of our common stock, warrants to purchase up to 20,316,327 shares of our common stock at an exercise price of $0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of our common stock at an exercise price of $0.01 per share. In addition, two members of our board of directors are affiliates of Baker Brothers. Under the terms of the warrants and pre-funded warrants issued to Baker Brothers, Baker Brothers is not permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 4.999% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. Baker Brothers has the right to increase this beneficial ownership limitation in its discretion on 61 days prior written notice to us, provided that in no event is Baker Brothers permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. After giving effect to the 4.999% beneficial ownership limitation currently in effect with respect to the warrants and pre-funded warrants held by Baker Brothers, as of July 15, 2015, and based on the securities held by Baker Brothers as of April 15, 2015, Baker Brothers beneficially owned 6.0% of our outstanding common stock. If the warrants and pre-funded warrants held by Baker Brothers could be exercised without this limitation, then as of July 15, 2015, and based on the securities held by Baker Brothers as of April 15, 2015, Baker Brothers would have beneficially owned 30.8% of our common stock.

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On February 9, 2015, we entered into a registration rights agreement with Baker Brothers, pursuant to which we are obligated to file a registration statement to register for resale the shares of our common stock (including shares issuable upon the exercise of warrants) held by Baker Brothers.

As of April 15, 2015, entities affiliated with Pillar Invest Corporation, which we refer to collectively as the Pillar Investment Entities, held 18,679,730 shares of our common stock and warrants to purchase up to 14,795,490 shares of our common stock at exercise prices ranging from $0.47 per share to $1.46 per share. In addition, one member of our board of directors is an affiliate of the Pillar Investment Entities. The Pillar Investment Entities are subject to contractual limitations that limit their ability to exercise any securities held by them that are exercisable into shares of our common stock to the extent that such exercise would result in the Pillar Investment Entities (and their affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such securities. After giving effect to the 19.99% beneficial ownership limitation currently in effect with respect to the securities held by the Pillar Investment Entities, as of July 15, 2015, the Pillar Investment Entities beneficially owned 19.99% of our outstanding common stock. If the warrants held by the Pillar Investment Entities could be exercised without these limitations, then as of July 15, 2015, and based on the securities held by Pillar Investment Entities as of April 15, 2015, the Pillar Investment Entities would have beneficially owned 25.3% of our common stock.

Although there are contractual limitations on the beneficial ownership of Baker Brothers and the Pillar Investment Entities, which we refer to collectively as our significant securityholders, if our significant securityholders were to exercise their warrants for common stock and were to choose to act together, they could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and either or both of our significant securityholders on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. Furthermore in the event of a sale of our company, whether by merger, sale of all or substantially all of our assets or otherwise, our significant securityholders would be entitled to receive, with respect to each share of common stock issuable upon exercise of the warrants then held by them and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as they would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because the significant securityholders would receive this sale consideration with respect to warrants not included in their reported beneficial ownership of our common stock, in the event of a sale of our company, they would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by their reported beneficial ownership of our common stock.

Our stock price has been and may in the future be extremely volatile. In addition, because our common stock has historically been traded at low volume levels, our investors ability to trade our common stock may be limited. As a result, investors may lose all or a significant portion of their investment.

Our stock price has been volatile. During the period from January 1, 2014 to July 15, 2015, the closing sales price of our common stock ranged from a high of $6.59 per share to a low of $1.96 per share. The stock market has also experienced periods of significant price and volume fluctuations and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

our cash resources;

timing and results of nonclinical studies and clinical trials of our drug candidates or those of our competitors;

the regulatory status of our drug candidates;

failure of any of our drug candidates, if approved, to achieve commercial success;

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

our ability to maintain the listing of our common stock on The Nasdaq Capital Market or an alternative national securities exchange;

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variations in our financial results or those of companies that are perceived to be similar to us;

the terms of any financing consummated by us;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations; and

general economic, industry, and market conditions.

In addition, our common stock has historically been traded at low volume levels and may continue to trade at low volume levels. As a result, any large purchase or sale of our common stock could have a significant impact on the price of our common stock and it may be difficult for investors to sell our common stock in the market without depressing the market price for the common stock or at all.

As a result of the foregoing, investors may not be able to resell their shares at or above the price they paid for such shares. Investors in our common stock must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of their investment in our stock could decline.

Because we do not intend to pay dividends on our common stock, investor returns will be limited to any increase in the value of our stock.

We have never declared or paid any cash dividends on our common stock. In addition, under the terms of our loan and security agreement with Oxford Finance LLC, we are required to obtain the prior written consent of Oxford Finance LLC in order to declare or pay a cash dividend on our common stock in an amount in excess of $500,000 in any fiscal year. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

ITEM 6. EXHIBITS.

The list of Exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index immediately preceding such Exhibits and is incorporated herein by this reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IDERA PHARMACEUTICALS, INC.

Date: August 6, 2015

/s/ Vincent J. Milano
Vincent J. Milano
President and Chief Executive Officer

(Principal Executive Officer)

Date: August 6, 2015

/s/ Louis J. Arcudi, III
Louis J. Arcudi, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

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Exhibit Index

Exhibit No.	
3.1	Restated Certificate of Incorporation of the Registrant, as amended.
10.1*	Amendment to Idera Pharmaceuticals, Inc. 2013 Stock Incentive Plan, as amended.
10.2	Employment Letter, dated June 5, 2015, by and between Idera Pharmaceuticals, Inc. and Mark J. Casey.
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on June 11, 2015 (SEC File No. 001-31918).