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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

or

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

For transition period from _____ to _____.

Commission File Number: 001-31918

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 ☒ No ☐

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

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

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

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

Common Stock, par value $.001 per share	147,653,120
Class	Outstanding as of October 28, 2016

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FORWARD-LOOKING STATEMENTS

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

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(UNAUDITED)

(In thousands, except per share amounts)	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,154	$ 26,586
Short-term investments	29,856	33,574
Prepaid expenses and other current assets	3,455	3,082
Total current assets	55,465	63,242
Long-term investments	1,408	26,997
Property and equipment, net	1,579	1,692
Restricted cash and other assets	26	345
Total assets	$ 58,478	$ 92,276
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 344	$ 1,169
Accrued expenses	6,118	4,274
Current portion of note payable	284	261
Current portion of deferred revenue	1,111	1,111
Total current liabilities	7,857	6,815
Deferred revenue, net of current portion	429	1,262
Note payable, net of current portion	285	501
Other liabilities	35	116
Total liabilities	8,606	8,694
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, $0.001 par value, Authorized — 280,000 shares; Issued and outstanding — 121,411 and 121,265 shares at September 30, 2016 and December 31, 2015, respectively	121	121
Additional paid-in capital	589,044	583,676
Accumulated deficit	(539,292)	(500,081)
Accumulated other comprehensive income (loss)	(1)	(134)
Total stockholders' equity	49,872	83,582
Total liabilities and stockholders' equity	$ 58,478	$ 92,276

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

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

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

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

IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

(In thousands)	Nine Months Ended September 30, 2016	2015
Cash Flows from Operating Activities:		
Net loss	$ (39,211)	$ (36,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-employee stock option expense	—	142
Stock-based compensation	5,127	4,013
Issuance of common stock for services rendered	129	90
Accretion of premiums and discounts on investments	466	397
Depreciation and amortization expense	484	346
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(48)	(1,163)
Accounts payable, accrued expenses, and other liabilities	937	(1,590)
Deferred revenue	(833)	—
Net cash used in operating activities	(32,949)	(34,330)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(2,946)	(63,106)
Proceeds from maturity of available-for-sale securities	29,946	23,602
Proceeds from sale of available-for-sale securities	1,974	999
Purchases of property and equipment	(369)	(659)
Net cash provided by (used in) investing activities	28,605	(39,164)
Cash Flows from Financing Activities:		
Proceeds from equity financings, net of issuance costs	—	80,599
Proceeds from exercise of common stock warrants and options and employee stock purchases	111	987
Payments on note payable	(193)	(59)
Payments on capital lease	(6)	(8)
Net cash (used in) provided by financing activities	(88)	81,519
Net (decrease) increase in cash and cash equivalents	(4,432)	8,025
Cash and cash equivalents, beginning of period	26,586	19,971
Cash and cash equivalents, end of period	$ 22,154	$ 27,996

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

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 2016

(UNAUDITED)

(1) Organization

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

The Company's business strategy is focused on the clinical development of drug candidates for oncology and rare diseases characterized by small, well-defined patient populations with serious unmet medical needs. The Company believes it can develop and commercialize these targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it plans to execute early-stage development through proof-of-concept clinical trials and explore potential collaborative alliances to support late-stage development and commercialization.

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

At September 30, 2016, the Company had an accumulated deficit of $539,292,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

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

(2) New Accounting Pronouncements - Recently Issued

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was amended by ASU No. 2015-14. ASU No. 2014-09, as amended by ASU No. 2015-14, requires an entity to recognize revenue from the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In particular, this ASU addresses contracts with more than one performance obligation, as well as the accounting for some costs to obtain or fulfill a contract with a customer, and provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers. This ASU will be effective for fiscal years beginning after December 15, 2017, including interim periods within that fiscal year. Early adoption of this ASU is permitted only for fiscal years beginning after December 15, 2016, including interim periods within that fiscal year. The Company is currently evaluating the effect that the adoption of this ASU will have on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 amends FASB Accounting Standards Codification ("ASC") 205-40, Presentation of Financial Statements — Going Concern, by providing guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements, including requiring management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements and providing certain disclosures if there is substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 will be effective for fiscal years ending after December 15, 2016 and for interim periods thereafter. Early adoption of ASU 2014-15 is permitted. The Company is currently evaluating ASU 2014-15 and has not yet adopted it. The Company believes that, based on its current operating plan, its existing cash, cash equivalents and investments, including the estimated $48.9 million of net proceeds raised in its October 2016 offering, including the partial exercise by the underwriters of their option to purchase additional shares of the offering and after deducting underwriters' discounts and commissions and estimated offering expenses (see Note 18, "Subsequent Events"), will enable the Company to fund its operations into the first quarter of 2018. The Company has and will continue to evaluate available alternatives to extend its operations beyond the first quarter of 2018.

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

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

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

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

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

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

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

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. GAAP for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2016 are not necessarily indicative of results that may be expected for the year ending December 31, 2016. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the SEC on March 10, 2016.

(4) Financial Instruments

The fair value of the Company's financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 6, "Fair Value of Assets and Liabilities." The Company is required to disclose the estimated fair values of its financial instruments. The Company's financial instruments consist of cash, cash equivalents, available-for-sale investments, receivables and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of September 30, 2016 and December 31, 2015. As of September 30, 2016 and December 31, 2015, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the note issued under the Company's loan and security agreement, which is discussed in Note 5(a) to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, including put and call features which the Company determined are clearly and closely associated with the debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial.

(5) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2016 and December 31, 2015 consisted of cash and money market funds.

(6) Fair Value of Assets and Liabilities

The Company measures fair value at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using assumptions that market participants would use in pricing the asset or liability (the "inputs") into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own

assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company's estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management's interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain. The Company applies ASU No. 2011-04, Fair Value Measurement (Topic 820), in its fair value measurements and disclosures.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2016 and December 31, 2015 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2016				
Assets				
Money market funds	$ 21,647	$ 21,647	$ —	$ —
Short-term investments – corporate bonds	22,591	—	22,591	—
Short-term investments – municipal bonds	7,265	—	7,265	—
Long-term investments – municipal bonds	1,408	—	1,408	—
Total Assets	$ 52,911	$ 21,647	$ 31,264	$ —
Total Liabilities	$ —	$ —	$ —	$ —
December 31, 2015				
Assets				
Money market funds	$ 26,056	$ 26,056	$ —	$ —
Short-term investments – commercial paper	3,974	—	3,974	—
Short-term investments – corporate bonds	24,575	—	24,575	—
Short-term investments – municipal bonds	5,025	—	5,025	—
Long-term investments – corporate bonds	21,186	—	21,186	—
Long-term investments – municipal bonds	5,811	—	5,811	—
Total Assets	$ 86,627	$ 26,056	$ 60,571	$ —
Total Liabilities	$ —	$ —	$ —	$ —

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond, commercial paper and municipal bond investments the fair value of which may not represent actual transactions of identical securities. The fair value of corporate and municipal bonds is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. The fair value of commercial paper is generally determined based on the relationship between the investment's discount rate and the discount rates of the same issuer's commercial paper available in the market which may not be actively traded daily. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders' equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value at September 30, 2016 or December 31, 2015.

(7) Investments

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

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

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

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

(8) Property and Equipment

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

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

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

(9) Restricted Cash

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

(10) Comprehensive Loss

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

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

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

(11) Collaboration with GlaxoSmithKline Intellectual Property Development Limited

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

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

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

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

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

Accounting Analysis

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

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

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

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

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

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

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

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

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

(12) Stock-Based Compensation

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

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

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

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

(13) Net Loss per Common Share

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

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

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

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

(15) Related Party Transactions

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

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

(16) Deferred Tax Assets

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

(17) Financing

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

(18) Subsequent Events

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

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

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

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

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

Overview

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

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

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

TLR Modulation Technology Platform

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

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

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

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

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

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

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

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

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

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

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

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

IMO-8400 in Rare Diseases

We have initiated clinical development of IMO-8400 for the treatment of rare diseases. We have selected dermatomyositis as the first rare disease for which we are developing IMO-8400. We selected this indication for development based on the reported increase in TLR expression in this disease state, expression of cytokines indicative of key TLR-mediated pathways and the presence of auto-antibodies that can induce TLR-mediated immune responses.

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

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

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

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

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

Third-generation Antisense (3GA)

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

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

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

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

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

Collaboration with GlaxoSmithKline Intellectual Property Development Limited

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

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

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

Additional Programs

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

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

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

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

Accumulated Deficit

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

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

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

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2016 and 2015

Alliance Revenue

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

Research and Development Expenses

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

	Three months ended September 30, (in thousands)		Percentage Increase	Nine months ended September 30, (in thousands)		Percentage Increase
	2016	2015	(Decrease)	2016	2015	(Decrease)
IMO-8400 external development expense	$ 2,771	$ 2,426	14%	$ 8,814	$ 6,952	27%
IMO-2125 external development expense	723	597	21%	2,330	597	290%
IMO-9200 external development expense	185	139	33%	471	2,404	(80%)
Other drug development expense	3,246	1,962	65%	9,668	8,673	11%
Basic discovery expense	2,468	2,330	6%	7,534	6,508	16%
	$ 9,393	$ 7,454	26%	$ 28,817	$ 25,134	15%

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

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

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

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

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

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

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

Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified 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 increases in other drug development expenses in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, were primarily due the costs of additional headcount associated with our expanded drug development programs and costs associated with the manufacture of 3GA drug supplies,

offset by lower consulting costs during the three and nine months ended September 30, 2016. In addition, the nine months ended September 30, 2015 included costs associated with the manufacture of IMO-2055 drug supply and other drug development expenses of IMO-2125 development expenses incurred prior to the commencement of its clinical development in our immuno-oncology program in July 2015. Costs associated with the clinical development of IMO-2125 since July 2015 are included in IMO-2125 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 3GA program. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The increases in basic discovery expenses in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, were primarily due to increases in payroll and stock-based compensation, the costs of laboratory supplies and facilities expenses during the three and nine months ended September 30, 2016. The increases in basic discovery expenses in the three and nine months ended September 30, 2016 were partially offset by decreases in external research and recruiting expenses in the three and nine months ended September 30, 2016.

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 clinical trial of IMO-8400, our ongoing clinical trial of IMO-2125, and our ongoing development of compounds in our 3GA 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.

General and Administrative Expenses

General and administrative expenses decreased by $123,000 from $4,030,000 in the three months ended September 30, 2015, to $3,907,000 in the three months ended September 30, 2016 and decreased by $87,000, from $11,688,000 in the nine months ended September 30, 2015, to $11,601,000 in the nine months ended September 30, 2016. General and administrative expenses consist primarily of salary expense, stock-based 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.

The changes in general and administrative expenses during the three and nine months ended September 30, 2016 reflect increases in salary expense, legal fees associated with our patent filing and maintenance and accounting and auditing fees, including the cost of Sarbanes-Oxley compliance and the related internal control audit, offset by decreases in corporate legal fees and investor relations expenses as compared to the three and nine months ended September 30, 2015. The changes in general and administrative expenses during the nine months ended September 30, 2016 also reflect an increase in stock-based compensation.

Interest Income

Interest income decreased by $33,000 from $123,000 in the three months ended September 30, 2015 to $90,000 in the three months ended September 30, 2016 and increased by $81,000 from $239,000 in the nine months ended September 30, 2015 to $320,000 in the nine months ended September 30, 2016. These variances were primarily due to fluctuations of investment balances in the three and nine months ended September 30, 2016 and 2015, which were impacted by the investment of funds obtained from our follow-on underwritten public offering in February 2015 and from warrant and option exercises since June 2015, offset by general spending.

Interest Expense

Interest expense decreased during the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, primarily due to a decrease in the outstanding principal amount of our note under our loan and security agreement with Oxford Finance LLC.

Net Loss

As a result of the factors discussed above, our net loss was $12,903,000 for the three months ended September 30, 2016, compared to $11,365,000 for the three months ended September 30, 2015 and $39,211,000 for the nine months ended September 30, 2016, compared to $36,565,000 for the nine months ended September 30, 2015. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2016, we incurred losses of $279,099,000. 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 earlier generation antisense technology. Since our inception, we had an accumulated deficit of $539,292,000 through September 30, 2016. 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.

We have an effective shelf registration statement on Form S-3 that permits us to offer and sell, as of October 28, 2016, up to an additional $61,300,000 of securities in one or more offerings.

Cash Flows

Nine Months Ended September 30, 2016

As of September 30, 2016, we had approximately $53,418,000 in cash, cash equivalents and investments, a net decrease of approximately $33,739,000 from December 31, 2015. Net cash used in operating activities totaled $32,949,000 during the nine months ended September 30, 2016, reflecting our $39,211,000 net loss for the period, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and amortization expense and accretion of investment premiums. Net cash used in operating activities also reflects changes in our prepaid expenses, accounts payable, accrued expenses and other liabilities and the recognition of deferred revenue.

The $28,605,000 net cash provided by investing activities during the nine months ended September 30, 2016 reflects proceeds from the maturity of $29,946,000 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, and proceeds from the sale of $1,974,000 of available-for-sale securities, partially offset by the purchase of $2,946,000 of available-for-sale securities and payments for the purchase of $369,000 in property and equipment.

The $88,000 net cash used in financing activities during the nine months ended September 30, 2016 reflects $ 193,000 in payments on our note payable, partially offset by $111,000 in net proceeds from employee stock purchases under our 1995 Employee Stock Purchase Plan, or ESPP.

Nine Months Ended September 30, 2015

As of September 30, 2015, we had approximately $94,694,000 in cash, cash equivalents and investments, a net increase of approximately $46,123,000 from December 31, 2014. Net cash used in operating activities totaled $34,330,000 during the nine months ended September 30, 2015, reflecting our $36,565,000 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 $39,164,000 net cash used in investing activities during the nine months ended September 30, 2015 reflects the purchase of $63,106,000 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 $23,602,000 of available-for-sale securities, the sale of $999,000 of available-for-sale securities, and payments for the purchase of $659,000 in property and equipment.

The $81,519,000 net cash provided by financing activities during the nine months ended September 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 $987,000 in net proceeds from employee stock purchases under our ESPP and the exercise of common stock options.

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 $539,292,000 at September 30, 2016. 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 October 15, 2016, 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 $53,418,000 at September 30, 2016. In October 2016, we received estimated net proceeds of approximately $48,902,000 from a follow-on public offering, including from the partial exercise by the underwriters of their option to purchase additional shares of the offering, after deducting underwriters' discounts and commissions and estimated offering expenses. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments, including the net proceeds from the offering, will enable us to fund our operations into the first quarter of 2018. Specifically, we believe that our available funds will be sufficient to enable us to:

- participate in an FDA End-of-Phase 1 meeting to obtain FDA feedback on the regulatory pathway for IMO-2125;
- complete our ongoing Phase 1/2 clinical trial of IMO-2125 in combination with ipilimumab or pembrolizumab in anti-PD1 refractory metastatic melanoma;
- prepare for the initiation of a pivotal Phase 3 clinical trial of IMO-2125 in combination with a checkpoint inhibitor for the treatment of anti-PD1 refractory metastatic melanoma;
- initiate a Phase 1 intra-tumoral monotherapy clinical trial of IMO-2125 in multiple refractory tumor types;
- initiate a Phase 2 multi-arm clinical trial of IMO-2125 in combination with a checkpoint inhibitor in multiple refractory tumor types;
- complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis; and
- submit an IND and initiate a Phase 1 human clinical proof-of-concept trial for one of our 3GA compounds.

We expect that we will need to raise additional funds in order to conduct any other clinical development of our TLR drug candidates or to conduct any other development of our 3GA technology, 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 rare disease program, our immuno-oncology program and our 3GA program, and our ability to advance our drug candidates and 3GA 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 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, 2015 that was filed with the SEC, 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 nine months ended September 30, 2016, 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, 2015.

As of September 30, 2016, we had no off-balance sheet arrangements.

New Accounting Pronouncements

New accounting pronouncements are discussed in Note 2 in the notes to the financial statements in this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As of September 30, 2016, 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 September 30, 2016, all of our invested funds were invested in two money market funds, classified in cash and cash equivalents on the accompanying balance sheet, corporate bonds and municipal bonds classified in short-term investments on the accompanying balance sheet and municipal bonds classified in long-term investments on the accompanying balance sheet.

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 Exchange Act) as of September 30, 2016. 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 September 30, 2016, 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 SEC'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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 $53.4 million at September 30, 2016. In October 2016, we received estimated net proceeds of approximately $48.9 million from a follow-on public offering, including the partial exercise by the underwriters of their option to purchase additional shares of the offering and after deducting underwriters' discounts and commissions and estimated offering expenses. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments, including the net proceeds of the offering, will enable us to fund our operations into the first quarter of 2018. Specifically, we believe that our available funds will be sufficient to enable us to:

- participate in an FDA End-of-Phase 1 meeting to obtain FDA feedback on the regulatory pathway for IMO-2125;
- complete our ongoing Phase 1/2 clinical trial of IMO-2125 in combination with ipilimumab or pembrolizumab in anti-PD1 refractory metastatic melanoma;
- prepare for the initiation of a pivotal Phase 3 clinical trial of IMO-2125 in combination with a checkpoint inhibitor for the treatment of anti-PD1 refractory metastatic melanoma;
- initiate a Phase 1 intra-tumoral monotherapy clinical trial of IMO-2125 in multiple refractory tumor types;
- initiate a Phase 2 multi-arm clinical trial of IMO-2125 in combination with a checkpoint inhibitor in multiple refractory tumor types;
- complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis; and
- submit an IND and initiate a Phase 1 human clinical proof-of-concept trial for one of our 3GA compounds.

We expect that we will need to raise additional funds in order to conduct any other clinical development of our TLR drug candidates or to conduct any other development of our 3GA technology, 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 rare disease program, our immuno-oncology program and our 3GA program, and our ability to advance our drug candidates and 3GA 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 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, 2015 that was filed with the SEC, 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 September 30, 2016, we had an accumulated deficit of $539.3 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to September 30, 2016, we incurred losses of $279.1 million. We incurred losses of $260.2 million prior to December 31, 2000, during which time we were primarily involved in the development of earlier generation 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 September 30, 2016, 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 rare diseases and in our immuno-oncology program and on the development of our 3GA 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 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 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 3GA program. For instance:

- we are conducting a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab or pembrolizumab in patients with anti-PD1 refractory metastatic melanoma;
- we plan to conduct additional clinical trials of IMO-2125 in our immuno-oncology program both as a monotherapy and in combination with checkpoint inhibitors for the treatment of multiple tumor types;
- we are conducting a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis; and
- we are developing compounds in our 3GA program and plan to initiate a clinical trial of one of these compounds in the second half of 2017.

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 rare disease and immuno-oncology programs, and the successful identification, development and commercialization of drug candidates in our 3GA program.

Our ability to generate milestone and royalty revenues under our collaborations with Merck & Co. and GSK, 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 under the collaborations.

Our efforts, and the efforts of Merck & Co. and GSK, to develop and commercialize compounds are at an early stage and are subject to many challenges. For instance, we previously experienced a setback with respect to our program for IMO-2125 for hepatitis C. 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. Additionally, in September 2016, we discontinued our development program of IMO-8400 for the treatment of B-cell lymphomas and suspended our ongoing Phase 1/2 clinical trials of IMO-8400 in patients with Waldenström's macroglobulinemia and in patients with DLBCL harboring the MYD88 L265P oncogenic mutation due to several factors, including the lack of a strong clinical signal for Waldenström's macroglobulinemia patients and the inability to adequately enroll patients with DLBCL.

We have entered into 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 additional applications of our 3GA technology program. Our previous setbacks with respect to our program for IMO-2125 in patients with chronic hepatitis C virus and our program for IMO-8400 in patients with B-cell lymphomas could negatively impact our ability to license any of such compounds, or any of our other compounds, particularly related 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, IMO-2125 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 ability to secure orphan drug exclusivity for our drug candidates either alone or in combination with other products;
- 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;
- favorable market conditions in which to raise additional capital;
- 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 in the early stages of developing our TLR9 agonists in combination with checkpoint inhibitors, which is a novel technology, and our efforts may not be successful or result in any approved and marketable products.

In June 2015, we entered into a strategic clinical research alliance with MD Anderson to advance clinical development of TLR9 agonists in combination with checkpoint inhibitors. We initiated the first trial from the research alliance, a Phase 1/2 clinical trial to assess the safety and efficacy of IMO-2125, administered intra-tumorally in combination with ipilimumab, a CTLA4 antibody, in patients with metastatic melanoma (anti-PD1 refractory) in the fourth quarter of 2015. While we have evaluated the safety profile of IMO-2125 in previous trials, in those trials we evaluated the safety profile of IMO-2125 by subcutaneous injection and not by intra-tumoral injection. In addition, while, as a marketed product, the safety profile of ipilimumab is known, the safety profile of the combination of IMO-2125 and ipilimumab has not been evaluated in previous trials. These factors may result in participating subjects experiencing serious adverse events or undesirable side effects or exposure to unacceptable health risks requiring us to suspend or terminate any clinical trials that we may conduct of IMO-2125 in combination with ipilimumab, or any other checkpoint inhibitor. Furthermore, we have expanded the Phase 1/2 clinical trial to include the assessment of safety and efficacy of IMO-2125, administered intra-tumorally in combination with pembrolizumab, an anti-PD1 antibody in patients with metastatic melanoma (anti-PD1 refractory). While, as a marketed product, the safety profile of pembrolizumab is known, the safety profile of the combination of IMO-2125 and pembrolizumab has not been evaluated in previous trials and may result in participating subjects experiencing serious adverse events or undesirable side effects or exposure to unacceptable health risks requiring us to suspend or terminate any clinical trials that we may conduct of IMO-2125 in combination with pembrolizumab, or any other checkpoint inhibitor.

In September 2016, we disclosed early clinical results from the Phase 1 portion of our ongoing Phase 1/2 clinical trial of IMO-2125. It is important to note that the clinical responses reported from the first two dosing cohorts of the Phase 1 portion of the trial were observed in only three of the patients enrolled through the second cohort, were achieved in an open-label setting, are not statistically significant, and might not be achieved by any other patient treated with IMO-2125. Moreover, we expect to release additional interim results from this trial as early as November 2016. These additional interim results as well as final results from this trial and results of future trials may not be positive or consistent with the results of this trial we have observed to date.

We are in the early stages of developing our 3GA 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 3GA 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 3GA drug candidates.

The future success of our 3GA 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 for development of drug candidates generated from our 3GA technology. We are developing 3GA compounds against two gene targets, NLRP3 and DUX4, and are conducting IND-enabling studies of a 3GA compound against NLRP3. We are also conducting preliminary analysis of 3GA compounds for other undisclosed potential gene targets.

However, many steps must be successfully achieved prior to the declaration of a 3GA 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 products as a result of our efforts with respect to our 3GA 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. For example, we recently suspended our clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation due to difficulty in enrolling patients. Additionally, because there are a limited number of patients with dermatomyositis, 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 anticipated. 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.

Patient enrollment is affected by other factors including the:

- severity of the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the TLR-targeted drug candidates under study;
- efforts to facilitate timely enrollment in clinical trials;
- availability of competing clinical trials or other therapies;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- 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. For example, in September 2016, we disclosed positive early data from the first two dosing cohorts of the Phase 1 portion of our ongoing Phase 1/2 clinical trial of IMO-2125. There is no assurance that any interim results or the final results of our ongoing Phase 1/2 clinical trial or any future trial of IMO-2125 will be positive or consistent with results previously reported. 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.

Other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. 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;
- 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 making continuation and/or completion improbable; 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, reduce the potential length of patent exclusivity 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 additional financing;
- 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 3GA drug candidates. Neither we nor any other company have obtained regulatory approval to market such TLR-targeted drug candidates or 3GA oligonucleotides 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 3GA 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.

Moreover, only one oligonucleotide anti-sense drug, Kynamro®, has been approved by the FDA for marketing in the United States since 1998 and is currently being marketed.

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 rare diseases and in our immuno-oncology program. We are conducting a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis. In addition, through our clinical alliance partner MD Anderson, we are conducting a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab, a CTLA4 antibody, or pembrolizumab in patients with metastatic melanoma and plan to initiate additional clinical trials of IMO-2125 in our immuno-oncology program both as a monotherapy and in combination with checkpoint inhibitors for the treatment of multiple tumor types. We also entered into a collaborative alliance agreement with GSK, and expect to seek to enter into additional collaborative alliances with pharmaceutical companies with respect to applications of our 3GA technology program. 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.

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. We are not aware of other new chemical or molecular entities being developed for the treatment of dermatomyositis.

We are aware that other companies including Dynavax, Checkmate Pharmaceuticals, Inc., or Checkmate, 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 may be developing TLR agonists for various indications, some of which are in the field of oncology.

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 and Checkmate is conducting a Phase 1b clinical trial of an investigational TLR9 agonist in combination with a checkpoint inhibitor.

We are also developing 3GA 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 3GA 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 Ionis and its partners. Ionis 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 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 is planned for our drug candidates upon commercialization, 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.

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, 2019, 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;
- warning letters or untitled letters;
- voluntary or mandatory product recalls;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of regulatory approvals and our products from the market;
- 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. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and purity. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

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 conducting a Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab or pembrolizumab in patients with anti-PD1 refractory metastatic melanoma;
- we plan to conduct additional clinical trials of IMO-2125 in our immuno-oncology program both as a monotherapy and in combination with checkpoint inhibitors for the treatment of multiple tumor types;
- we are conducting a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis; and
- we are developing compounds in our 3GA program and plan to initiate a clinical trial of one of these compounds in the second half of 2017.

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. In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate. If we do not obtain necessary regulatory approvals, or there are delays in doing so, our business will be adversely affected.

We may not be able to obtain orphan drug exclusivity for applications of our TLR 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 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 the same indication for that exclusivity 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 such 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 had 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

designation or exclusivity for any other disease indications for which we develop IMO-8400, for IMO-2125, or for our other drug candidates. Even if 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 required by the FDA to obtain approval of a companion diagnostic in connection with and as a condition to approval of a drug candidate, and we do not obtain or we experience delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize the drug candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Under the Federal Food, Drug, and Cosmetic Act, companion diagnostics are regulated as medical devices and the FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain Premarket Approval, or a PMA. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA approval is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

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. 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
- 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.

Our relationships with healthcare providers, physicians and third party payors are subject, directly or indirectly, to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our arrangements with healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we for which we are seeking to obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our drug candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of our drug candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our drug candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models.

Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

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 November 2015, we entered into a collaboration and license agreement with GSK for the development of our 3GA technology for certain renal indications.

Any collaboration that we enter into may not be successful. 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 or right to use technology and intellectual property 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;
- 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 collaboration 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 collaboration 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 collaboration with us or terminate the strategic collaboration. 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. The termination or expiration of our agreement with Merck & Co. or GSK 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 have entered into 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 additional applications of our 3GA 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 rare diseases and in our immuno-oncology program and on 3GA 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 3GA 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 or IMO-8400, given our setbacks with respect to these drug candidates. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology or our 3GA 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 currently pending 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 October 15, 2016, 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 and IMO-2125, as well as other compounds. As of October 15, 2016, all of our patent rights covering immune modulatory compositions and methods of their use are based on discoveries made solely by us. Patents that have issued to us are expected to expire at various dates ranging from 2017 to 2034. 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 one U.S. patent application and one issued U.S. patent that cover the chemical composition for IMO-9200 and methods of its use. The issued patent has a statutory expiration date in 2034. 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 has a statutory expiration date in 2025.

As of October 15, 2016, we owned two issued U.S. patents, 21 issued foreign patents, seven pending U.S. patent applications and 7 foreign patent applications related to our 3GA technology and methods of its use. The issued patents covering our 3GA technologies have statutory expiration dates in 2030 and 2031.

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 immunostimulatory polynucleotides and their use to stimulate an immune response, as well as to 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 current or future drug candidates of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our drug candidates, 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, or may be delayed in doing so. Either of these results could have a material adverse effect on our business.

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.

In addition to litigation, we may become involved in patent office proceedings, including 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.

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 or otherwise, 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. 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 October 15, 2016, 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 2 clinical trial of IMO-8400 in patients with dermatomyositis, and our Phase 1/2 clinical trial of IMO-2125, administered intra-tumorally, in combination with ipilimumab or pembrolizumab, in patients with metastatic melanoma and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for 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.

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
- 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 health care legislation on our future profitability and financial condition, the 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;
- 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 October 15, 2016, Baker Bros. Advisors LP, and certain of its affiliated funds, which we refer to collectively as Baker Brothers, held 10,272,314 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 October 15, 2016, Baker Brothers beneficially owned 7.1% 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 October 15, 2016, Baker Brothers would have beneficially owned 28.0% of our common stock. The information in this paragraph is based on a Schedule 13G filed with the SEC on February 16, 2016 and a Schedule 13D filed with the SEC on October 11, 2016, on Form 4s filed with the SEC on April 5, 2016, July 6, 2016 and October 11, 2016 and on information provided to us by Baker Brothers. On February 9, 2015, we entered into a registration rights agreement with Baker Brothers, pursuant to which we agreed to file registration statements to register for resale the shares of our common stock, including shares issuable upon the exercise of warrants, held by Baker Brothers. We filed a registration statement under this agreement in the first quarter of 2016.

As of October 15, 2016, entities affiliated with Pillar Invest Corporation, which we refer to collectively as the Pillar Investment Entities, held 20,346,942 shares of our common stock and warrants to purchase up to 11,962,731 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 October 15, 2016, 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 October 15, 2016, the Pillar Investment Entities would have beneficially owned 20.5% of our common stock. The information in this paragraph is based on information provided to us by the Pillar Investment Entities and on Form 4s filed with the SEC on April 5, 2016 and July 6, 2016, a Form 3 filed with the SEC on October 12, 2016 and a Schedule 13D/A filed with the SEC on October 17, 2016.

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, 2015 to October 15, 2016, the closing sales price of our common stock ranged from a high of $5.37 per share to a low of $1.32 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;
- 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.

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: November 1, 2016

/s/ Vincent J. Milano

Vincent J. Milano
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2016

/s/ Louis J. Arcudi, III

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

Exhibit Index

Exhibit No.	
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

EXHIBIT 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

I, Vincent J. Milano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 1, 2016

/s/ VINCENT J. MILANO
Vincent J. Milano
Chief Executive Officer

EXHIBIT 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

I, Louis J. Arcudi, III certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 1, 2016

/s/ LOUIS J. ARCUDI, III

Louis J. Arcudi, III

Chief Financial Officer

EXHIBIT 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

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vincent J. Milano, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: November 1, 2016

/s/ VINCENT J. MILANO
Vincent J. Milano
Chief Executive Officer

EXHIBIT 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

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Louis J. Arcudi, III, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: November 1, 2016

/s/ LOUIS J. ARCUDI, III
Louis J. Arcudi, III
Chief Financial Officer