
**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 June 30, 2014

or

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

For transition period from _____ to _____.

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

167 Sidney Street
Cambridge, Massachusetts
(Address of principal executive offices)

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

02139
(Zip code)

(617) 679-5500
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

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

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

[Table of Contents](#)

IDERA PHARMACEUTICALS, INC.
FORM 10-Q
INDEX

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
Item 1 — Financial Statements — Unaudited	1
Condensed Balance Sheets as of June 30, 2014 and December 31, 2013	1
Condensed Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2014 and 2013	2
Condensed Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013	3
Notes to Condensed Financial Statements	4
Item 2 — Management’s Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3 — Quantitative and Qualitative Disclosures About Market Risk	18
Item 4 — Controls and Procedures	19
<u>PART II — OTHER INFORMATION</u>	
Item 1A — Risk Factors	20
Item 6 — Exhibits	39
Signatures	40

IMO® and Idera® are our trademarks. All other trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “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 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)

	June 30, 2014	December 31, 2013
(In thousands, except per share amounts)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,886	\$ 26,278
Short-term investments	8,844	3,125
Prepaid expenses and other current assets	836	874
Total current assets	64,566	30,277
Long-term investments	1,004	6,189
Property and equipment, net	686	90
Restricted cash	311	311
Total assets	\$ 66,567	\$ 36,867
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,026	\$ 904
Accrued expenses	4,221	3,506
Total current liabilities	6,247	4,410
Other liabilities	59	5
Total liabilities	6,306	4,415
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares		
Series E convertible preferred stock, Designated, issued and outstanding — 424 shares	5,528	5,528
Series D convertible preferred stock, Designated, issued and outstanding — zero shares and 1,124 shares at June 30, 2014 and December 31, 2013, respectively	—	5,464
Series A convertible preferred stock, Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, \$0.001 par value, Authorized — 280,000 shares ; Issued and outstanding — 83,758 and 66,252 shares at June 30, 2014 and December 31, 2013, respectively	84	66
Additional paid-in capital	484,799	434,285
Accumulated deficit	(430,153)	(412,884)
Accumulated other comprehensive gain (loss)	3	(7)
Total stockholders' equity	60,261	32,452
Total liabilities and stockholders' equity	\$ 66,567	\$ 36,867

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

IDERA PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)**

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

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

IDERA PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

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

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

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

June 30, 2014

(UNAUDITED)

(1) Organization

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

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

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

At June 30, 2014, the Company had an accumulated deficit of \$430,153,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

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

(2) New Accounting Pronouncements - Recently Issued

In April 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-08 – Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this ASU require that a disposal representing a strategic shift that has (or will have) a major effect on an entity’s operations and financial results or a business activity classified as held for sale should be reported as discontinued operations. The amendments also expand the disclosure requirements for discontinued operations and add new disclosure requirements for individually significant components that do not qualify as discontinued operations. This ASU will be effective prospectively for fiscal years beginning on or after December 15, 2014. Early adoption is permitted, but only for disposals that have not been previously reported in financial statements previously issued. The Company does not expect the adoption of this ASU to have a material effect on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09 – Revenue from Contracts with Customers (Topic 606). This ASU requires an entity to recognize revenue from the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In particular, this ASU addresses contracts with more than one performance obligation, as well as the accounting for some costs to obtain or fulfill a contract with a customer, and provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers. This ASU will be effective for fiscal years beginning after December 15, 2016. Early adoption of this ASU is not permitted. The Company is currently evaluating the effect that the adoption of this ASU will have on its financial statements.

[Table of Contents](#)

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with United States Generally Accepted Accounting Principles (“U.S. GAAP”) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the six months ended June 30, 2014 are not necessarily indicative of results that may be expected for the year ended December 31, 2014. For further information, refer to the financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2013, which was filed with the SEC on March 13, 2014.

(4) Financial Instruments

The fair value of the Company’s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 6, “Fair Value of Assets and Liabilities.” The Company is required to disclose the estimated fair values of its financial instruments. The Company’s financial instruments consist of cash, cash equivalents, available-for-sale investments and receivables. The estimated fair values of these financial instruments approximate their carrying values as of June 30, 2014 and December 31, 2013. As of June 30, 2014 and December 31, 2013, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the Company’s Series E convertible preferred stock (the “Series E preferred stock”), the embedded features of which are discussed in Note 8(g) to the financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2013.

(5) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at June 30, 2014 and December 31, 2013 consisted of cash and money market funds.

(6) Fair Value of Assets and Liabilities

The Company measures fair value at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using assumptions that market participants would use in pricing the asset or liability (the “inputs”) into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company’s estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management’s interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain. The Company applies Accounting Standards Update (“ASU”) No. 2011-04, “Fair Value Measurement (Topic 820),” in its fair value measurements and disclosures.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at June 30, 2014 and December 31, 2013 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
June 30, 2014				
Assets				
Money market funds	\$54,814	\$ 54,814	\$ —	\$ —
Short-term investments – commercial paper	998	—	998	—
Short-term investments – corporate bonds	7,846	—	7,846	—
Long-term investments – corporate bonds	1,004	—	1,004	—
Total Assets	\$64,662	\$ 54,814	\$ 9,848	\$ —

[Table of Contents](#)

(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)
December 31, 2013				
Assets				
Money market funds	\$25,201	\$ 25,201	\$ —	\$ —
Short-term investments – commercial paper	1,997	—	1,997	—
Short-term investments – corporate bonds	1,128	—	1,128	—
Long-term investments – corporate bonds	6,189	—	6,189	—
Total Assets	\$34,515	\$ 25,201	\$ 9,314	\$ —

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

(7) Investments

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

	June 30, 2014			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Commercial paper due in one year or less	\$ 998	\$ —	\$ —	\$ 998
Corporate bonds due in one year or less	7,842	—	4	7,846
Total short-term investments	8,840	—	4	8,844
Total long-term investments	1,005	(1)	—	1,004
Total investments	\$9,845	\$ (1)	\$ 4	\$ 9,848

	December 31, 2013			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Commercial paper due in one year or less	\$1,997	\$ —	\$ —	\$ 1,997
Corporate bonds due in one year or less	1,128	—	—	1,128
Total short-term investments	3,125	—	—	3,125
Corporate bonds due in one year or more	6,196	(7)	—	6,189
Total long-term investments	6,196	(7)	—	6,189
Total investments	\$9,321	\$ (7)	\$ —	\$ 9,314

The Company had no realized gains or losses from available-for-sale securities in the six months ended June 30, 2014 and 2013. There were no losses or other-than-temporary declines in value included in "Investment income, net" on the Company's condensed statements of operations and comprehensive loss for any securities for the three and six months ended June 30, 2014 and 2013. The Company had no auction rate securities as of June 30, 2014 and December 31, 2013. See Note 4, "Financial Instruments," and Note 6, "Fair Value of Assets and Liabilities" for additional information related to the Company's investments.

[Table of Contents](#)**(8) Property and Equipment**

At June 30, 2014 and December 31, 2013, net property and equipment at cost consisted of the following:

(In thousands)	June 30, 2014	December 31, 2013
Leasehold improvements	\$ 525	\$ 525
Laboratory equipment and other	3,238	2,854
Total property and equipment, at cost	3,763	3,379
Less: accumulated depreciation	3,077	3,289
Property and equipment, net	\$ 686	\$ 90

Depreciation and amortization expense was approximately \$47,000 and \$33,000 in the three months ended June 30, 2014 and 2013, respectively, and approximately \$78,000 and \$75,000 in the six months ended June 30, 2014 and 2013, respectively.

(9) Restricted Cash

As part of the Company's lease arrangement for its office and laboratory facility, the Company is required to restrict cash held in a certificate of deposit securing a line of credit for the lessor. As of June 30, 2014 and December 31, 2013, the restricted cash amounted to \$311,000 held in certificates of deposit securing a line of credit for the lessor.

(10) Collaborations*(a) Collaboration with Abbott Molecular Inc.*

In May 2014, the Company entered into a collaboration with Abbott Molecular, Inc. ("Abbott Molecular") for the development of a companion diagnostic that can be used to identify patients with the MYD88 L265P oncogenic mutation. Under the agreement, Abbott Molecular has agreed to develop the companion diagnostic to comply with the requirements of the U.S. Food and Drug Administration ("FDA") Center for Devices and Radiological Health. The Company expects to pay approximately \$6,700,000 in external development expenses over five years under the agreement to develop an assay as the prototype of the companion diagnostic, to validate the prototype during a Phase 2 clinical trial of IMO-8400, and to complete FDA regulatory requirements and launch activities of the final version of the companion diagnostic. Such expenses are subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if the Company is required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs. The Company will not receive any revenues from future sales, if any, of the companion diagnostic. The Company expects to use the prototype companion diagnostic developed by Abbott Molecular in its ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and in future clinical trials of IMO-8400. The Company incurred \$1,300,000 in expenses under the Abbott Molecular agreement through June 30, 2014.

(b) Amendment to Exclusive License and Research Collaboration Agreement with Merck Sharp & Dohme Corp.

In April 2014, the Company entered into an amendment to its exclusive license and research collaboration agreement with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc. ("Merck & Co.")). Under the license and research collaboration agreement, which the Company entered into with Merck & Co. in December 2006, the Company had granted Merck & Co. worldwide exclusive rights to its TLR7, TLR8, and TLR9 agonists for use in combination with Merck & Co.'s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer's disease. As a result of this amendment, Merck & Co.'s rights under the license and research collaboration agreement have been limited to specified TLR7, TLR8, and TLR9 agonists that Merck & Co. selected in January 2012, and the Company regained the rights to pursue its other independently discovered TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer's disease so that it now has the right to pursue its TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in all fields. Merck & Co.'s obligations under the agreement to pay the Company milestone payments and royalties continue in effect with respect to the specified TLR7, TLR8, and TLR9 agonists. However, in connection with this amendment, the Company agreed that, to the extent that the Company licenses to third parties any TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer's disease and receives income under such licenses, Merck & Co. may credit against any milestone payments and royalties it owes to the Company an amount equal to 15% of the license income received by the Company under the third-party licenses, up to a maximum of \$60.0 million in credits.

[Table of Contents](#)

(11) Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss for the six months ended June 30, 2014 and 2013 is comprised of reported net loss and any change in net unrealized gains and losses on investments during each period, which is included in accumulated other comprehensive gain (loss) on the accompanying balance sheets. The Company applies ASU No. 2011-05, "Comprehensive Income" by presenting the components of net income and other comprehensive income as one continuous statement.

The following table includes the changes in the accumulated balance of the component of other comprehensive gain (loss) for the six months ended June 30, 2014:

(In thousands)	Six Months ended June 30, 2014
Accumulated unrealized loss on available-for-sale securities at beginning of period	\$ (7)
Change during the period	10
Accumulated unrealized gain on available-for-sale securities at end of period	<u>\$ 3</u>

There was no accumulated unrealized gain or loss on available-for-sale securities during the six months ended June 30, 2013.

(12) Stock-Based Compensation

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

The Company recorded charges of \$785,000 and \$265,000 in its statements of operations and comprehensive loss for the three months ended June 30, 2014 and 2013, respectively, and \$1,320,000 and \$518,000 in its statements of operations and comprehensive loss for the six months ended June 30, 2014 and 2013, respectively, for stock-based compensation expense attributable to share-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 assumptions apply to the options to purchase 2,116,000 and 1,720,083 shares of common stock granted to employees and directors during the six months ended June 30, 2014 and 2013, respectively:

	Six Months Ended June 30, 2014	2013
Average risk free interest rate	1.6%	0.9%
Expected dividend yield	—	—
Expected lives (years)	4.8	5.0
Expected volatility	83.0%	61.0%
Weighted average grant date fair value of options granted during the period (per share)	\$ 2.61	\$ 0.36
Weighted average exercise price of options granted during the period (per share)	\$ 4.01	\$ 0.69

The expected lives and the expected volatility of the options granted during the six months ended June 30, 2014 and 2013 are based on historical experience. All options granted during the six months ended June 30, 2014 and 2013 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

(13) Net Loss per Common Share Applicable to Common Stockholders

For the three and six months ended June 30, 2014 and 2013, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were 80,016,676 and 85,807,964 for the six months ended June 30, 2014 and 2013, respectively, and consist of stock options, preferred stock and warrants.

[Table of Contents](#)

For the three months ended June 30, 2014, net loss per common share applicable to common stockholders reflects \$118,000 in dividends accrued on shares of the Series E preferred stock. For the six months ended June 30, 2014, net loss per common share applicable to common stockholders reflects \$303,000 in dividends accrued on shares of the Company's Series D convertible preferred stock ("Series D preferred stock") and the Series E preferred stock. As discussed in Note 15, "Related Party Transactions," the Series D preferred stock was converted to common stock on February 6, 2014. For the three and six months ended June 30, 2013, net loss per common share applicable to common stockholders reflects \$1,750,000 related to the loss on extinguishment of the Series D preferred stock and the Series E preferred stock that the Company issued in November 2011 and November 2012, respectively, that has been charged to net loss applicable to common stockholders as a preferred stock dividend, and \$280,000 and \$559,000, respectively, in dividends payable on shares of Series D preferred stock and Series E preferred stock. The \$1,750,000 loss on extinguishment of the Series D preferred stock and the Series E preferred stock in the three and six months ended June 30, 2013 was recorded following the irrevocable waiver by the holder of the Series D preferred stock of the Series D preferred stock redemption rights and liquidation preferences and by the holders of the Series E preferred stock of the Series E preferred stock liquidation preferences, which irrevocable waivers became effective when the Company completed its follow-on underwritten public offering on May 7, 2013. The Company determined that the irrevocable waivers represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock and therefore accounted for them as an extinguishment of the Series D preferred stock and the Series E preferred stock.

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

During the six months ended June 30, 2014, the Company issued 3,364,033 shares of common stock in connection with warrant and stock option exercises and purchases under the Company's 1995 Employee Stock Purchase Plan (the "ESPP") resulting in total proceeds to the Company of \$6,780,000.

During the six months ended June 30, 2013, the Company issued 3,574 shares of common stock in connection with employee stock purchases under the ESPP, which resulted in total proceeds to the Company of \$2,000. During this period, there were no warrant or option exercises.

(15) Related Party Transactions

February 6, 2014 Conversion of Series D Preferred Stock

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

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

Director Stock Purchases

The Company issued 8,546 and 18,617 shares of common stock in lieu of director board and committee fees of approximately \$36,000 and \$9,000 pursuant to the Company's director compensation program during the six months ended June 30, 2014 and 2013, respectively.

(16) Financing

February 10, 2014 Follow-on Underwritten Public Offering

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

[Table of Contents](#)

May 7, 2013 Follow-on Underwritten Public Offering

On May 7, 2013, the Company closed a follow-on underwritten public offering, in which it sold 17,500,000 shares of common stock, together with matching warrants to purchase up to 17,500,000 shares of common stock, and pre-funded warrants to purchase up to 15,816,327 shares of common stock, together with matching warrants to purchase up to 15,816,327 shares of common stock, for aggregate gross proceeds of \$16.5 million as follows:

	Combined Price to the Public (per share of common stock)	Common Stock	Pre-funded Warrants	Matching Warrants
Common stock and matching warrants sold (shares)	\$ 0.50	17,500,000	—	17,500,000
Pre-funded warrants and matching warrants sold (shares)	\$ 0.49	—	15,816,327	15,816,327
Total (shares)		17,500,000	15,816,327	33,316,327
Warrant exercise price (per share)	—	—	\$ 0.01	\$ 0.47
Term of warrant (years)	—	—	7.0	5.0

The net proceeds to the Company from the offering, after deducting underwriters' discounts and commissions and offering costs and expenses and excluding the proceeds of the future exercise of the warrants, if any, were approximately \$14.5 million.

The warrants and the pre-funded warrants each provide that, after the second anniversary of the date of issuance, the Company may redeem the warrants for \$0.01 per share of common stock issuable on exercise of the warrants following 30 days' prior written notice to the holder if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to \$2.80.

(17) Subsequent Events

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

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

GENERAL

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

Programs for Toll-like Receptor Antagonists

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

[Table of Contents](#)

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

Program in Genetically Defined Forms of B-cell Lymphoma. Independent research has suggested that the inhibition of specific TLRs may be a useful approach to the treatment of certain B-cell lymphoma characterized by the presence of the oncogenic mutation referred to scientifically as MYD88 L265P. Oncogenic mutations are changes in the DNA of tumor cells that promote the survival and proliferation of the tumor cells. The MYD88 L265P oncogenic mutation has been reported in patients with Waldenström's macroglobulinemia, diffuse large B-cell lymphoma, or DLBCL, and other forms of B-cell malignancies, including Burkitt's lymphoma, cutaneous diffuse large B-cell lymphoma (leg type), chronic lymphocytic leukemia, gastric mucosa-associated lymphoid tissue lymphoma, marginal zone lymphoma, and splenic marginal zone lymphoma. In this research, the inhibition of TLR7 and TLR9 suppressed MYD88 L265P induced signaling and promoted tumor cell death.

We presented results from our preclinical studies of IMO-8400 in April 2014 at the annual meeting of the American Association for Cancer Research, and in August 2014 at the American Society of Hematology Meeting on Lymphoma Biology. In these studies, IMO-8400 induced cell death in human Waldenström's macroglobulinemia and DLBCL tumor cells harboring the MYD88 L265P oncogenic mutation. Consistent with its proposed mechanism of action, IMO-8400 treatment in these studies inhibited cell signaling pathways that promote tumor cell survival and proliferation including those referred to scientifically as IRAK1/4, NF- κ B, STAT3 p38, and BTK. Further, in these studies, IMO-8400 suppressed tumor cell production of cytokines, such as interleukin-10, or IL-10, that create a favorable microenvironment for tumor cell survival and proliferation. In addition to inducing tumor cell death *in vitro*, IMO-8400 treatment of mice in xenograft models decreased tumor burden, even in studies where treatment was initiated after tumors had become well established. Tumor cells that did not harbor the MYD88 L265P mutation were not affected by IMO-8400 treatment, demonstrating the specificity of the treatment effect.

The preclinical observations reported by independent researchers and the preclinical data generated by us with IMO-8400 support our plans for the clinical development of IMO-8400 in B-cell lymphomas harboring the MYD88 L265P oncogenic mutation. In April 2014, we initiated patient treatment in an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia who have relapsed or were refractory to prior therapy. It has been reported that approximately 90% of patients with Waldenström's macroglobulinemia have the MYD88 L265P oncogenic mutation. Objectives of the trial include evaluation of safety and tolerability and assessment of the clinical activity of escalating IMO-8400 dose levels using disease-specific international guidelines for classifying clinical response. The initial dose level is 0.6 mg/kg once per week, administered by subcutaneous injection. We expect to enroll up to approximately 30 patients in this trial. Initial data from a limited number of patients are expected by year end 2014.

We are also conducting an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL who have relapsed or were refractory to prior therapy. With the concurrence of the U.S. Food and Drug Administration, or FDA, Center for Devices and Radiological Health, or CDRH, we will enroll in this trial only patients who are positive for the presence of the MYD88 L265P oncogenic mutation. Objectives of the trial include evaluation of safety and tolerability and assessment of the clinical activity of escalating IMO-8400 dose levels using disease-specific international guidelines for classifying clinical response. The initial dose level is 0.3 mg/kg twice per week, administered by subcutaneous injection. We expect to enroll up to approximately 30 patients in this trial, and expect to initiate patient treatment in the second half of 2014.

We believe that Waldenström's macroglobulinemia and DLBCL in patients with the MYD88 L265P mutation are each orphan indications with unmet medical need, based on prevalence of the indications. If we observe a therapeutic effect in either or both of our Phase 1/2 clinical trials, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory path for the applicable program. We cannot predict whether or when any of our product candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval.

In May 2014, we entered into a collaboration with Abbott Molecular, Inc., or Abbott Molecular, for the development of a companion diagnostic that can be used to identify patients with the MYD88 L265P oncogenic mutation. Under the agreement, Abbott Molecular has agreed to develop the companion diagnostic to comply with the requirements of the FDA CDRH. We expect to pay approximately \$6,700,000 in external development expenses over five years under the agreement to develop an assay as the prototype of the companion diagnostic, to validate the prototype during a Phase 2 clinical trial of IMO-8400, and to complete FDA regulatory requirements and launch activities of the resultant final version of the companion diagnostic. Such expenses are subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if we are required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs. We will not receive any revenues from future sales, if any, of the companion diagnostic. We expect to use the prototype companion diagnostic developed by Abbott Molecular in our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and in future clinical trials of IMO-8400.

[Table of Contents](#)

Program in Autoimmune Diseases with Orphan Designation. We are planning to initiate clinical development of IMO-8400 for the treatment of autoimmune diseases which have been designated as orphan indications. We have evaluated autoimmune diseases with orphan indications for which we may develop our TLR antagonist candidates using selection criteria that include: the reported involvement of altered TLR expression; cytokine profile indicative of key TLR-mediated pathways; auto-antibody profile indicative of self-derived nucleic acids that can induce TLR-mediated immune responses; the identification of prospective clinical biomarkers for evaluation in early clinical trials; high unmet medical need; and established clinical diagnosis.

Based on these selection criteria, we have prioritized polymyositis, dermatomyositis, and graft-versus-host disease, or GvHD, as the initial orphan autoimmune disease indications for clinical evaluation. We anticipate initiating patient treatment in a clinical trial in patients with polymyositis or dermatomyositis and in a clinical trial in patients with GvHD by year end 2014. If we observe a therapeutic effect in one or more of these indications, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory path for the applicable program. We cannot predict whether or when any of our product candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval. We are continuing to use the above criteria to prioritize additional autoimmune diseases with orphan indications for which we may develop our TLR antagonist candidates.

Expanding the Pipeline of TLR Antagonist Drug Candidates. We are developing a second novel antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. We have completed preclinical studies of IMO-9200 to support initiation of clinical development in the second half of 2014.

Clinical Proof-of-Concept for TLR Antagonism. We believe that clinical proof-of-concept for TLR antagonists as a potential therapeutic approach for autoimmune diseases has been demonstrated by the results of randomized, double-blinded Phase 2 clinical trials of TLR antagonists that we have conducted in patients with moderate to severe psoriasis. In a recently completed Phase 2 trial, we evaluated IMO-8400 at four dose levels of 0.075, 0.15, 0.3, and 0.6 mg/kg, or placebo, administered weekly for 12 weeks in 44 patients with moderate to severe plaque psoriasis. The primary objective of the trial was to evaluate safety and tolerability of IMO-8400 over a 12 week treatment period, with a secondary objective to evaluate the clinical activity of IMO-8400. The trial met its primary objective, as treatments at all dose levels were well tolerated 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 Psoriasis Area Severity Index (PASI). We intend to submit data from the Phase 2 clinical trial of IMO-8400 in patients with psoriasis for presentation at a medical meeting within 2014.

The Phase 2 trials in patients with psoriasis were conducted to establish clinical proof of concept for application of TLR antagonists in the treatment of diseases in which TLR-mediated immune responses are implicated. Based on our business strategy, we are advancing clinical development of IMO-8400 in orphan diseases such as genetically defined B-cell lymphomas, polymyositis, dermatomyositis, and GvHD.

Other TLR Programs

Our pipeline of drug candidates also includes IMO-2055, a TLR9 agonist for potential applications as an immune therapy for the treatment of cancer. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. IMO-2055 has been well-tolerated and has shown evidence of clinical activity in completed Phase 1/2 trials in multiple cancer indications involving over 300 patients. Currently we are conducting preclinical studies of IMO-2055 to evaluate its therapeutic potential in combination with checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system.

Gene Silencing Oligonucleotide Technology to Target RNA

We are developing GSOs to inhibit the expression of disease-associated proteins by targeting RNA. Based on evaluations of GSOs targeted to disease-associated RNA in preclinical models, we believe our GSO technology has the potential to overcome several of the hurdles of antisense and RNA interference, or RNAi, technologies. We are currently undertaking an analysis of priority disease indications for development of drug candidates from our GSO technology. Our key considerations in identifying disease indications in our GSO program are: 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 for action; and unmet

[Table of Contents](#)

medical need to allow for a rapid development path to approval. We expect to identify the first two disease indications to be targeted in our GSO program in the second half of 2014, with the goal of initiating disease model studies and an IND-enabling development program in the first half of 2015. Based on this timeline, we could initiate Phase I proof-of-concept clinical trials for the first two disease indications as early as the second half of 2015.

Our business strategy for our GSO program is focused on the further development of our GSO technology. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program.

At June 30, 2014, we had an accumulated deficit of \$430,153,000. We expect to incur substantial operating losses in future periods. We do not expect to generate product revenue, sales-based milestones or royalties 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 revenue recognition, stock-based compensation and our convertible preferred stock and related common stock warrants. 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, 2013. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to stock-based compensation and convertible preferred stock and related common stock warrants, 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, 2013, fit the description of critical accounting estimates and judgments. There were no changes in these policies during the three and six months ended June 30, 2014.

RESULTS OF OPERATIONS

Three and Six Months Ended June 30, 2014

Alliance Revenue

Alliance revenue consisted primarily of reimbursement by licensees of costs associated with patent maintenance, amounting to \$38,000 and \$29,000 in the three months ended June 30, 2014 and 2013, respectively, and \$41,000 and \$36,000 in the six months ended June 30, 2014 and 2013, respectively.

[Table of Contents](#)

Research and Development Expenses

Research and development expenses increased by \$3,640,000, or 182%, from \$1,997,000 for the three months ended June 30, 2013, to \$5,637,000 for the three months ended June 30, 2014. Research and development expenses increased by \$8,245,000, or 191%, from \$4,325,000 for the six months ended June 30, 2013 to \$12,570,000 for the six months ended June 30, 2014. In the following table, research and development expenses are set forth in the following four categories which are discussed beneath the table:

	Three Months Ended June 30, (in thousands)		Percentage Increase (Decrease)	Six Months Ended June 30, (in thousands)		Percentage Increase (Decrease)
	2014	2013		2014	2013	
IMO-8400 external development expense	\$ 1,407	\$ 596	136%	\$ 3,840	\$ 1,196	221%
Companion diagnostic external development expense	500	—	—	1,300	—	—
Other drug development expense	1,885	617	206%	4,409	1,526	189%
Basic discovery expense	1,845	784	135%	3,021	1,603	88%
	<u>\$ 5,637</u>	<u>\$ 1,997</u>	182%	<u>\$ 12,570</u>	<u>\$ 4,325</u>	191%

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 \$7,803,000 in external development expenses through June 30, 2014, including costs associated with our Phase 1 clinical trial in healthy subjects, preparation for and conduct of our Phase 2 clinical trial in patients with psoriasis, preparation for and conduct of our ongoing Phase 1/2 clinical trial in patients with Waldenström's macroglobulinemia and our ongoing Phase 1/2 clinical trial in patients with DLBCL, and additional nonclinical studies.

The increases in our IMO-8400 external development expenses in the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, were primarily attributable to costs incurred in 2014 in connection with preparation for and conduct of our Phase 1/2 clinical trials in patients with genetically defined forms of B-cell lymphoma and the conduct of long-term nonclinical safety studies. The increase in the six months ended June 30, 2014 was also attributable to costs incurred in the first quarter of 2014 in connection with the manufacture of additional drug substance for use in our ongoing and planned clinical trials. These increases were partially offset by 2013 costs associated with our Phase 1 clinical trial of IMO-8400 in healthy subjects and with our Phase 2 clinical trial of IMO-8400 in patients with psoriasis.

We expect our IMO-8400 external development expenses to increase in the second half of 2014 due to patient enrollment as we conduct our ongoing Phase 1/2 clinical trials of IMO-8400 in patients with genetically defined forms of B-cell lymphoma, our planned Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis, and our planned Phase 1/2 clinical trial of IMO-8400 in patients with GvHD, and due to manufacturing costs for additional drug supplies of IMO-8400 for use in our ongoing and planned clinical trials and the conduct of ongoing long-term nonclinical safety studies of IMO-8400.

Companion Diagnostic External Development Expenses. These expenses include external expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with B-cell lymphomas harboring the MYD88 L265P oncogenic mutation since January 2014, when development of the companion diagnostic commenced. During the three and six months ended June 30, 2014, we incurred \$500,000 and \$1,300,000, respectively, in companion diagnostic external development expenses, reflecting costs associated with start-up activities and the initiation of development of an assay as the prototype of the companion diagnostic. We will not receive any revenues from future sales of the companion diagnostic, if any.

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. Internal expenses associated with products in clinical development include costs associated with our Autoimmune Disease Scientific Advisory Board. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed.

[Table of Contents](#)

The increases in other drug development expenses in the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, were primarily due to costs of preclinical studies and manufacturing activities to support the initiation of a planned Phase 1 clinical trial of IMO-9200 in the second half of 2014. Increasing payroll costs, including the addition of a Chief Medical Officer in January 2014 and additional headcount associated with our increasing drug development programs and higher stock based compensation costs attributable to options granted after May 15, 2013, also contributed to the increase in other drug development expenses during the three and six months ended June 30, 2014. The increase in other drug development expenses in the three and six months ended June 30, 2014 was partially offset by a decrease in IMO-3100 development expenses, reflecting our decision in the second quarter of 2013 to focus our resources on the development of IMO-8400. We expect other drug development expenses to increase in the second half of 2014 due to costs associated with the planned clinical development of IMO-9200 and increased headcount to support our drug development programs.

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, TLR antisense, and our GSO 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 six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, were primarily due to increases in the cost of employee compensation and laboratory supplies reflecting increased activity and headcount associated with our GSO program. We anticipate an increase in basic discovery expenses in 2014 as we increase headcount and laboratory supply expenses consistent with our strategic plans to identify lead drug candidates for the first two disease indications to be targeted in our GSO program.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, and without knowing the results from our ongoing and planned clinical trials of IMO-8400 and IMO-9200 and our planned IND-enabling development programs and subsequent Phase 1 proof-of-concept clinical trials in each of the first two disease indications selected for further development in our GSO 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 increased by \$1,131,000, or 71%, from \$1,599,000 in the three months ended June 30, 2013, to \$2,730,000 in the three months ended June 30, 2014 and increased by \$1,647,000, or 53%, from \$3,126,000 in the six months ended June 30, 2013 to \$4,773,000 in the six months ended June 30, 2014. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives. The increases in general and administrative expenses during the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, were primarily due to higher stock based compensation costs primarily attributable to options granted after May 15, 2013, higher cash compensation costs, including additional headcount associated with our strategic focus on our orphan disease and oncology programs and the accrual of incentive compensation, and increases in corporate communications, investor relations and recruiting expenses.

Investment Income, Net

Investment income, net increased by \$14,000, from \$2,000 in the three months ended June 30, 2013 to \$16,000 in the three months ended June 30, 2014, and by \$27,000, from \$4,000 in the six months ended June 30, 2013 to \$31,000 in the six months ended June 30, 2014 primarily due to an increase in investment balances, including corporate debt securities, in the 2014 periods resulting from our follow-on underwritten public offerings in September 2013 and February 2014 and warrant and option exercises.

Foreign Currency Exchange Gain (Loss)

Our foreign currency exchange gains were \$5,000 and \$2,000 in the three and six months ended June 30, 2014, respectively, primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during these periods. Our foreign currency exchange loss was \$26,000 in the three months ended June 30, 2013 primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during this period. Our foreign currency exchange gain was \$13,000 in the six months ended June 30, 2013 primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during this period.

[Table of Contents](#)

Loss on Extinguishment of Convertible Preferred Stock and Preferred Stock Dividends

The \$118,000 in preferred stock dividends in the three months ended June 30, 2014 reflects dividends accrued on shares of our Series E convertible preferred stock, or Series E preferred stock. The \$303,000 in preferred stock dividends in the six months ended June 30, 2014 reflects dividends accrued on shares of our Series D convertible preferred stock, or Series D preferred stock, and our Series E preferred stock. Our Series D preferred stock was converted into common stock on February 6, 2014 at which time dividends on our Series D preferred stock ceased to accrue.

The \$2,030,000 in preferred stock dividends in the three months ended June 30, 2013 consisted of \$1,750,000 related to the loss on extinguishment of the Series D preferred stock and the Series E preferred stock that we charged to net loss applicable to common stockholders as a preferred stock dividend, \$211,000 in dividends payable on shares of our Series D preferred stock and \$69,000 in dividends payable on shares of our Series E preferred stock. The \$2,309,000 in preferred stock dividends in the six months ended June 30, 2013 consisted of \$1,750,000 related to the loss on extinguishment, of the Series D preferred stock and the Series E preferred stock that we charged to net loss applicable to common stockholders as a preferred stock dividend, \$422,000 in dividends payable on shares of our Series D preferred stock and \$137,000 in dividends payable on shares of our Series E preferred stock. The \$1,750,000 loss on extinguishment of the Series D preferred stock and the Series E preferred stock in the three and six months ended June 30, 2013 was recorded following the irrevocable waiver by the holder of our Series D preferred stock of the Series D preferred stock redemption rights and liquidation preferences and by the holders of the Series E preferred stock of Series E preferred stock liquidation preferences, which irrevocable waivers became effective when we completed our follow-on underwritten public offering on May 7, 2013. We determined that the irrevocable waivers represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock and therefore accounted for them as an extinguishment of the Series D preferred stock and the Series E preferred stock.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was \$8,426,000 for the three months ended June 30, 2014, compared to \$5,621,000 for the three months ended June 30, 2013 and \$17,572,000 for the six months ended June 30, 2014 compared to \$9,707,000 for the six months ended June 30, 2013. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through June 30, 2014, we incurred losses of \$169,960,000. 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 non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of \$430,153,000 through June 30, 2014. We expect to continue to incur substantial operating losses in the future.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

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

- sale of common stock, preferred stock and warrants and warrant exercises;
- debt financing, including capital leases;
- license fees, research funding and milestone payments under collaborative and license agreements; and
- interest income.

February 10, 2014 Follow-on Underwritten Public Offering

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

[Table of Contents](#)

Cash Flows

Six Months Ended June 30, 2014

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

The net cash used in investing activities during the six months ended June 30, 2014 reflects the purchase of \$2,619,000 of available-for-sale securities, which are investments that we do not have the positive intent to hold to maturity at the time of purchase, the maturity of \$2,000,000 of available-for-sale securities, and payments for the purchase of \$533,000 in property and equipment.

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

Six Months Ended June 30, 2013

As of June 30, 2013, we had approximately \$16,301,000 in cash and cash equivalents, a net increase of approximately \$6,205,000 from December 31, 2012. Net cash used in operating activities totaled \$8,006,000 during the six months ended June 30, 2013, reflecting our \$7,398,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation and depreciation. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The \$14,212,000 net cash provided by financing activities during the six months ended June 30, 2013 primarily reflects \$14,832,000 in net proceeds from our follow-on underwritten public offering of our securities in May, 2013 which were partially offset by \$111,000 in costs related to our 2012 Series E financing that were paid in 2013 and dividends paid on our Series D preferred stock and our Series E preferred stock.

Funding Requirements

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of \$430,153,000 at June 30, 2014. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. We have received no revenues from the sale of drugs. As of July 15, 2014, almost 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 \$64,734,000 at June 30, 2014. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations through the second quarter of 2016. Specifically, we believe that our existing cash, cash equivalents and investments will be sufficient to enable us to:

- finalize our Phase 2 clinical trial of IMO-8400 in patients with psoriasis;
- complete our ongoing Phase 1/2 clinical trial in patients with Waldenström's macroglobulinemia and our ongoing Phase 1/2 clinical trial in patients with DLBCL and the MYD88 L265P oncogenic mutation;
- conduct a Phase 1 clinical trial of IMO-9200;
- conduct a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD as the initial orphan indications that we have selected for further development in our autoimmune disease program;

[Table of Contents](#)

- conduct disease model studies and IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program; and
- conduct a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program.

We will need additional funds in order to conduct further clinical development of IMO-8400 or IMO-9200, or to conduct any further development of our GSO technology and our other drug candidates or technologies.

We may 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 autoimmune disease and genetically defined forms of B-cell lymphoma programs and our GSO program and our ability to advance our product candidates and GSO technology on the timelines anticipated;
- the cost, timing and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors' receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. 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 financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. The terms of any financing may adversely affect the holdings or the rights of existing stockholders.

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

Contractual Obligations

During the six months ended June 30, 2014, 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, 2013.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Foreign currency exchange gains and losses may result from amounts to be paid under our terminated Merck KGaA collaboration and termination agreements and payments under our clinical trial agreements that are denominated in Euros. As of June 30, 2014, we had net accrued obligations of €665,000 (\$908,000 using a June 30, 2014 exchange rate). All other assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. We do not own auction rate securities or derivative financial investment instruments in our investment portfolio. At June 30, 2014, all of our invested funds were invested in a money market fund, classified in cash and cash equivalents on the accompanying balance sheet, corporate bonds and commercial paper classified in short-term investments.

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

ITEM 4. CONTROLS AND PROCEDURES.

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2014. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of June 30, 2014, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting occurred during the fiscal quarter ended June 30, 2014 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 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 \$64.7 million at June 30, 2014. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations through the second quarter of 2016. Specifically, we believe that our existing cash, cash equivalents and investments will be sufficient to enable us to:

- finalize our Phase 2 clinical trial of IMO-8400 in patients with psoriasis;
- complete our ongoing Phase 1/2 clinical trial in patients with Waldenström's macroglobulinemia and our ongoing Phase 1/2 clinical trial in patients with DLBCL and the MYD88 L265P oncogenic mutation;
- conduct a Phase 1 clinical trial of IMO-9200;
- conduct a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD as the initial orphan indications that we have selected for further development in our autoimmune disease program;
- conduct disease model studies and IND-enabling development program in each of the first two disease indications selected for further development in our GSO program; and
- conduct a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program.

We will need additional funds in order to conduct further clinical development of IMO-8400 or IMO-9200, or to conduct any further development of our GSO technology and our other drug candidates or technologies.

We expect that we will require substantial additional funds to conduct additional research and development, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We may 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 autoimmune disease and genetically defined forms of B-cell lymphoma programs and our GSO program and our ability to advance our product candidates and GSO 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.

[Table of Contents](#)

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

Additional 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 financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders.

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

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

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of June 30, 2014, we had an accumulated deficit of \$430.2 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to June 30, 2014, we incurred losses of \$170.0 million. We incurred losses of \$260.2 million prior to December 31, 2000, during which time we were primarily involved in the development of non-TLR-targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of July 15, 2014, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

Risks Relating to Our Business, Strategy and Industry

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

We have invested a significant portion of our time and financial resources in the development of TLR-targeted clinical stage lead drug candidates as part of our autoimmune 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, including IMO-8400 and IMO-9200 for the treatment of certain genetically defined forms of B-cell lymphoma and for orphan autoimmune diseases. We also plan to invest substantial time and resources to further advance the development of our GSOs under our GSO program. For instance:

- we initiated patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia in the first half of 2014 and are planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation in the second half of 2014;
- we completed preclinical studies of IMO-9200 and expect to initiate a Phase 1 clinical trial of IMO-9200 in the second half of 2014;
- we are planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and in a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD by year end 2014; and
- we are planning to initiate a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

[Table of Contents](#)

We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our drug candidates in our genetically defined forms of B-cell lymphoma and our autoimmune disease programs, and the successful identification, development and commercialization of drug candidates in our GSO program.

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

Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055, including:

- During the fourth quarter of 2010, we commenced additional nonclinical studies of IMO-3100 in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies and that were inconsistent with observations made in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted. In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis, over a four-week treatment period. In December 2011, the FDA removed the clinical hold. We subsequently initiated in the second quarter of 2012 the four-week Phase 2 clinical trial that we completed in the fourth quarter of 2012. We cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 in patients with psoriasis for treatment periods of more than four weeks or at all without additional clinical or preclinical data.
- 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 preliminary observations 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. During the third quarter of 2011, we re-assessed and prioritized our drug development programs, and determined to discontinue further investment of internal resources on the development of IMO-2125 for the treatment of HCV.
- In July 2011, Merck KGaA, Darmstadt, Germany, or Merck KGaA, informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line squamous cell carcinoma of the head and neck, or SCCHN, and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In November 2011, as part of an agreed-upon termination of our collaboration with Merck KGaA, we regained global rights to IMO-2055 and our other TLR9 agonists, including preclinical lead drug candidates selected for further evaluation under the collaboration, for the treatment of cancer. In May 2012, we announced that in the Phase 2 trial of IMO-2055 in combination with cetuximab in patients with second-line SCCHN, the combination of IMO-2055 and cetuximab did not meet the primary endpoint of the trial.

We may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus and arthritis. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program. Our setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

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

- the drug candidates demonstrating activity in clinical trials;
- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;
- timely enrollment in clinical trials of IMO-8400 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;
- satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;
- the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;
- timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;

[Table of Contents](#)

- the ability to combine our drug candidates and the drug candidates being developed by Merck & Co. and any other collaborators safely and successfully with other therapeutic agents;
- achieving and maintaining compliance with all regulatory requirements applicable to the products;
- establishment of commercial manufacturing arrangements with third-party manufacturers;
- the successful commercial launch of the drug candidates, assuming FDA approval is obtained, whether alone or in combination with other products;
- acceptance of the products as safe and effective by patients, the medical community, and third-party payors;
- competition from other companies and their therapies;
- changes in treatment regimens;
- successful protection of our intellectual property rights from competing products in the United States and abroad; and
- a continued acceptable safety and efficacy profile of the drug candidates following marketing approval.

We have recently begun to focus our efforts on the research and development of product candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma, and our approach for the treatment of these genetically defined B-cell lymphomas is novel and may not result in any approved and marketable products.

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

We are in the early stages of developing our GSO 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 GSO 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 GSOs.

The future success of our GSO 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 disease indications and development strategies to determine next steps in developing our GSO technology. However, we do not expect to identify the first two disease indications in our GSO program until the second half of 2014 at the earliest and, if and when a disease indication is identified, do not anticipate initiating our Phase 1 proof-of-concept clinical trials prior to the second half of 2015. Many steps must be successfully achieved prior to any initiation of clinical development with respect to a GSO-based product candidate. Given the level of uncertainty of our ability to successfully achieve these many steps and the uncertainty of the clinical development process in general, there can be no assurance that we will succeed in developing any marketable product as a result of our efforts with respect to our GSO 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 product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because there are a limited number of patients with Waldenström's macroglobulinemia or DLBCL and the MYD88 L265P oncogenic mutation, and a limited number of patients with polymyositis, dermatomyositis, GvHD, or other autoimmune diseases having orphan indications for which we may determine to develop our TLR antagonists, our ability to enroll

[Table of Contents](#)

eligible patients in any clinical trials for these indications may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

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

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product 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 products.

In order to obtain regulatory approvals for the commercial sale of our products, 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. For example, in July 2011, the FDA placed a clinical hold on a protocol we had submitted for a proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks in clinical trials, even after demonstrating promising results in earlier trials. Moreover, effects seen in nonclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on clinical trials. Numerous unforeseen events may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

Other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of Actilon®, a TLR9 agonist, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis, discontinued the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, an investigational vaccine which contained a TLR9 agonist adjuvant, and in February 2013 Dynavax announced receipt of a Complete Response Letter from FDA regarding its Biological License Application for HEPLISAV®, which is an investigational hepatitis B vaccine that contains a TLR9 agonist adjuvant. These may result in enhanced scrutiny by regulators or institutional review boards, or IRBs, of clinical trials of our drug candidates and GSOs, 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 and GSOs.

[Table of Contents](#)

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 products, or the rejection of data developed with the involvement of such person(s);
- the cost of our clinical trials may be greater than we currently anticipate; and
- our products may not cause the desired effects or may cause undesirable side effects or our products 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 products.

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 product development costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

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

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

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

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs and on GSOs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will 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 GSOs 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.

[Table of Contents](#)

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 products 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 products 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 products as compared to competitive products will also affect market acceptance.

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

We are developing our TLR-targeted drug candidates for use in the treatment of certain genetically defined B-cell lymphoma and autoimmune diseases and for use as vaccine adjuvants. We have one drug candidate, IMO-8400, in clinical development for the treatment of certain genetically defined B-cell lymphomas, including Waldenström's macroglobulinemia and DLBCL with the MYD88 L265P oncogenic mutation, and our autoimmune disease program. We are also collaborating with Merck & Co. for the use of agonists of TLR7, TLR8 and TLR9 as vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease. Finally, we may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus and arthritis. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

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

Our principal competitor developing TLR-targeted compounds for autoimmune diseases is Dynavax, with its collaborator GlaxoSmithKline. Merck & Co.'s vaccines using our TLR7, TLR8, or TLR9 agonists as adjuvants may compete with vaccines using TLR agonists as adjuvants being developed or marketed by GlaxoSmithKline, Novartis, Dynavax, VaxInnate, Inc., Intercell AG, and Cytos Biotechnology AG.

In addition, we are developing GSOs 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 GSO technology. We are aware of multiple companies that are developing technologies that use oligonucleotide-based compounds to inhibit the production of disease associated proteins. These technologies include, but are not limited to, antisense technology as well as RNAi. In the field of antisense technologies, we compete with multiple companies, including Isis and its partners. Isis is currently marketing an antisense drug, Kynamro®, and has several antisense product candidates in clinical trials. In the field of RNAi, our primary competition is with Alnylam Pharmaceuticals, Inc., or Alnylam, and its partners. Alnylam is currently developing multiple RNAi-based technologies and has several product candidates in clinical trials. Any of the competing companies may develop gene-silencing technologies more rapidly and more effectively than us, and antisense technology and RNAi may become the preferred technology for drugs that target RNA in order to inhibit the production of disease-associated proteins.

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

[Table of Contents](#)

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 products and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our products 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 Dr. Sudhir Agrawal. Dr. Agrawal serves as our President and Chief Executive Officer. Dr. Agrawal has made significant contributions to the field of oligonucleotide-based drug candidates, and he has led the discovery and development of our compounds targeted to TLRs and our GSOs.

He is named as an inventor on over 400 patents and patent applications in countries around the world. Dr. Agrawal provides us with leadership for our management team and research and development activities. The loss of Dr. Agrawal's services would be detrimental to our ongoing scientific progress and the execution of our business plan.

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2016, 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 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 products 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 product 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, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product 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 product 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.

[Table of Contents](#)

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;
- restrictions on our products or the marketing or manufacturing of our products;
- withdrawal of our products from the market;
- warning letters;
- voluntary or mandatory product recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizure or detention;
- refusal to permit the import or export of our products;
- injunctions or the imposition of civil penalties; and
- criminal penalties.

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

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

- finalizing a Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis;
- conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation in the second half of 2014;
- planning to initiate a Phase 1 clinical trial of IMO-9200 in the second half of 2014;
- planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and in a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD by year end 2014; and
- planning to initiate a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

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

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

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

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

[Table of Contents](#)

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 product 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 product 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 product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some applications of our product 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 product 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 product 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 product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

We plan to develop companion diagnostics for our TLR antagonist product candidates in our genetically defined forms of B-cell lymphoma program. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our TLR antagonist product candidates specifically for the treatment of patients with a genetically defined form of B-cell lymphoma. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely on third parties or collaborators to perform these functions. In May 2014, we entered into an agreement with Abbott Molecular for the development and potential commercialization of a companion diagnostic with respect to our identification of patients with B-cell lymphomas harboring the MYD88 L265P oncogenic mutation in our genetically defined forms of B-cell lymphoma program with our TLR antagonist product candidate IMO-8400. We may enter into similar agreements for our other product candidates and possible expansion indications for IMO-8400. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

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

- the development of our TLR antagonist product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our TLR antagonist product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and

[Table of Contents](#)

- we may not realize the full commercial potential of any TLR antagonist product 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 product 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 products are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.

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

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

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

Risks Relating to Collaborators

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 may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus and arthritis. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program.

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of certain genetically defined forms of B-cell lymphoma and autoimmune diseases and on GSOs. 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 GSO technology. For example, potential partners may note that our TLR collaborations with Novartis and with Merck KGaA have been terminated. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-3100, IMO-2055, and our other TLR-targeted drug candidates, given our setbacks with respect to these drug candidates. Additionally, in the event we seek collaborations for our GSO program, any potential collaborators may not be willing to enter into a collaboration with us due to the early stage of this technology. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology or our GSO 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.

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

An important element of our business strategy includes entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2006, we entered into an exclusive license and research collaboration with Merck & Co. to research, develop, and commercialize vaccine products containing our TLR7, TLR8 and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer's disease. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines.

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

- our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;
- our collaborators may control the development of the companion diagnostic to be developed for use in conjunction with our drug candidates including the timing of development;
- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions;
- our collaborators may challenge our intellectual property rights or utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- our collaborators may not comply with all applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements;
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. For example, we have a strategic partnership with Merck & Co., which merged with Schering-Plough, which has been involved with certain TLR-targeted research and development programs. Although the merger has not affected our partnership with Merck & Co. to date, management of the combined company could determine to reduce the efforts and resources that the combined company will apply to its strategic partnership with us or terminate the strategic partnership. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products;
- our collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or development of our products; and
- our collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely affect their willingness or ability to fulfill their obligations to us.

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

Risks Relating to Intellectual Property

If we are unable to obtain 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 patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect our trade secrets.

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

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

As of July 31, 2014, 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 novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-3100, IMO-8400, IMO-9200, and IMO-2055. As of July 15, 2014, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-3100, we have issued U.S. patents that cover the chemical composition of matter of IMO-3100 and methods of its use that will expire at the earliest in 2026. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and methods of its use that will expire at the earliest in 2031. With respect to IMO-9200, we have a U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which, if issued, would expire at the earliest in 2034.

As of July 31, 2014, we owned one issued U.S. patent, two U.S. patent applications and six foreign patent applications for our GSO compounds and methods of their use. The issued patent covering our GSO technologies would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of July 31, 2014, our antisense patent portfolio included more than 45 U.S. patents and more than 60 patents throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates through 2023.

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 products. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of third-party U.S. patents that contain broad claims related to the use of certain oligonucleotides for stimulating an immune response, although we do not believe that these claims are valid. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from U.S. and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

[Table of Contents](#)

We may lose our rights to patents, patent applications or technologies of third parties if our licenses from these third parties are terminated. In such an event, we might not be able to develop or commercialize products covered by the licenses.

Currently, we have not in-licensed any patents or patent applications related to our TLR-targeted drug candidate programs or our GSO compounds and methods of their use. However, we are party to five royalty-bearing license agreements under which we have acquired rights to patents, patent applications, and technology of third parties in the field of antisense technology, which may be applicable to our TLR-targeted antisense. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance, and other obligations on us.

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates through 2023. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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 or require us to stop our development and commercialization efforts.

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. For instance, in 2002, 2003, and 2005, we became involved in interference proceedings declared by the USPTO for some of our antisense and ribozyme patents. All of these interferences have since been resolved. We are neither practicing nor intending to practice the intellectual property that is associated with any of these interference proceedings.

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.

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 products. 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 products 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.

[Table of Contents](#)

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

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

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

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of June 30, 2014, 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 NDA/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 a large number of 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 products 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 contracted with contract research organizations to manage our Phase 1 clinical trial of IMO-8400, our Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia, and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation, 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. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. 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 infrastructure.

[Table of Contents](#)

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

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

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

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

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

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

[Table of Contents](#)

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 products. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

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

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could limit the price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

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

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

- decreased demand for our drug candidates and products;
- damage to our reputation;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- 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 an Investment in 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, would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock.

As of March 14, 2014, Baker Bros. Advisors LLC, and certain of its affiliated funds, which we refer to collectively as Baker Brothers, held 1,613,076 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 4.99% 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 4.99% beneficial ownership limitation currently in effect with respect to the warrants and pre-funded warrants held by Baker Brothers, as of July 15, 2014, and based on the securities held by Baker Brothers as of March 14, 2014, Baker Brothers beneficially owned 4.99% of our outstanding common stock. If the warrants and pre-funded warrants held by Baker Brothers could be exercised without this limitation, then as of July 15, 2014, and based on the securities held by Baker Brothers as of March 14, 2014, Baker Brothers would have beneficially owned 34.9% of our common stock.

As of March 14, 2014, entities affiliated with Pillar Invest Corporation, which we refer to collectively as the Pillar Investment Entities, held 13,626,469 shares of our common stock, 424,242 shares of our Series E preferred stock, which are convertible into 8,484,840 shares of our common stock, and warrants to purchase up to 18,295,490 shares of our common stock at exercise prices ranging from \$0.47 per share to \$1.46 per share. In connection with their ownership of shares of our Series E preferred stock, the Pillar Investment Entities obtained various rights, preferences and privileges that are not held by the holders of our common stock and that in certain instances are preferential to the rights of the holders of our common stock. 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 convert or exercise any securities held by them that are convertible or exercisable into shares of our common stock to the extent that such conversion or 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 conversion or exercise of such securities. After giving effect to the 19.99% beneficial ownership limitation currently in effect with respect to the securities held by the Pillar Investment Entities, as of July 15, 2014, and based on the securities held by the Pillar Investment Entities as of March 14, 2014, the Pillar Investment Entities beneficially owned 19.99% of our outstanding common stock. If the Series E preferred stock and warrants held by the Pillar Investment Entities could be converted and exercised without these limitations, then as of July 15, 2014, and based on the securities held by the Pillar Investment Entities as of March 14, 2014, the Pillar Investment Entities would have beneficially owned 36.6% of our common stock.

[Table of Contents](#)

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, and on the voting rights of the Pillar Investment Entities, if our significant securityholders were to convert or exercise their preferred stock and warrants into 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, 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 conversion or exercise of the preferred stock and 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 preferred stock and 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, 2013 to July 15, 2014, the closing sales price of our common stock ranged from a high of \$6.59 per share to a low of \$0.46 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.

[Table of Contents](#)

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.

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: August 12, 2014

/s/ Sudhir Agrawal
Sudhir Agrawal
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2014

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

Exhibit Index

Exhibit No.

10.1	Policy on Treatment of Stock Options in the Event of Retirement, approved April 28, 2014.
10.2†	Amendment No. 1 to Exclusive License and Research Collaboration Agreement, dated April 29, 2014, by and between Merck Sharp & Dohme Corp. and Idera Pharmaceuticals, Inc.
10.3†	Development and Commercialization Agreement, dated May 1, 2014, by and between Abbott Molecular Inc. and Idera Pharmaceuticals, Inc.
10.4*	2013 Stock Incentive Plan, as amended.
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

† Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commission.

* Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 13, 2014 (SEC File No. 001-31918).

Idera Pharmaceuticals, Inc.

Policy on Treatment of Stock Options in the Event of Retirement*

- 1) For purposes of this policy, a non-employee member of the Board of Directors (the “Board”) of Idera Pharmaceuticals, Inc. (“Idera”) will be deemed to have retired if:
 - a) the non-employee director resigns from the Board or determines not to stand for reelection or is not nominated for reelection at a meeting of the stockholders and has served as a director for more than 10 years, or
 - b) the non-employee director does not stand for reelection or is not nominated for reelection due to the fact that he or she is or will be older than 75 at the end of such director’s term.
- 2) For purposes of this policy, an employee of Idera will be deemed to have retired if the employee terminates his or her employment with Idera, has been an employee of Idera for more than 10 years and is older than 65 upon termination of employment.
- 3) If a non-employee director or employee retires, then (i) all outstanding options will automatically vest in full and (ii) the period during which the director or employee may exercise the options will be extended to the expiration of the option under the plan.

* Approved by the Board of Directors on April 28, 2014.

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

Amendment No. 1
to
Exclusive License and Research Collaboration Agreement
by and between
Merck Sharp & Dohme Corp. and
Idera Pharmaceuticals, Inc.

This Amendment ("Amendment No. 1") effective as of date of last signature ("Amendment No. 1 Effective Date") confirms the mutual understanding between Merck Sharp & Dohme Corp. ("Merck"), and Idera Pharmaceuticals, Inc. ("Idera") to amend certain terms and conditions of the Exclusive License and Research Collaboration Agreement between the Parties dated December 8, 2006, as modified by those certain letter agreements dated November 3, 2008, November 13, 2009, December 8, 2011, January 3, 2012, and January 6, 2012 (collectively, the "Agreement").

WHEREAS, Idera desires the right to create, research, develop, manufacture and commercialize IMO compounds that are not Selected Collaboration Compounds or Non-Selected Collaboration Compounds (as specified in that certain letter dated January 6, 2012, which is attached to this Amendment No. 1 as Attachment A) for use in the Fields;

WHEREAS, Merck desires to grant such rights to Idera, while Merck shall retain all the license rights granted in the Agreement as such rights pertain to Selected Collaboration Compounds or Non-Selected Collaboration Compounds for use in the Fields;

WHEREAS, the Parties desire to make certain other modifications to the terms and conditions of the Agreement as appropriate to the granting of the rights above; and

WHEREAS, the Parties agree to be bound by the terms and conditions of the Agreement, as amended herein.

NOW, THEREFORE, in consideration of the above, the Parties hereby agree to amend the Agreement as of the Amendment No. 1 Effective Date as follows:

1. The following definitions in Article 1 shall be deleted and replaced in their entirety as follows:
 - 1.4 "Alzheimer's Disease Field" shall mean use as an Adjuvant contained or administered in conjunction with all prophylactic and therapeutic Vaccine(s) for the prevention and/or treatment of Alzheimer's disease.
 - 1.37 "Infectious Disease Field" shall mean use as an Adjuvant contained or administered in conjunction with all prophylactic and therapeutic Vaccine(s) for the prevention and/or treatment of any viral and/or microbial infectious disease, provided that, with respect to the rights and licenses granted to Merck under this Agreement, the following diseases shall be excluded: [**].

-
- 1.58** “**Oncology Field**” shall mean use as an Adjuvant contained or administered in conjunction with all prophylactic and therapeutic Vaccine(s) for the prevention and/or treatment of any type of cancer. For avoidance of doubt, Vaccines for the prevention and/or treatment of human papilloma virus and other viruses that are considered precursors to cancer are included in the Oncology Field.
2. The following new definitions shall be added to Article 1 as follows:
- 1.85** “**Idera Combination Product(s)**” shall mean, on a country by country basis, with respect to a given Idera Product, an Idera Product that contains one or more Antigens in addition to the Antigen(s) contained in the given Idera Product at the time it achieves First Commercial Sale in such country. For example, if a given Idera Product in a country, at the time it achieves First Commercial Sale contains Antigens A and B, an Idera Combination Product with respect to such given Idera Product in such country would be an Idera Product that contains at least one other Antigen, in addition to Antigens A and B, and achieves First Commercial Sale in such country after the given Idera Product has achieved First Commercial Sale.
- 1.86** “**Idera Compound(s)**” shall mean IMO compounds that are not Selected Collaboration Compounds or Non-Selected Collaboration Compounds. For purposes of clarity, the Idera Compounds shall be of different composition of matter from Selected Collaboration Compounds or Non-Selected Collaboration Compounds.
- 1.87** “**Idera Product(s)**” shall mean any prophylactic and therapeutic Vaccine(s) that contains Idera Compound(s) or is administered in conjunction with Idera Compound(s), for any and all uses in the Fields, including without limitation any Idera Combination Product, (i) in final form for sale by prescription, over-the-counter or any other method, or (ii) for administration in a Clinical Trial.
3. Section 2.12, Exclusive Efforts, shall be deleted and replaced in its entirety as follows:
- 2.12** Exclusive Efforts. As of the Amendment No. 1 Effective Date, except as set forth on Schedule 2.12, Idera shall work exclusively (even as to Idera itself) with Merck and its Affiliates in efforts to develop and commercialize any Selected Collaboration Compounds or Non-Selected Collaboration Compounds for use in conjunction with Vaccine(s) or Vaccine products containing such Selected Collaboration Compounds or Non-Selected Collaboration Compounds in the Fields; provided that, nothing in this Section 2.12 shall imply that any research, development or other work obligations of Idera remain to be performed by Idera under the Agreement as of the Amendment No. 1 Effective Date.

-
4. Section 2.8.4, Designation of Non-Selected Collaboration Compounds, shall be deleted and replaced in its entirety as follows:

2.8.4 Designation and Use of Non-Selected Collaboration Compounds. On or before Jan 9, 2012, Merck previously designated among the Evaluation Collaboration Compounds which ones shall be deemed the “**Non-Selected Collaboration Compounds**”. For avoidance of doubt, Merck and its Affiliates shall retain the right to use the Non-Selected Collaboration Compounds that are claimed in or covered by the Joint Information and Inventions solely for internal research purposes of Merck or its Affiliates which includes research carried out by any Third Party on behalf of Merck or its Affiliates; provided, however that each such Merck Affiliate and Third Party on behalf of Merck or its Affiliates shall be bound by the applicable terms of this Agreement, as amended. Idera may develop and commercialize the Non-Selected Collaboration Compounds only in the Idera Field. Idera or its Affiliates shall have the right to use any Non-Selected Collaboration Compounds outside the Idera Field solely for internal research purposes of Idera or its Affiliates which includes research carried out by any Third Party on behalf of Idera or its Affiliates; provided, however that each such Idera Affiliate and Third Party on behalf of Idera or its Affiliates shall be bound by the applicable terms of this Agreement, as amended. Internal research purposes expressly excludes the use of any Non-Selected Collaboration Compounds either by Merck and its Related Parties or by Idera and its Related Parties in any Clinical Trial.

5. Section 3.1, License Grants to Merck, shall be deleted and replaced in its entirety as follows:

3.1 License Grants to Merck

3.1.1 Exclusive License Grant. Subject to the terms and conditions of the Agreement, as amended, Idera hereby grants to Merck an exclusive license (even as to Idera) in the Territory under Idera Technology and Idera’s interest in Joint Program Technology, with a right of sublicense, (a) to research and develop Selected Collaboration Compounds and Non-Selected Collaboration Compounds in the Fields and (b) to research, develop, make, have made, use, offer to sell, sell, have sold, import and export Selected Collaboration Compound(s) and Product(s) in the Fields. The foregoing exclusive license is subject to the non-exclusive rights granted to The Immune Response Corporation as set forth in Schedule 2.12 attached to the Agreement. Notwithstanding anything to the contrary contained in this Agreement, as amended, Idera retains all rights under Idera Technology and Idera’s interest in Joint Program Technology (x) to research, develop, make, have made, use,

offer to sell, sell, have sold, import and export IMO-2055 and IMO-2125 outside the Fields, both during and after the Research Program Term, and (y) to research, develop, make, have made, use, offer to sell, sell, have sold, import and export Idera Compound(s) and Idera Product(s) in the Fields.

3.1.2 Non-Exclusive License Grant. In the event that the researching, developing, making, having made, use, offer for sale, sale, import or export by Merck, or Merck's Related Parties, of Non-Selected Collaboration Compound(s), Selected Collaboration Compound(s) or Product(s) in accordance with the license granted pursuant to Section 3.1.1 would infringe during the term of this Agreement, as amended, a claim of issued letters patent which Idera Controls and which patents are not covered by the grant in Section 3.1.1, Idera hereby grants to Merck, to the extent Idera is legally able to do so, a non-exclusive, sublicensable, royalty-free license in the Territory under such issued letters patent for Merck and Merck's Related Parties to research, develop, make, have made, use, sell, offer for sale, import and export such Non-Selected Collaboration Compound(s), Selected Collaboration Compound(s) and Product(s) in the Fields.

3.1.3 Sublicense Rights. Subject to the terms and conditions of this Agreement, as amended, Merck shall have the right to grant sublicenses of the rights granted to it under this Section 3.1 to (i) its Affiliates, (ii) Third Parties engaged in research, development and marketing of Products, and (iii) contract service providers providing services for Merck or its Affiliates, to the extent such sublicenses are necessary for the research, development, manufacturing and commercialization of Non-Selected Collaboration Compounds, Selected Collaboration Compounds and Products in the Fields by or on behalf of Merck or its Affiliates. Merck shall require each sublicensee to be bound by the applicable terms of this Agreement, as amended.

6. Section 3.4, Development and Commercialization, shall be deleted and replaced in its entirety as follows:

3.4 Development and Commercialization. During the term of the Agreement, Merck and Idera each agree to notify the other Party promptly in writing upon the achievement of any business event that would trigger milestone payments, royalty payments or off-set credits due the other Party under this Agreement, as amended.

7. Section 3.5, Excused Performance, shall be deleted in its entirety and left intentionally blank.

8. Section 3.7, Adverse Experience Reporting, shall be deleted and replaced in its entirety as follows:

3.7 Adverse Experience Reporting. Idera and Merck each agrees throughout the term of this Agreement to notify the other Party within two (2) working days in English of any information of which Idera or Merck becomes aware in the Territory concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, whether or not determined to be attributable to IMO-2055 or IMO-2125 (hereinafter “Adverse Experience”), where such Adverse Experience is serious and associated with the clinical uses, studies, investigations, tests and marketing of IMO-2055 or IMO-2125, whether or not determined to be attributable to IMO-2055 or IMO-2125. With respect to all other adverse experiences (non-serious expected or non-serious unexpected adverse experiences), Idera or Merck shall furnish the other Party with copies of such non-serious adverse experiences reported to it in connection with the marketing of IMO-2055 or IMO-2125 in English within 10 working days after receipt. For clarity, Idera shall provide Adverse Experience reports to Merck with respect to those Adverse Experiences relating to IMO-2055 under The Immune Response Corporation Agreement, to the extent Idera is aware of such information, in accordance with the term of this Section 3.7. Notwithstanding the foregoing, Idera shall not provide Adverse Experience reports to Merck with respect to Adverse Experiences relating to IMO-2055 or IMO-2125, unless and until Merck notifies Idera in writing that Merck has determined to pursue development of any Selected Collaboration Compounds or Non-Selected Collaboration Compounds pursuant to Section 3.1.1. Merck shall provide Adverse Experience reports to Idera with respect to IMO-2055 and IMO-2125 within the same time frames as set forth above. The Parties acknowledge that information provided in the timeframes set forth in this Section 3.7 may be in the form of raw data.

“Serious” as used in this Section 3.7 refers to an experience which results in death, is immediately life threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization, or prolongation of existing hospitalization, or is a congenital anomaly, cancer or an overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes previously listed should also be considered serious. “Unexpected” as used in this Section 3.7 refers to a condition or development not listed in the current labeling for IMO-2055 or IMO-2125, and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of increased frequency or greater severity or specificity.

It is understood and agreed that these adverse experience reporting requirement provisions are based on the policies and procedures of Merck and Idera and regulatory reporting requirements. Accordingly, in the event of changes to regulatory requirements for adverse experience reporting, Idera and Merck each agrees to comply with such revised notification requirements.

As soon as practicable before the start of any Clinical Trials involving IMO-2055 or IMO-2125, the Parties shall enter into a separate and more detailed agreement concerning adverse experience exchange and reporting.

9. Section 5.5, Reports: Payment of Royalty, shall be retitled: “Reports by Merck; Payment of Royalties”.

10. Section 5.6, Audits, shall be retitled: “Audits of Merck Reports”.

11. New Section 5.9 shall be added as follows:

5.9 Credits Accrued by Merck. Merck shall accrue credits, which may be applied solely against amounts payable by Merck to Idera under the Agreement, in accordance with this Section 5.9. With respect to the first [**] Dollars (USD \$[**]) of aggregate fair market value for cash or other consideration received by Idera from Third Party licensees for the license, development, approval, or net sales of Idera Products by Third Party licensees, Merck shall accrue credits of fifteen percent (15%) of such amounts against milestone and royalty payments owed to Idera by Merck pursuant to Sections 5.3 and 5.4, provided that no such credit shall reduce any individual payment to Idera to less than [**] percent ([**]%) of the payment amount otherwise payable. With respect to the next [**] Dollars (USD \$[**]) of aggregate fair market value for cash or other consideration received by Idera from Third Party licensees for the license, development, approval, or net sales of Idera Products by Third Party licensees, Merck shall accrue credits of fifteen percent (15%) of such amounts against milestone and royalty payments owed to Idera by Merck pursuant to Sections 5.3 and 5.4, provided that no such credit shall reduce any individual payment to Idera to less than [**] percent ([**]%) of the payment amount otherwise payable. For the avoidance of doubt, any unused credits accrued shall be carried forward to offset any successive amounts that would otherwise be owed by Merck to Idera. Merck shall not accrue any credit amount with respect to the fair market value of cash or other consideration received by Idera from Third Party licensees for the license, development, approval, or net sales of Idera Products by Third Party licensees exceeding [**] Dollars (USD \$[**]) in aggregate. Income from Third Party licensees shall exclude income received for funding research and development activities and for the fair market value of Idera’s securities issued to the licensee. The crediting of the amounts as set forth above shall be Merck’s sole and exclusive compensation with respect to Idera Products. In no event shall the aggregate amount of the credits to which Merck may receive with respect to consideration received by Idera from Third Party licensees for the license, development, approval, or net sales of Idera Products exceed Sixty Million Dollars (USD \$60,000,000).

-
12. New Section 5.10 shall be added as follows:

5.10 Reports by Idera

Idera shall promptly notify Merck of each Third Party license granted by Idera under which Idera is entitled to payments that may result in the accrual of credits by Merck pursuant to Section 5.9. Idera shall furnish to Merck a quarterly written report showing all payments received by Idera under such Third Party license agreements giving rise to credits pursuant to Section 5.9 during the prior Calendar Quarter. Reports shall be due on the [**] day following the close of each Calendar Quarter. Idera shall keep complete and accurate records in sufficient detail to enable the credit accruals hereunder to be determined.

13. New Section 5.11 shall be added as follows:

5.11 Audits of Idera Reports

- (a) Upon the written request of Merck and not more than once in each Calendar Year, Idera shall permit an independent certified public accounting firm of nationally recognized standing selected by Merck and reasonably acceptable to Idera, at Merck's expense, to have access during normal business hours to such of the records of Idera as may be reasonably necessary to verify the accuracy of the credit accrual reports hereunder for any year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Merck only whether the credit accrual reports are correct or incorrect and the amount of any discrepancy. No other information shall be provided to Merck.
- (b) If such accounting firm correctly identifies a discrepancy made during such period, the credits to which Merck is entitled pursuant to Section 5.9 shall be adjusted accordingly during the next Calendar Quarter. The fees charged by such accounting firm shall be paid by Merck; provided, however, that if such audit uncovers an underreporting of credits by Idera that exceeds [**] Dollars (USD \$[**]) and five percent (5%) of the total credits owed, then the fees of such accounting firm shall be paid by Idera.
- (c) Upon the expiration of twenty-four (24) months following the end of any year, the calculation of credits accrued with respect to such year shall be binding and conclusive upon Merck, and Idera shall be released from any liability or accountability with respect to credit accrual for such year.
- (d) Merck shall treat all financial information subject to review under this Section 5.11(d) in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Idera obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

-
14. In Section 7.1(d), the final sentence shall be deleted and replaced in its entirety as follows:

Except as provided in Section 7.1(e) or Section 7.2(b), the filing Party shall be responsible for payment of all costs and expenses related to all filings hereunder.

15. Section 7.1(e) shall be amended to add the following at the end:

Idera Patent Rights that claim or cover Selected Collaboration Compounds are listed in Attachment B attached to this Amendment No. 1. For any Idera Patent Rights listed on Attachment B for which Merck is identified as having responsibility for any reimbursement of patent costs and expenses, the Parties shall mutually agree, on a country-by-country basis, on the continued maintenance and prosecution of such Idera Patent Rights and the country validations for granted EP patents in the Idera Patent Rights. To the extent that such Idera Patent Rights continue to claim or cover Selected Collaboration Compounds, (i) Merck shall reimburse Idera for the expenses incurred after the Amendment No. 1 Effective Date in prosecuting and maintaining the Idera Patent Rights listed on Attachment B as to which Merck is identified as the Party responsible for prosecution costs in Attachment B; and (ii) Merck shall reimburse Idera for fifty percent (50%) of the expenses incurred after the Amendment No. 1 Effective Date in maintaining the Idera Patent Rights listed on Attachment B as to which Attachment B specifies that the Parties will share in such prosecution costs; provided, however, that in the case of clause (i) above, at any time after the Amendment No. 1 Effective Date, in the event Idera licenses to any Third Party the rights to practice (except as to Selected Collaboration Compounds) under the Idera Patent Rights listed on Attachment B for which Merck is identified as having responsibility for any reimbursement of patent costs and expenses, then Merck shall reimburse Idera for fifty percent (50%) of the expenses incurred after the effective date of the first such Third Party license in maintaining such Idera Patent Rights that Idera licenses to any Third Party after the Amendment No. 1 Effective Date. Such reimbursement obligations shall also extend to continuing patent applications of, and patents issuing from, the Idera Patent Rights listed on Attachment B that continue to claim or cover Selected Collaboration Compounds, to the same extent that Merck's reimbursement obligations apply to the Idera Patent Rights listed on Attachment B that continue to claim or cover Selected Collaboration Compounds. For reimbursement of patent costs and expenses hereunder, Idera shall provide an invoice and supporting documentation to Merck at the end of the applicable Calendar Quarter.

16. New Section 10.2.5 shall be added as follows:

The terms of this Amendment No. 1 shall be binding upon any Third Party assignee or acquirer of Idera in the event of an assignment by Idera of the Agreement to a Third Party or upon Change of Control of Idera, in either case as if such Third Party were Idera.

All capitalized terms used and not otherwise defined in this Amendment No. 1 shall have the meanings set forth in the Agreement.

It is the intent of the Parties that the terms of this Amendment No. 1 be read and interpreted as being additive to and in harmony with and, except as expressly set out herein, not as replacing or contradicting the terms and conditions of the Agreement. All other terms and conditions to the Agreement remain unchanged and in full force and effect except to the extent superseded by the terms and conditions of this Amendment No. 1.

The Agreement, as modified by this Amendment No. 1, contains the entire understanding of the Parties with respect to the subject matter.

This Amendment No. 1 may be executed in one or more counterparts, each of which shall be an original, and all of which taken together shall constitute a single instrument. After facsimile or electronic transmission, the Parties agree to execute and exchange documents with original signatures.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 1 to be executed by their duly authorized representatives.

Merck Sharp & Dohme Corp.

BY: /s/ illegible

TITLE: SVP Research Development

DATE: 29th April 2014

Idera Pharmaceuticals, Inc.

BY: /s/ Louis J. Arcudi

TITLE: Louis J. Arcudi, III
Chief Financial Officer
Idera Pharmaceuticals, Inc.

DATE: April 29, 2014

Attachment A
[letter dated January 6, 2012 attached below]

Alliance Management

Merck
WS1AB-30
One Merck Drive
Whitehouse Station, NJ 08889
merck.com

January 6, 2012
Idera Pharmaceuticals, Inc.
Attn: Sudhir Agrawal, D. Phil.
Chief Executive Officer and President



167 Sidney Street
Cambridge, MA 02139
Via UPS and Facsimile

Re: Exclusive License and Research Collaboration Agreement by and between Merck Sharp & Dohme Corp. ("Merck") and Idera Pharmaceuticals, Inc. ("Idera") dated December 8, 2006 (the Agreement")

Dear Sudhir:

In a letter dated January 3, 2012, Merck and Idera mutually agreed to revise Section 2.8.3 of the Agreement to allow Merck to select [**] Selected Collaboration Compounds targeting TLR9 and [**] Selected Collaboration Compounds targeted to TLR 7 and/or TLR 8. Therefore, pursuant to Section 2.8.3, the attached Schedule 1 designates Selected Collaboration Compounds. Please note that selection of IMO-2055 was previously designated in a letter dated July 20, 2007, it is included on Schedule 1 for completeness.

In addition, pursuant to Section 2.8.4, the attached Schedule 2 designates Non-Selected Collaboration Compounds.

We look forward to continuation of our collaboration.

Very truly yours,

/s/
Ellen Locker
Executive Director — Alliance Management

cc: A. Bert, D. Casimiro, C. Gawron-Burke, G. McMahon, A. Misyan, S. Ritter (Idera)

Schedule 1
Selected Collaboration Compounds

TLR 9
[**]

TLR 7 and/or TLR 8
[**]

Schedule 2
Non-Selected Collaboration Compounds

[**]

SELECTED COLLABORATION COMPOUNDS
TLR9 AGONISTSParty
Responsible
for
Prosecution
and
Maintenance
Costs

[**]

Patent Office Application

Serial Number	Country	Application Filing Date	Status	Patent Number	
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

[**]

Patent Office Application

Serial Number	Country	Application Filing Date	Status	Patent Number	
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]		[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

TLR7 and/or TLR8 AGONISTS

[[**]]

Patent Office Application

Serial Number	Country	Filing Date	Status	Patent Number	
***	***	***	***	***	***
***	***	***	***		***
***	***	***	***	***	***
***	***	***	***		***
***	***	***	***		***
***	***	***	***		***
***	***	***	***		***
***	***	***	***		***
***	***	***	***		***
***	***	***	***		***
***	***	***	***	***	***
***	***	***	***	***	***

[[**]]

Patent Office Application

[illegible]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (this “Agreement”) is effective as of May 1, 2014 (“Effective Date”), by and between Abbott Molecular Inc., a corporation organized under the laws of Delaware (“Abbott”), and Idera Pharmaceuticals, Inc., a corporation organized under the laws of Delaware (“Idera”).

RECITALS

A. Idera is developing a certain proprietary compound, IMO-8400, and backups therefor, for the treatment of Diffuse Large B-Cell Lymphoma (“DLBCL”) and certain other forms of non-Hodgkin lymphoma.

B. Abbott is in the business of developing and marketing in vitro diagnostic devices and has developed certain technology and possesses expertise relating to the preparation and development of PCR assays performed on a multiplicity of specimens.

C. Idera desires that Abbott develop a MYD88 L265P mutation PCR diagnostic test (as further defined herein, the “Diagnostic Test”) utilizing genomic DNA from formalin fixed paraffin-embedded (“FFPE”) sections of primary lymph node tissue on the Abbott *m2000* System, and register and make commercially available the Diagnostic Test in conjunction with Idera’s registration, marketing and sale of Idera Products (defined below), and Abbott is willing to undertake such activities pursuant to the provisions of this Agreement.

NOW, THEREFORE, in consideration of these premises and the terms and conditions contained herein, the Parties hereto agree as follows.

ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings, whether used in the singular or plural:

“Abbott” shall have the meaning set forth in the Preamble.

“Abbott Claim” shall have the meaning set forth in Section 10.1(a).

“Abbott Diagnostics” shall mean any and all existing PCR assay platforms/systems (including the *m2000*TM) and Diagnostic Test Components, associated reagents, kits and protocols for use on existing PCR assay platforms/systems developed, Controlled, or sold by Abbott, and all related development, manufacturing and commercialization activities, including the Diagnostic Test.

“Abbott Inventions” shall have the meaning set forth in Section 7.7(b).

“Abbott Losses” shall have the meaning set forth in Section 10.1.

“Abbott Know-How” means all Know-How relating to or arising from the Abbott Diagnostics which is (i) existing as of the Effective Date or at any time thereafter, and (ii) Controlled by Abbott or any of its Affiliates other than pursuant to a license granted to Abbott under this Agreement, and (iii) necessary for the development or commercialization of the Diagnostic Test or the Idera Product.

“Abbott Party” shall have the meaning set forth in Section 10.1(a).

“Abbott Patent Rights” means all Patent Rights (a) covering Abbott Diagnostics, (b) covering the Diagnostic Test or (c) covering the Idera Product or the use of the Diagnostic Test for the Diagnostic Test Intended Use in connection with the Idera Product, which are Controlled as of the Effective Date or at any time thereafter by Abbott or any of its Affiliates other than pursuant to a license granted to Abbott under this Agreement.

“Abbott Technology” shall mean, collectively, Abbott Patent Rights and Abbott Know-How, to the extent such Abbott Patent Rights and Abbott Know-How specifically relate to Abbott Diagnostics and the Diagnostic Test.

“Affiliate” shall mean any Person which controls, is controlled by, or is under common control with the applicable Person. For purposes of this definition, “control” shall mean: (a) in the case of corporate entities, direct or indirect ownership of fifty percent (50%) or more of the stock or shares (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote for the election of directors, or otherwise having the power to control or direct the affairs of such Person; and (b) in the case of non-corporate entities, direct or indirect ownership of at least 50% of the equity interest or the power to direct the management and policies of such noncorporate entities.

“Agreement” shall have the meaning set forth in the Preamble.

“Alliance Lead” shall have the meaning set forth in Section 4.7.

“Analytical Data” shall mean clinical data resulting from the use of the Diagnostic Test on patient specimens including patient information collected on the case report form but not including (a) personal identifying information and/or (b) clinical data relating to the Compound.

“Applicable Law” shall mean all applicable provisions of all statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards judgments, permits and licenses of or from governmental authorities, including those relating to or governing the use or regulation of the subject item and the listing standards or agreements of any national or international securities exchange.

“Breaching Party” shall have the meaning set forth in Section 9.2.

“Breakup Fee” shall have the meaning set forth in Section 9.5.

“CDA” shall mean the Mutual Confidential Disclosure Agreement executed by the Parties as of October 17, 2013.

“Claim” shall have the meaning set forth in Section 10.3(a).

“Clinical Trial Site Costs” shall include costs incurred by Abbott in performing clinical studies; validation studies; laboratory start-up costs; investigational review board costs; case report forms; shipping cost for supplies and slides; monitoring visits (including travel costs); and reagents and other consumable products, all as necessary in connection with conducting clinical trials to obtain required Regulatory Approvals for the Diagnostic Test for the Diagnostic Test Intended Use or to support submission of Idera Products for Regulatory Approval.

“Commercially Reasonable Efforts” shall mean, (a) with respect to the research, development and sale of the Idera Product by Idera, such efforts and resources substantially equivalent to those efforts and resources commonly used by a biotechnology company for a therapeutic product, which product is at a similar stage in its development or product life and is of similar market potential, taking into account efficacy, safety, approved labeling, the competitiveness of alternative Third Party products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of patent or other intellectual property rights, and other relevant factors, and (b) with respect to the research, development and sale of the Diagnostic Test by Abbott, such efforts and resources substantially equivalent to those efforts and resources commonly used by a diagnostic company for a companion diagnostic, the development costs of which have been funded by the owner of the associated therapeutic product in exchange for the diagnostic company’s commitment to develop and commercialize the companion diagnostic, taking into account relevant technical, safety and liability factors. Commercially Reasonable Efforts shall be determined on a market-by-market basis for a particular product, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the product and the market(s) involved.

“Commercialization Lead” shall have the meaning set forth in Section 4.5(b).

“Commercialization Plan” shall have the meaning set forth in Section 3.1.

“Compound” shall mean an Idera inhibitor of Toll-like receptors (TLRs) 7, 8 and 9, the current development code of which is IMO-8400 or, if Idera develops a successor compound in lieu of IMO-8400, such successor compound, it being understood that if a successor compound is pursued by Idera, appropriate changes to the Development Plan and payments to Abbott hereunder may be made pursuant to Sections 2.1 and 5.2.

“Confidential Information” shall mean any and all non-public information, materials, data, samples, business plans, financial information, marketing plans, reports, forecasts, technical or commercial information that is provided by Disclosing Party to a Receiving Party hereunder and which is either disclosed in writing and marked as confidential at the time of disclosure, or disclosed orally, including any and all information regarding, related to, arising from or associated with this Agreement or the activities contemplated hereby, the Compound, any Idera Product, the Diagnostic Test, Inventions, and the existence, terms and conditions of this Agreement.

“Control” or “Controlled” means, with respect to a Party and with respect to an item of Abbott Technology or Idera Technology, as applicable, the possession, whether by ownership or license (other than pursuant to this Agreement), by such Party of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement with any Third Party.

“Data” shall mean any and all data, including Analytical Data, results, conclusions, reports, and other information generated by or for Idera resulting from the activities performed under the Development Plan.

“Development Lead” shall have the meaning as set forth in Section 4.5(a).

“Development Plan” shall have the meaning as set forth in Section 2.1.

“Diagnostic Test” shall mean the PCR assay to detect MYD88 L265P mutation developed by Abbott pursuant to the provisions of this Agreement.

“Diagnostic Test Components” shall mean primers, probes, calibrators and controls for the Diagnostic Test.

“Diagnostic Test Intended Use” shall mean the identification of patients who are appropriate candidates for treatment with an Idera Product, based on the detection, using the Diagnostic Test, in such patients of MYD88 L265P mutation, as approved by a Regulatory Authority.

“Diagnostic Test Trademarks” shall mean the Trademarks used in conjunction with the Diagnostic Test for the Diagnostic Test Intended Use in the Territory (excluding, however all Idera owned or Controlled Trademarks).

“Disclosing Party” shall have the meaning set forth in Section 6.1.

“Effective Date” shall have the meaning set forth in the Preamble.

“EU” shall mean all member states of the European Union.

“FDA” shall mean the United States Food and Drug Administration, or any successor agency thereto.

“Field” shall mean the treatment of DLBCL and certain other forms of non-Hodgkin lymphoma, as described in the clinical trial protocol(s) for the Idera Product.

“First Commercial Sale” shall mean with respect to the Diagnostic Test for the Diagnostic Test Intended Use, and any country in the Territory, the first commercial sale by Abbott or its Affiliates, sublicensees or distributors of the Diagnostic Test in that country to a Third Party, after such Diagnostic Test has been granted final Regulatory Approval by the competent Regulatory Authorities in such country.

“Idera” shall have the meaning set forth in the Preamble.

“Idera Claim” shall have the meaning set forth in Section 10.2(a).

“Idera Inventions” shall have the meaning set forth in Section 7.7(c).

“Idera Know-How” means all Know-How (i) existing as of the Effective Date or at any time thereafter, and (ii) Controlled by Idera or any of its Affiliates other than pursuant to a license granted to Idera under this Agreement, and (iii) is necessary for the development or commercialization of the Idera Product or the Diagnostic Test.

“Idera Losses” shall have the meaning set forth in Section 10.2.

“Idera Materials” shall meaning set forth in Section 2.2(a).

“Idera Party” shall have the meaning set forth in Section 10.2(a).

“Idera Patent Rights” means all Patent Rights claiming or covering: (a) the use of Compound or Idera Product; and/or (b) the use of the Diagnostic Test or the Diagnostic Test for the Diagnostic Test Intended Use, in each case Controlled as of the Effective Date or at any time thereafter by Idera or any of its Affiliates other than pursuant to a license granted to Idera under this Agreement.

“Idera Product” means any pharmaceutical or biological preparation in final form containing the Compound for any and all uses (i) for sale by prescription, over-the-counter or any other method; or (ii) for administration to human patients in a clinical trial, including in each case any monotherapy containing the Compound, any combination product containing the Compound, or any concomitant administration of a preparation containing the Compound with a preparation containing a small molecule or biological.

“Idera Technology” shall mean, collectively, Idera Patent Rights and Idera Know-How, to the extent such Idera Patent Rights and Idera Know-How specifically relate to the Compound and any Idera Product.

“Invention” shall mean and include any and all inventions and discoveries which are, or may be, patentable or otherwise protectable under the patent or other intellectual property laws of any country, which are conceived or discovered by either Party, its Affiliates or sublicensees during its or their respective activities pursuant to the Development Plan, the Regulatory Plan and the Commercialization Plan during the term of this Agreement.

“Joint Inventions” shall have the meaning as defined in Section 7.7(d).

“Joint Patent Right” shall have the meaning as set forth in Section 7.7(f).

“JSC” shall mean the Joint Steering Committee established pursuant to Section 4.2.

“Know-How” shall mean technical and other information which is not in the public domain, including information comprising or relating to concepts, discoveries, data (including raw data), designs, formulae, ideas, inventions, materials, methods, models, research plans, procedures, designs for experiments and tests and results of experimentation and testing, processes, laboratory records, chemical, pharmacological, toxicological clinical, analytical and quality control data, pre-clinical, clinical and non-clinical trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to an information from ethical committees and Regulatory Authorities. Know-How includes documents containing Know-How, including any rights including trade secrets, copyright, database or design rights protecting such Know-How.

“m2000™” shall mean Abbott’s proprietary consolidated workstation for real time PCR processing.

“Major Market Countries” means United States, Japan, United Kingdom, Italy, Spain, France and Germany.

“Non-Breaching Party” shall have the meaning set forth in Section 9.2.

“Orange Book” shall mean the publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), or any successor thereto, as published from time to time by the FDA.

“Party” or “Parties” shall mean Idera or Abbott, or Idera and Abbott, as the context admits.

“Patent Right” shall mean any and all (i) patents, (ii) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisionals, renewals, and all patents granted thereon, (iii) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term extensions, supplementary protection certificates or the equivalent thereof, and (iv) all counterparts of any of the foregoing in any country of the Territory.

“PCR” means polymerase chain reaction.

“Person” shall mean any natural person, corporation, unincorporated organization, partnership, association, joint stock company, joint venture, limited liability company, trust or government, or any agency or political subdivision of any government, or any other entity.

“Plans” shall mean the Development Plan, the Regulatory Plan and the Commercialization Plan.

“Project Timeline Leads” shall have the meaning set forth in Section 4.8.

“Receiving Party” shall have the meaning set forth in Section 6.1.

“Regulatory Approvals” shall mean and include all licenses, permits, authorizations and approvals of, and all registrations, filings and other notifications to any Regulatory Authority, governmental agency or department within the Territory (including applications therefore) necessary or appropriate for the development, testing, manufacture, production, distribution, marketing, sale and/or use, as applicable, of the Diagnostic Test or any Idera Product in a particular country or region of the Territory.

“Regulatory Authority(ies)” shall mean any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the reviewing, granting or revoking of Regulatory Approvals for the Diagnostic Test.

“Regulatory Plan” shall have the meaning set forth in Section 2.3(a).

“Specifications” shall mean the specifications applicable to the Diagnostic Test for the Diagnostic Test Intended Use as set forth in Exhibit A. The Specifications may be amended, in writing, from time-to-time as deemed necessary by the JSC, provided both Parties consent in writing to such amendment.

“Territory” shall mean the entire world.

“Third Party” means any Person other than Idera or Abbott (or their respective Affiliates).

“Trademarks” shall mean all registered and unregistered trademarks (including all common law rights thereto), service marks, trade names, brand names, logos, taglines, slogans, certification marks, Internet domain names, trade dress, corporate names, business names and other indicia of origin, together with the goodwill associated with any of the foregoing and all applications, registrations, extensions and renewals thereof throughout the world, and all rights therein provided by international treaties and conventions.

ARTICLE 2 DEVELOPMENT

2.1 Development Plan. Abbott, with Idera’s cooperation, shall develop the Diagnostic Test pursuant to the provisions of a development plan which shall set forth, *inter alia*:

- (a) the activities to be performed by each Party; and
- (b) the timelines for the project.

(as amended from time to time, the “Development Plan”). The initial Development Plan is attached hereto as Exhibit B. The Parties acknowledge that the initial Development Plan does not address all of the items set forth above, but the Parties agree that, as soon as practicable

following the Effective Date, the initial Development Plan will be modified and made more comprehensive pursuant to the provisions of this Agreement. Thereafter, as may be necessary from time-to-time, the Development Leads shall suggest appropriate revisions to the Development Plan to the JSC for its prior written review and approval. If the JSC approves such revisions, and the Parties consent in writing to such revisions, then the JSC shall revise the Development Plan accordingly without need for amending this Agreement. The revised Development Plan shall thereafter be the Development Plan for all purposes of this Agreement. The Parties shall each use their Commercially Reasonable Efforts to perform all of their obligations under the Development Plan in accordance with generally accepted ethical, good laboratory, and good clinical practices and in compliance with Applicable Law.

2.2 Idera Materials.

(a) Idera will furnish to Abbott or Abbott shall procure using funding provided by Idera pursuant to this Agreement the quantities of clinical trial specimens, and such other biological and pharmaceutical materials, agreed upon and set forth in the Development Plan, the Regulatory Plan or the Commercialization Plan ("Idera Materials"). Abbott will comply with all Applicable Laws relating to the Idera Materials. Without limiting the foregoing, to the extent that the Idera Materials include human specimens provided by Idera, Idera represents and warrants to Abbott that either it has obtained all informed consents and Institutional Review Board (IRB)/Ethics Committee (EC) approval(s) required by Applicable Law with respect to such Idera Materials or that it is not required under Applicable Law to obtain such informed consents and/or has received a waiver for consent from an IRB/EC.

(b) Abbott agrees to retain possession of the Idera Materials and not to provide the Idera Materials to any Third Party (except for Third Parties conducting clinical trials on Abbott's behalf pursuant to this Agreement) and not to use or permit the use of the Idera Materials for any purpose other than the development and commercialization of the Diagnostic Test for the Diagnostic Test Intended Use without Idera's prior written consent.

(c) Idera shall not deliberately transmit any data that identifies or could be used to identify an individual ("Personal Data"), provided that both Parties shall use Commercially Reasonable Efforts to comply with all Applicable Laws with respect to the collection, use, storage and disclosure of Personal Data, including Personal Data that may be inadvertently transmitted.

(d) Abbott shall keep, and provide copies to Idera upon reasonable request of, records of its use of Idera Materials and upon completion of the activities for which the Idera Materials have been provided, or upon expiration or termination of this Agreement, if earlier, Abbott shall account for all use of such materials. Abbott agrees to retain remaining Idera Materials for later use for the Diagnostic Test Intended Use as permitted by Applicable Law.

2.3 Regulatory Approvals.

(a) In addition to the responsibilities set forth in the Development Plan, Abbott, with Idera's cooperation, shall obtain the necessary Regulatory Approvals in any country requested by Idera in which Abbott's *m2000*TM system is in use as of the Effective Date (and, at Idera's request, the Parties shall discuss additional countries in which Idera expects to commercialize the Idera Product) for the commercialization of the Diagnostic Test with the Diagnostic Test Intended Use. The Parties shall agree upon a priority list of countries which Abbott shall attempt to first obtain Regulatory Approvals. Abbott shall be responsible for the responsibilities set forth in Exhibit C (the "Regulatory Plan") with respect to obtaining and maintaining in good standing for the periods covered by the Development Plan and the Commercialization Plan all necessary Regulatory Approvals from the relevant Regulatory Authorities that are required for the development, commercialization and sale of the Diagnostic Test pursuant to the Development Plan and the Commercialization Plan. The Parties acknowledge that the initial Regulatory Plan may not address all steps necessary to obtain all of the necessary Regulatory Approvals, but the Parties agree that, as soon as practicable following the Effective Date, the initial Regulatory Plan will be modified and made more comprehensive pursuant to the provisions of this Agreement. Thereafter, as may be necessary from time-to-time, the Regulatory lead representatives of each Party shall suggest appropriate revisions to the Regulatory Plan to the JSC for its written review and approval. If the JSC approves such revisions, and the Parties consent in writing to such revisions, then the JSC shall revise the Regulatory Plan accordingly without need for amending this Agreement. The revised Regulatory Plan shall thereafter be the Regulatory Plan for all purposes of this Agreement.

(b) Idera shall be responsible for reimbursing Abbott for all costs and expenses incurred by Abbott in obtaining all Regulatory Approvals for the Diagnostic Test for the Diagnostic Test Intended Use that are approved by Idera; provided that, the budget for such costs (i) [**]. Abbott shall [**] Idera [**]. Idera will [**].

2.4 Rights of Reference. Idera hereby grants to Abbott a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in 21 CFR 314.3(b) and comparable regulations outside the United States) with respect to Idera's clinical trial data and results related to any Idera Product, as necessary for Abbott and its permitted assigns and sublicensees to prepare and submit submissions to Regulatory Authorities and maintain Regulatory Approvals related to the Diagnostic Test and related matters, in each case for the Diagnostic Test Intended Use. Abbott hereby grants to Idera a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in 21 CFR 314.3(b) and comparable regulations outside the United States) with respect to Abbott's clinical sample analytical trial data and results related to the Diagnostic Test, as necessary for Idera and its permitted assigns and sublicensees to prepare and submit submissions to Regulatory Authorities, and to maintain Regulatory Approvals, related to any Idera Product and related matters, in each case for the Diagnostic Test Intended Use.

2.5 Right of Reference – Analytical Data. Idera hereby grants to Abbott a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in 21 CFR 314.3(b) and comparable regulations outside the United States) with respect to Analytical Data as necessary for Abbott and its permitted assigns and sublicensees to prepare and submit submissions to Regulatory Authorities and maintain Regulatory Approvals related to a PCR assay to detect MDY88 L265P mutations and related matters.

ARTICLE 3
COMMERCIALIZATION

3.1 Commercialization Plan. Abbott, with Idera's cooperation, shall commercialize the Diagnostic Test for the Diagnostic Test Intended Use pursuant to the provisions of a commercialization plan, which shall include the following:

- (a) the activities to be performed by each Party and the deliverables related thereto;
- (b) the timelines for each activity under the Commercialization Plan;
- (c) the overarching commercial goals including the availability and distribution of the Diagnostic Test;
- (d) customer service;
- (e) responsibilities for and restrictions on public relations activity/Direct-To-Consumer and other promotional advertising activity;
- (f) coordination of the pre-launch/launch and post launch of Abbott/Idera sales teams and scientific teams;
- (g) forecasting and measurement of sales and distribution data, including reporting of sales units of the Diagnostic Test to Idera and the Idera Product to Abbott;
- (h) the establishment of "launch success factors" for each market. Such launch success factors shall be agreed upon by the Parties prior to any launch;
- (i) activities to be performed post-launch with respect to the Diagnostic Test Intended Use, including fulfilling any commitment(s) imposed by Regulatory Authorities;
- (j) plans for manufacturing and supplying the Diagnostic Test; and
- (k) plans for maintaining acceptable levels of regulatory and GMP/GLP compliance during development, manufacture and marketing of the Diagnostic Test, including responsibility for timely and comprehensive resolution of any compliance findings or actions of Regulatory Authorities during audits (pre and post-approval)

(as amended from time to time, the "Commercialization Plan"). The initial Commercialization Plan is attached hereto as Exhibit D. The Parties acknowledge that the initial Commercialization Plan does not address all of the items set forth above, but the Parties agree that, as soon as practicable following the Effective Date, the initial Commercialization Plan will be modified and

made more comprehensive pursuant to the provisions of this Agreement. Thereafter, as may be necessary from time-to-time, in particular as the Diagnostic Test gets closer to commercialization, the Commercialization Team Lead shall suggest appropriate revisions to the Commercialization Plan to the JSC for its prior written review and approval. If the JSC approves such revisions, and the Parties consent in writing to such revisions, then the JSC shall revise the Commercialization Plan accordingly without need for amending this Agreement. The revised Commercialization Plan shall thereafter be the Commercialization Plan for all purposes of this Agreement. The Parties shall each use their Commercially Reasonable Efforts to perform all of their obligations under the Commercialization Plan in accordance with generally accepted ethical, good sales and marketing practices and in compliance with Applicable Law, provided however that Abbott shall have the right to delay First Commercial Sale in accordance with Section 7.9.

3.2 Forecasts. So as to allow Abbott to engage in appropriate manufacturing and supply forecasting activities with regard to the Diagnostic Test, beginning in the [**] immediately prior to the anticipated date of the First Commercial Sale in the Territory, Idera shall furnish on a [**] basis (at least [**] days prior to the beginning of each [**]) with a confidential, non-binding good faith rolling [**] forecast (broken-down to the extent reasonable and feasible by country and [**]) as to Idera's predicted unit demand for the Diagnostic Test, provided that Idera shall not be required to engage in any market studies or other information gathering in which Idera would not otherwise engage in order to generate such forecasts. These forecasts shall be informational only, and Idera shall have no liability whatsoever for any reliance Abbott places on such forecasts.

3.3 Sales of Diagnostic Test. The price charged for the Diagnostic Test will be determined by Abbott in its sole and reasonable discretion and shall be consistent with Abbott's pricing of its similar (i.e., PCR tests) marketed diagnostic tests generally. Abbott shall use Commercially Reasonable Efforts to obtain appropriate pricing and reimbursement approvals for the Diagnostic Test.

3.4 Manufacturing; Failure to Supply the Diagnostic Test; Supply Priority.

(a) Abbott shall be responsible for manufacturing of the Diagnostic Test to meet supply requirements in each country in the Territory where the Idera Product is sold or where a clinical trial of the Idera Product is planned or being conducted as described in the Plans, or where sale of the Idera Product is contemplated in the Regulatory Plan, and shall be responsible for the performance of any subcontractors or Third Party manufacturers in relation thereto. Idera shall have the right to review and inspect the Diagnostic Test manufacturing process and facilities at any time during the Term of this Agreement during normal business hours upon reasonable advance notice for quality control; *provided* that no such review and inspection shall take place within [**] months of any previous review and inspection, unless the previous review and inspection identified a material quality or safety deficiency or violation of applicable regulations or any such deficiency or violation is identified by any Regulatory Authority.

(b) Abbott shall assure the continued supply of the Diagnostic Test in the countries specified for development and commercialization pursuant to [Article 2](#) and reflected in the Plans, subject to [Article 5](#). Abbott agrees to maintain a safety stock of rare reagents sufficient in its determination to meet the needs of the [**] month rolling forecast provided by Idera. Abbott shall not be liable to Idera or any Third Party in any way for failure to supply the Diagnostic Test for reasons not within Abbott's direct control, *provided* that Abbott shall provide Idera [**] months (or such shorter period as is reasonable under the particular circumstances) prior written notice of any possible shortfall in meeting such forecast, and the Parties shall promptly meet and discuss all reasonable commercial resolutions if Abbott is unable to assure supply as needed to meet such forecast. If, for any reason (other than an event that is solely attributable to Idera or their Affiliates, force majeure conditions, delay of launch under Article 7.9 or termination under Article 9) Abbott is unable to supply the Diagnostic Test for the Diagnostic Test Intended Use in numbers sufficient to meet the demand therefor and such inability continues for a period exceeding [**] days, then Abbott agrees it shall grant Idera or its designee a non-exclusive, fully paid-up, royalty free, perpetual, license in the Field, in the Territory to the Diagnostic Test Components, not restricted by Third Party obligations, under commercially reasonable terms, for the development and commercialization of the Diagnostic Test, solely for the purpose of allowing Idera to continue the development or commercialization of the Diagnostic Test for the Diagnostic Test Intended Use.

ARTICLE 4

GOVERNANCE OF AGREEMENT

4.1 Governance of Agreement. As set forth in this Article 4, the Parties agree to govern the Agreement by way of the following five collaborative groups: (1) Joint Steering Committee; (2) Development and Commercialization Leads; (3) Team Leads; (4) Alliance Leads; (5) Project Timeline Leads. Charts showing such governance and roles and responsibilities of each group are set forth in Exhibit G.

4.2 Joint Steering Committee. The Parties shall form a Joint Steering Committee (the "JSC"), which shall have the primary role in monitoring and ensuring the overall success of the development and commercialization of the Diagnostic Test for the Diagnostic Test Intended Use. The JSC shall be comprised of [**] professionally and technically qualified representatives, [**] from each Party and comprised of representatives with sufficient qualifications to make decisions regarding the Development Plan, Regulatory Plan and Commercialization Plan, considering the stage of development or commercialization of the Diagnostic Test. The JSC shall meet for the first time within [**] days after the Effective Date and thereafter at least [**] during the term of this Agreement, unless the Parties or the JSC decide that more or less frequent meetings are required; *provided, however*, that in the event of an emergent situation, including a situation in which a decision by the JSC is required, a meeting shall be held within [**] business days after written request for such meeting by either Party. Each Party shall appoint co-chairpersons of the JSC from among the members of the JSC, who shall be responsible for scheduling meetings, setting the agenda for JSC meetings, and issuing minutes of JSC meetings. Unanimous concurring votes of all JSC members shall be required for all actions required of the JSC, and no action may be taken unless at least one representative of each Party is present and votes. In the event of an impasse, the matter shall be resolved pursuant to Section 4.4. The organization of the

meeting and the meeting place shall alternate between the offices of Idera in Cambridge, Massachusetts, and the offices of Abbott in Des Plaines, Illinois or as otherwise decided by the JSC. JSC meetings may be conducted in person, by telephone or videoconference as agreed by the JSC. Each Party shall provide the other Party with written notice of its representatives for the JSC promptly after the Effective Date of this Agreement. Each Party may substitute or replace any of its representatives on the JSC at any time and for any reason upon written notice to the other Party. Additionally, Project Managers shall attend JSC meetings as warranted by the proposed agenda of the JSC as non-voting members, and each Party may invite a reasonable number of other guests to the meetings, in order to discuss special technical or commercial topics relevant to the applicable agenda; *provided*, that any guests are subject to the confidentiality provisions set forth in Article 6.

4.3 JSC Responsibilities. The JSC's activities shall include the following responsibilities with regard to the Diagnostic Test for the Diagnostic Test Intended Use:

(a) review, confirmation, modification and/or update of the Development Plan, the Regulatory Plan and the Commercialization Plan, subject to final approval by the Parties;

(b) monitoring of the development, regulatory and commercialization activities under the Development Plan, the Regulatory Plan and Commercialization Plan, respectively;

(c) resolution of issues raised by the Project Managers;

(d) exchange of development and commercialization information; and

(e) alignment of the regulatory submissions and Regulatory Approvals between any Idera Product and the Diagnostic Test.

The JSC shall keep accurate and complete confidential minutes of its meetings. The co-chairpersons for each meeting, or their designee, shall be responsible for taking such minutes and distributing them to the other JSC members for their review and comment within [**] business days after the date of each meeting, and within [**] business days after the receipt thereof, the other JSC members shall remit such minutes back to the Chairperson with their comments, if any. The JSC members shall in good faith attempt as quickly as is reasonably possible to resolve any disputes as to the content of such minutes so as to have a final agreed version as quickly as is reasonably possible. Each Party shall be responsible for all expenses incurred by its representatives on the JSC in connection with performing their duties hereunder, including all costs of travel, lodging and meals. For the avoidance of doubt, the JSC shall not have the authority to amend this Agreement, and shall have authority to amend the Development Plan, the Regulatory Plan and/or the Commercialization Plan only as expressly set forth herein, with the written consent of the Parties.

4.4 JSC Decisions. All decisions of the JSC shall be made in good faith in the interest of furthering the purposes of this Agreement and the JSC members shall endeavor to take decisions unanimously. If the JSC is unable to agree on any matter after good faith attempts to resolve such disagreement in a commercially reasonable fashion, then for matters that are material to furthering the purposes of this Agreement, the co-chairpersons of the JSC may refer the disagreement to a meeting between the Chief Executive Officer of Idera and the President of Abbott, which meeting shall take place as soon as practicable, but in no event later than [**] days after the date of the relevant referral. Notwithstanding the foregoing, except as otherwise provided in this Agreement: (a) Idera will have the unilateral right to make final decisions that solely impact the development, manufacture or marketing of any Idera Product; and (b) Abbott will have the unilateral right to make final decisions that solely impact the development, manufacture or marketing of the Diagnostic Test; provided that neither Party shall be entitled to make a unilateral decision which imposes an obligation on the other Party to take on a financial obligation or deviates from the previously approved Development Plan, Regulatory Plan or Commercialization Plan or which is inconsistent with such Party's obligations under this Agreement. A description of the escalation process is set forth in Exhibit F.

4.5 Development and Commercial Leads.

(a) Each Party shall designate a single individual to serve as its "Development Lead." The Development Leads shall be the principal point of contact for each Party for matters relating to the Development Plan and shall be responsible for implementing and coordinating, on a day-to-day basis, all development activities and facilitating the exchange of information between the Parties regarding the Development Plan. For the avoidance of doubt, a Development Lead may also be a Project Manager, Commercialization Lead, Team Lead, Alliance Lead and/or Project Timeline Lead.

(b) Each Party shall designate a single individual to serve as its "Commercialization Lead." The Commercialization Leads shall be the principal point of contact for each Party for matters relating to the Commercialization Plan and shall be responsible for implementing and coordinating, on a day-to-day basis, all commercialization activities and facilitating the exchange of information between the Parties regarding the Commercialization Plan. For the avoidance of doubt, a Commercialization Lead may also be a Project Manager, Development Lead, Team Lead, Alliance Lead and/or Project Timeline Lead.

(c) Within [**] days after the Effective Date, each Party shall provide the other Party with the names of its Commercialization Lead and Development Lead. Each Party may replace its Commercialization Lead and Development Lead at any time and for any reason upon written notice to the other Party.

(d) The Development Leads from each Party and the Commercialization Leads from each Party, respectively, shall meet as soon as practicable after the Effective Date and thereafter during the performance of the Development Plan, the Regulatory Plan and the Commercialization Plan, as applicable, at least [**] and at such additional times as the Parties reasonably deem appropriate. Meetings of the Leads may be conducted in person, by telephone or videoconference as agreed by the Project Managers or the Parties. Additionally, the Project Managers (or their designees) shall maintain close regular communications with each other as to the status of the ongoing and planned activities under the Development Plan, the Regulatory Plan and Commercialization Plan, as applicable.

4.6 Team Leads

The Parties, at appropriate times, as agreed upon by the JSC, shall form smaller teams of employees who will work together on the following teams: Clinical, Regulatory, Quality, Supply Chain, Reimbursement/Market Access, Business Development & Licensing, and others as defined by the project scope and as the Parties may agree to form ("Team"). Each Party shall designate a single individual to serve as Team Leads for each Team. Each Team shall meet as frequently as the Team may decide. For the avoidance of doubt, a Team Lead may also be a Project Manager, Development Lead, Commercialization Lead, Alliance Lead and/or Project Timeline Lead.

4.7 Alliance Leads

Each Party shall designate a single individual to serve as its "Alliance Lead." The Alliance Leads shall be the principal point of contact for each Party for matters relating to the overall governance of the collaboration, including leadership of team collaboration and interactions between the Parties, which includes scheduling, coordinating and chairing Team and JSC meetings, drafting agendas, and assuring that there is clear and smooth communications between the Parties. For the avoidance of doubt, an Alliance Lead may also be a Project Manager, Development Lead, Commercialization Lead, Team Lead and/or Project Timeline Lead.

4.8 Project Timeline Leads

Each party shall designate an individual to serve as its "Project Timeline Lead." The Project Timeline Leads will develop, track and update the Project timelines for the development and commercialization of the Diagnostic Test and the Compound. The Project Timeline Leads will coordinate the timelines for the Diagnostic Test and the Compound to enable both Parties to meet the contract deliverables. For the avoidance of doubt, a Project Timeline Lead may also be a Project Manager, Development Lead, Commercialization Lead, Team Lead and/or Alliance Lead.

4.9 Escalation. Any matter that cannot be resolved by unanimous consent of the relevant teams or team members, as the case may be, shall be submitted to the relevant Alliance Leads for resolution and thereafter for further resolution in accordance with Section 4.4 of the Agreement. The escalation structure is described in Exhibit E.

4.10 Other Governance Matters

(a) Neither the Development Leads, Commercialization Leads, Team Leads, Alliance Leads, Project Timeline Leads nor the JSC shall have authority to amend this Agreement. None of the foregoing shall have authority to amend the Development Plan, the Regulatory Plan or the Commercialization Plan, which may be modified only as permitted pursuant to Sections 2.1, 2.3(a) or 3.1, as applicable.

(b) Unless otherwise provided for herein, each Party shall be responsible for all expenses incurred by its employees in connection with performing their duties hereunder, including all costs of travel, lodging and meals.

ARTICLE 5
PAYMENTS

5.1 Payments. As consideration for Abbott's activities under the Development Plan, the Regulatory Plan and the Commercialization Plan, Idera shall remit the following payments to Abbott on a [**] basis, up to an aggregate amount of Five Million Eight Hundred Fifteen Thousand U.S. Dollars (\$5,815,000.00) (unless increased pursuant to Section 5.2). In addition, Idera shall pay a non-refundable upfront payment of [**] U.S. Dollars (\$[**]) within [**] days of the Effective Date of this Agreement. Summarized in the table below is a high level timeline and price estimate by phase of development.

Key Activities	Duration	Price (USD)
1. Project Engagement Fee	Within [**] days of contract execution	\$[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

5.2 Additional or Amended Payments. If either: (a) an unexpected additional material requirement is added to the Development Plan, the Regulatory Plan or the Commercialization Plan; (b) the Specifications are amended so as to impose additional material obligations or costs on Abbott; (c) there is a delay in the [**] referenced in row 5 of the table set forth in Section 5.1 that is not attributable to any failure to perform or delay in performance by Abbott of Abbott's responsibilities under the Development Plan, which results in Abbott incurring additional costs to monitor the delayed [**]; or (d) Idera is required to conduct additional or different [**] which cause added costs and expenses for Abbott, including but not limited to such added costs and expenses resulting from (i) a requirement that Idera [**] or (ii) the [**], then the Parties shall amend existing payments(s), to cover the additional costs associated with such requirements or amendments; *provided, however*, that if the unexpected additional requirements or amendments

to the Specifications would increase Abbott's actual total development costs for any particular year by more than [**] percent ([**]%), Abbott shall not be required to commence complying with such additional requirement unless and until the Parties reach agreement as to an additional appropriate payments(s), or amendment to existing payments(s), to cover such costs; *provided further, however*, that any additional costs that Idera may be required to pay due to a delay described in the foregoing clause (c) shall be limited to Abbott's actual costs resulting from the delay, not to exceed \$[**], and pro rated for any partial [**] of delay.

5.3 Invoices. Abbott shall invoice Idera [**].

5.4 Clinical Trial Site Costs. In addition to the payments set forth in Section 5.1 and 5.2, Idera shall pay, or reimburse Abbott for all Clinical Trial Site Costs for the first Idera Product, as such estimated costs are \$[**]. The estimated sample cost includes estimated costs to be incurred by Abbott in performing clinical studies; validation studies; laboratory start-up costs; investigational review board costs; case report forms; shipping cost for supplies and slides; monitoring visits (including travel costs); and reagents and other consumable products, all as necessary in connection with conducting clinical trials, as further detailed in Exhibit H. Abbott shall notify Idera in writing and obtain approval if the cost per sample exceeds the estimated \$[**] prior to study start. If at any time during any Clinical Trial, it becomes apparent that such Clinical Trial Site Costs will exceed by more than [**] percent ([**]%) the estimated total Clinical Trial Site Costs, Abbott shall so notify Idera, and Abbott shall not incur such additional Clinical Trial Site Costs until such additional Clinical Trial Site Costs are approved in writing by Idera. Abbott shall not be required to perform any task if the cost will be more than the budget and Idera has not approved such additional costs. Abbott will invoice Idera for the Clinical Trial Site Costs on a [**] basis. Idera shall pay all such invoices within [**] days of receipt in the manner described in Section 5.5.

5.5 Payment Terms. The payment terms for all payments shall be as follows:

(a) Payments are payable within [**] days after Idera's receipt of an invoice from Abbott.

(b) All payments by Idera to Abbott under this Agreement shall be made in U.S. Dollars to the following account: [**]

(c) If applicable laws, rules or regulations require the withholding of taxes, Idera shall make such withholding payments and shall subtract the amount thereof from the Agreement Payments. Idera shall submit to Abbott appropriate proof of payment of the withheld taxes as well as the official receipts within a reasonable period of time. Idera shall provide Abbott reasonable assistance in order to allow Abbott to obtain the benefit of any present or future treaty against double taxation which may apply to the applicable payments hereunder.

ARTICLE 6
CONFIDENTIALITY, PUBLICITY AND PUBLICATIONS

6.1 Confidentiality. As of and after the Effective Date, all Confidential Information disclosed, revealed or otherwise made available by one Party (“Disclosing Party”) to the other Party (“Receiving Party”) under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party’s Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party’s Confidential Information available to any other person, firm, corporation or other entity, without the prior written authorization of the Disclosing Party. As of and after the Effective Date all exchanges of Confidential Information shall be governed by the provisions of this Agreement and no longer by the CDA (which shall remain in effect pursuant to the provisions thereof with respect to all exchanges of Confidential Information prior to the Effective Date).

6.2 Safeguarding of Confidential Information. In furtherance of the Receiving Party’s obligations under Section 6.1, the Receiving Party shall protect the Disclosing Party’s Confidential Information to the same extent it protects its own confidential information of like kind and sensitivity. Without limiting the generality of this Section 6.2, the Receiving Party shall disclose any of the Disclosing Party’s Confidential Information only to those of its officers, employees, licensees, sublicensees, consultants, and attorneys that have a need to know the Disclosing Party’s Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, licensees, sublicensees, consultants, attorneys and financial advisors are subject to agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party’s Confidential Information. The Receiving Party shall promptly furnish the Disclosing Party with written notice of any known unauthorized use or disclosure of any of the Disclosing Party’s Confidential Information by any officer, employee, licensee, sublicensees, consultants, attorneys or financial advisors of the Receiving Party, and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party’s Confidential Information.

6.3 Exceptions. Confidential Information shall not include information that:

- (a) is or becomes publicly available through no breach of this Agreement by the Receiving Party;
- (b) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party (as evidenced by the Receiving Party’s written records);
- (c) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that, to the Receiving Party’s knowledge, is under no obligation of confidentiality relating to such information; or
- (d) was independently developed by or for the Receiving Party or its Affiliate without use of or reference to the Confidential Information of the other Party (as evidenced by the Receiving Party’s or its Affiliates’ written records).

Notwithstanding the provisions of Section 6.2, a Receiving Party may disclose Confidential Information if such Receiving Party is required to disclose such Confidential Information under Applicable Law, or in connection with any application by the Receiving Party for any Regulatory Approvals; *provided, however,* that the Receiving Party shall furnish the Disclosing Party with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, and at its sole expense, to take appropriate action, including seeking a protective order, in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public. Such Confidential Information disclosed pursuant to this paragraph shall remain Confidential Information under this Agreement despite such required disclosure, unless an exception set forth in Section 6.3(a) through (d) applies.

6.4 Term of Confidentiality Obligations. All of the Receiving Party's obligations under Sections 6.1 and 6.2 with respect to the protection of the Disclosing Party's Confidential Information shall survive for a period of [**] years following the expiration or termination of this Agreement for any reason.

6.5 Publicity. No public announcement concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the prior written approval of the other Party and agreement upon the nature and text of such public announcement, which such agreement and approval shall not be unreasonably withheld. Notwithstanding the foregoing, if, in the opinion of legal counsel for the Party desiring to make such public announcement, such disclosure is required under Applicable Law, subject to Section 6.3 above, the Party required to make such public announcement shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, which shall be not less than [**] business days (or such shorter period as may be required under Applicable Law) prior to release of such proposed public announcement, and shall provide the other Party with a written copy thereof in order to allow such other Party to comment upon such public announcement. The Receiving Party shall reasonably cooperate with the Disclosing Party (at the Disclosing Party's expense) with respect to all disclosures regarding this Agreement required under Applicable Law, including requests for confidential treatment of proprietary information of the Disclosing Party included in any such disclosure. Notwithstanding the foregoing, Idera shall release a press release in the form attached hereto as Exhibit J. Any future press releases will remain subject to this Section 6.5.

6.6 Applicable Law. Nothing in this Agreement shall be construed as preventing or in any way inhibiting either Party from complying with Applicable Law governing activities and obligations undertaken pursuant to this Agreement, in any manner which it reasonably deems appropriate, including, for example, by disclosing to Regulatory Authorities confidential or other information received from the other Party, subject to Section 6.3 and 6.5.

6.7 Non-Use of Names. Except as otherwise provided in this Agreement, neither Party (or its Affiliates) shall use, either directly or indirectly, the names of any of their officers, employees or board members in any publicity, marketing, advertising or other documents (or other disclosures) unless a copy or transcript of the proposed disclosure is submitted to and

approved in advance in writing by the other Party (in its sole discretion), except in the case in which a Regulatory Authority requires the use in the sale or distribution of the Diagnostic Test or any Idera Product. Each Party will use Commercially Reasonable Efforts to review and approve any proposed disclosure within [**] business days of its receipt from the other Party of a copy or transcript of the proposed disclosure. If a Party approves the other Party's usage of the names of any of their officers, employees or board members in accordance with this Section 6.7, the other Party shall comply with any usage guidelines or requirements imposed by the approving Party.

6.8 Publications. Idera and Abbott each acknowledge the other Party's interest in publishing the results of its research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 6.3, either Party, its employee(s) or consultant(s) wishing to make a publication in a journal, paper, magazine, or a presentation, relating to the Diagnostic Test shall deliver to the other Party a copy of the proposed written publication at least [**] days prior to submission for publication or presentation (or in the case of an abstract or presentation at least [**] days prior to submission of such abstract for publication). The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of [**] days to enable patent applications protecting each Party's rights in such information to be filed in accordance with the laws governing intellectual property protection. Upon expiration of such [**] days, the publishing Party shall be free to proceed with the publication or presentation. If the non-publishing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication or presentation to prevent disclosure of trade secret or proprietary business information Controlled by the non-publishing Party prior to submission of the publication or presentation. Idera's and/or Abbott's contribution shall be acknowledged in any publication by co-authorship or acknowledgment, whichever is appropriate.

ARTICLE 7

INTELLECTUAL PROPERTY

7.1 License Grants.

(a) Abbott grants to Idera, as of the Effective Date, a perpetual, royalty-free, non-exclusive license in the Territory under the Abbott Patent Rights, Abbott Know-How and Abbott Inventions to research, develop, make, use (including for use with the Diagnostic Test), sell, offer for sale and import only the Idera Product(s). Abbott further grants to Idera, as of the Effective Date, a perpetual, royalty-free, non-exclusive license to refer to or recommend the use of the Diagnostic Test in Idera's label, package insert, promotional or regulatory material for any Idera Product in each country of the Territory in which Idera has obtained Regulatory Approval for any Idera Product.

(b) Idera grants to Abbott, as of the Effective Date, a perpetual, royalty-free non-exclusive license in the Territory under the Idera Patent Rights, Idera Know-How and Idera Inventions to research, develop, make, use (including for the Diagnostic Test Intended Use), sell, offer for sale and import only the Diagnostic Test. Idera further grants to Abbott, as of the Effective Date, a perpetual, royalty-free, non-exclusive license in the Territory to refer to the Compound and any Idera Product, as may be required pursuant to Applicable Law, in Abbott's label, package insert, promotional or regulatory material for the Diagnostic Test in each country of the Territory in which Abbott has obtained Regulatory Approval for the Diagnostic Test.

(c) Idera and Abbott each grant to the other, a royalty-free, non-exclusive license (without the right to grant sublicenses except to Affiliates and Third Party research collaborators under confidentiality agreements) in the Territory, under Idera Technology or Abbott Technology, as applicable, for each Party's performance of its obligations under the Development Plan and the Regulatory Plan.

7.2 Right to Sublicense. Both Parties shall be entitled to sublicense all or any of their rights under Section 7.1(a) and Section 7.1(b) (subject to any applicable restrictions on any intellectual property in-licensed from Third Parties) (i) to their respective Affiliates; (ii) in the case of Abbott, to Third Party contractors used in the development, manufacturing and commercialization of the Diagnostic Test; (iii) in the case of Idera, to Third Party contractors used in the development, manufacturing and commercialization of any Idera Product; (iv) in the case of Idera, to a Third Party that acquires the exclusive rights in a country to develop or commercialize an Idera Product or is a party to a collaboration with Idera or another Third Party with respect to the development or commercialization of an Idera Product in a country, and (v) in the case of Abbott, to a Third Party that acquires the exclusive, rights in a country to develop or commercialize the Diagnostic Test.

7.3 Further Actions. Each Party shall execute all documents and give all declarations regarding the licenses granted in Section 7.1 and reasonably cooperate with the other Party, to the extent such documents, declarations and/or cooperation are reasonably required for the recording or registration of the licenses granted hereunder at the various intellectual property offices in the Territory for the benefit of the licensee Party.

7.4 No Other Licenses. Nothing in this Agreement shall be deemed or implied to be, and the Parties disclaim all implied rights to, the grant by either Party to the other Party of any license, right, title or interest in either Party's product, intellectual property rights (including Patent Rights, Know-How, trade secrets, copyrights, and Trademarks), any formulation technology or know-how, manufacturing technology or know-how, operating procedures, marketing materials or strategies, intangibles, material or proprietary rights or any other tangible or intangible property, except as are expressly set forth in this Agreement.

7.5 Trademarks.

(a) Abbott shall own all right, title and interest in and to any Trademarks developed by or for Abbott for use in connection with the Diagnostic Test ("Abbott's Trademarks"). Abbott hereby grants to Idera a royalty-free non-exclusive license to use Abbott's Trademarks in connection with advertising and marketing for the Diagnostic Test Intended Use. Any and all goodwill derived from the use of Abbott's Trademarks shall inure solely to the benefit of Abbott.

(b) Idera shall own all right, title and interest in and to all Trademarks developed by or for Idera for use in connection with the Idera Product ("Idera's Trademarks"). Idera hereby grants to Abbott a royalty-free non-exclusive license to use Idera's Trademarks in connection with advertising and marketing the Diagnostic Test. Any and all goodwill derived from the use of Idera's Trademarks shall inure solely to the benefit of Idera.

(c) Each party agrees that the use of the other Party's Trademarks in connection only with the advertising and marketing the Diagnostic Test for the Diagnostic Test Intended Use or any Idera Product shall be in accordance with the terms of this Agreement and shall comply with all federal, state and local laws and regulations.

(d) Approval of Trademark Use.

(1) Each party agrees to provide artwork for any packaging, labeling and promotional materials that display the other Party's Trademarks for approval prior to any use or distribution of such materials. Each party shall respond in writing with its approval or requested changes, such approval not to be unreasonably withheld, within [**] business days after receipt of such artwork from the other Party.

(2) Once a proposed use of the Trademarks has been approved by the Party that is the licensor, and provided that the Party that is the licensee does not make any changes to the presentation of the Trademarks in such approved product packaging, labeling or promotional materials, the Party using the Trademarks under license may utilize the same approved presentation in other product packaging, labeling or promotional materials.

(e) Each party will refrain from any use of the other's Trademarks in a manner that threatens to damage the goodwill associated with the respective Trademarks or which threatens to tarnish the reputation or otherwise reflect unfavorably upon the owner of the Trademarks.

(f) Idera shall not, during or after the term of the Agreement, anywhere in the world, take any action that in Abbott's sole and absolute discretion impairs or contests or tends to impair or contest the validity of Abbott's right, title and interest in and to Abbott's Trademarks, including, but not limited to, using, or filing an application to register, any word, mark, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of Abbott's Trademarks.

(g) Abbott shall not, during or after the term of the Agreement, anywhere in the world, take any action that in Idera's sole and absolute discretion impairs or contests or tends to impair or contest the validity of Idera's right, title and interest in and to Idera's Trademarks, including, but not limited to, using, or filing an application to register, any word, mark, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of Idera's Trademarks.

(h) If either Idera or Abbott becomes aware of any infringement of the other's Trademarks, anywhere in the world, it will promptly notify the other Party in writing. Each Party agrees to fully cooperate with the Party that is the owner of the Trademarks regarding any action the owner may take with respect to such infringement or violation. The Party that is the owner of the Trademarks shall have the exclusive right, exercisable in its sole and unlimited discretion, to institute in its own name and to control all actions against Third Parties relating to such Trademarks, at the owner's expense. The Party that is the owner of the Trademarks shall be entitled to receive and retain all amounts awarded, if any, as damages, profits or otherwise in connection with such actions.

7.6 Ownership of Existing Technology. As between the Parties, Abbott shall retain sole and exclusive ownership of the Abbott Technology. As between the Parties, Idera shall retain sole and exclusive ownership of the Idera Technology.

7.7 Inventions.

(a) All Inventions shall be promptly disclosed to the other Party hereto in confidence and in writing.

(b) Abbott shall have, and Idera hereby assigns to Abbott, exclusive ownership of and title to any and all Inventions solely related to the Diagnostic Test, the Abbott Diagnostics and to all intellectual property rights solely related thereto or arising therefrom ("Abbott Inventions"), that are discovered or reduced to practice solely by employees or agents of either Party, or jointly by employees or agents of either Party, during the term of this Agreement. Abbott shall, at its own cost, have the sole right, but not the obligation, to file for, prosecute, maintain, enforce and defend any and all Patent Rights claiming the Abbott Inventions, and shall have the right, in its sole discretion, whether or not, or where, to file a patent application, to abandon the prosecution of any patent or patent application, to discontinue the maintenance of, or enforce any such patent or patent application.

(c) Idera shall have, and Abbott hereby assigns to Idera, exclusive ownership of and title to all Inventions solely related to the Data, the Compound and any Idera Product, and to all intellectual property rights related thereto or arising therefrom ("Idera Inventions"), that are discovered or reduced to practice solely by employees or agents of either Party, or jointly by employees or agents of either Party, during the term of this Agreement. Idera shall, at its own cost, have the sole right, but not the obligation, to file for, prosecute, maintain, enforce and defend any and all patents claiming the Idera Inventions, and shall have the right, in its sole discretion, whether or not, or where, to file a patent application, to abandon the prosecution of any patent or patent application, to discontinue the maintenance of, or to enforce any such patent or patent application.

(d) As for all Inventions not covered by Section 7.7(b) or Section 7.7(c), the ownership and title thereto (including the ownership and title to all intellectual property rights related thereto or arising there from) shall be based on inventorship, as determined pursuant to the inventorship principles arising under the patent laws of the United States of America, and any such Inventions having an employee and/or collaborator of each Party as co-inventors shall be "Joint Inventions."

(e) Neither Party shall be entitled to use or exploit any Joint Invention without the prior written consent of the other Party except that: (i) each Party shall be entitled to use in the Territory, without consideration to the other Party, any Joint Inventions in its internal research programs, including research performed under confidentiality agreements with Third Party collaborators, with the other Party receiving a non-exclusive, royalty-free license to use any subsequent inventions directly resulting from the use of such Joint Invention in its internal research programs; (ii) each Party shall be entitled to use in the Territory any Joint Inventions for the purpose of performing its obligations under this Agreement, without consideration to the other Party; (iii) Idera and its Affiliates shall be entitled to use in the Territory any Joint Inventions, with the right to license such Joint Inventions, without the prior written consent of Abbott, without consideration to Abbott, and without accounting to Abbott, to make, have made, use, have used, sell, have sold, offer for sale, and import any therapeutic product, including without limitation the Compound and any Idera Product; and (iv) Abbott and its Affiliates shall be entitled to use in the Territory any Joint Inventions, with the right to license such Joint Inventions, without the prior written consent of Idera, without consideration to Idera, and without accounting to Idera, to make, have made, use, have used, sell, have sold, offer for sale, and import diagnostic tests.

(f) If the Parties create a Joint Invention, the Parties shall promptly meet to discuss and decide whether to seek patent protection therefore ("Joint Patent Right"). If the Parties decide to seek patent protection on a Joint Invention, Idera has the first right, at its own expense, to prepare, file, prosecute and maintain any Joint Patent Right throughout the world on behalf of both Parties. Idera shall give Abbott an opportunity to review and comment on any patent application with respect to such Joint Patent Right before filing, shall consult with Abbott with respect thereto, and shall supply Abbott with a copy of the patent application as filed, together with notice of its filing date and serial number. Idera shall keep Abbott advised of the status of the actual and prospective patent filings. Preparation, filing, prosecution and maintenance of such Joint Patent Rights will be handled by patent counsel acceptable to both Parties. If Idera elects not to file a patent application on a Joint Invention or to cease the prosecution and/or maintenance of any Joint Patent Right in any country of the Territory, Idera shall provide Abbott with written notice upon the decision to not file or continue the prosecution of such application or maintenance of such Joint Patent Right, in any event not later than [**] days before any relevant deadline relating to or any public disclosure or loss of the relevant Joint Patent Rights. In such event, Idera shall permit Abbott to file and/or continue prosecution and/or maintenance of such Joint Patent Rights in the names of both Parties but at Abbott's own expense. Each Party agrees to provide documents and perform such acts, at such Party's expense, as may be reasonably necessary to permit the other Party to file, prosecute and/or maintain such Joint Patent Rights in accordance with this Section 7.7(f).

(g) If either Idera or Abbott becomes aware of any infringement, anywhere in the world, of any issued patent within the Joint Patent Rights, it will promptly notify the other Party in writing to that effect.

(h) Idera shall have the first right, but not the obligation, to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer of any Joint Patent Rights within [**] days from the date of notice and to join Abbott as a party plaintiff. Idera shall bear all the expenses of any suit brought by it claiming infringement of any Joint Patent Right. Abbott will reasonably cooperate with Idera, at Abbott's expense, in any such suit and shall have the right to consult with Idera and to participate in and be represented by independent counsel in such litigation at its own expense. If, after the expiration of such [**]-day period (or, if earlier, the date upon which Idera provides written notice that it does not plan to bring suit), Idera has not obtained a discontinuance of infringement of the Joint Patent Right or filed suit against any such Third Party infringer of the Joint Patent Right, then Abbott shall have the right, but not the obligation, to bring suit against such Third Party infringer of the Joint Patent Right, *provided* that Abbott shall bear all the expenses of such suit, and further *provided* that such infringement is not the result of a notice to Idera from such Third Party infringer under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) ("Paragraph IV Notice") with respect to any Joint Patent Right and any pharmaceutical product for which Idera holds an approved New Drug Application. Idera will reasonably cooperate with Abbott, at Idera's expense, in any such suit for infringement of a Joint Patent Right brought by Abbott against a Third Party, and shall have the right to consult with Abbott and to participate in and be represented by independent counsel in such litigation at its own expense. Any recoveries obtained by Idera or Abbott, as applicable, as a result of any proceeding against such a Third Party infringer shall be allocated as follows: (A) such recovery shall first be used to reimburse each Party for all reasonable attorney fees and other litigation costs actually incurred in connection with such litigation by that Party, and (B) any remainder shall be shared in proportion to the costs incurred by each Party in the litigation; *provided, however*, that Idera shall be entitled to retain all such recoveries if the proceeding against a Third Party infringer is a result of the Third Party's filing of a Paragraph IV Notice with respect to a pharmaceutical product for which Idera holds an approved New Drug Application.

(i) Abbott and Idera agree to cooperate with respect to filing for and prosecuting any application for patent term extension of any Joint Patent Right to the extent such patent term extension is not based on the approval of any New Drug Application or any other regulatory approval for an Idera Product ("Term Extension"). Idera shall have the first right, but not the obligation, to file and prosecute a Term Extension, at its sole cost and expense. Where Idera decides not to file for a Term Extension, it shall provide Abbott written notice thereof at least [**] days before the deadline for filing a Term Extension for the particular Joint Patent Right. After such notice, Abbott shall have the right, but not the obligation, to file and prosecute a Term Extension, at its sole cost and expense. The party prosecuting a Term Extension will keep the other party apprised of the prosecution. For the avoidance of doubt, Idera shall have no obligation to seek or permit Abbott to seek any patent term extension relating to any regulatory approval of an Idera Product.

(j) Abbott agrees that Idera shall have the right to list any Joint Patent Right in an Orange Book filing for the Compound and any Idera Product, in its sole discretion, where Idera reasonably determines the particular Joint Patent Right is eligible for listing in the Orange Book as applicable to the Compound or any Idera Product.

7.8 Additional Documents. Each Party agrees to cooperate reasonably and in good faith in the execution and filing of any necessary applications, assignments, powers of attorney, or other filings or documents as may be reasonably deemed necessary by the other Party to vest in and ensure the proper ownership, Control, and maintenance of the Inventions pursuant to this Article 7, and each Party shall obtain the cooperation of its employees or agents to execute the same.

7.9 Notification of Infringement. If the making, having made, importing, exporting, using, distributing, marketing, promoting, offering for sale or selling of the Diagnostic Test is alleged by a Third Party to infringe a Third Party's intellectual property rights, the Party becoming aware of such allegation shall promptly notify the other Party. Additionally, if either Party determines based upon a reasonable analysis of a Third Party's intellectual property rights, it is necessary to obtain a license from such Third Party with respect thereto; such Party shall promptly notify the other Party of such determination and the Parties shall consult with one another regarding a mutually acceptable resolution of such issue. If the Parties fail to reach a mutually acceptable resolution of such issue prior to the First Commercial Sale of the Diagnostic Test in a country, and, in Abbott's reasonable opinion, after a reasonable analysis, such issue represents a material risk with respect to the commercialization of the Diagnostic Test in such country, Abbott may delay the First Commercial Sale in such country until such issue has been resolved.

ARTICLE 8

REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 General. Each of Abbott and Idera hereby represents, warrants and covenants to the other Party as follows as of the Effective Date:

- (a) it is a corporation or entity duly organized and validly existing under the laws of its state of incorporation;
- (b) the execution, delivery and performance of this Agreement by such Party does not conflict with any other agreement by which it is bound, and has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;
- (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and
- (d) it shall at all times comply with all Applicable Laws relating to its activities under this Agreement.

8.2 Intellectual Property. Each Party hereby represents and warrants that as of the Effective Date it currently owns and/or has (other than the Trademarks for use in connection with the Diagnostic Test, which will be developed by or for Abbott after the Effective Date and the Trademarks for use in connection with the Idera Product, which will be developed by or for Idera after the Effective Date), and will maintain throughout the term of this Agreement, the right and ability to grant the other Party the licenses under its intellectual property that are set forth in this Agreement. Nothing in this Agreement shall be construed as a warranty by either Party that their respective intellectual property rights will be valid or enforceable.

8.3 Disclaimer. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS AGREEMENT, NEITHER ABBOTT NOR IDERA MAKES, AND EACH HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, WHETHER IN FACT OR IN LAW, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

8.4 No Representations Regarding Approval or Commercial Success. Neither Party makes any representations or warranties as to: (a) whether the any Idera Product or the Diagnostic Test will be approved for commercial sale by the applicable Regulatory Authorities; or (b) the commercial potential or success of any Idera Product or the Diagnostic Test.

8.5 Other Indications. If Idera develops an indication outside the Field for the Compound or any Idera Product and Idera requests that Abbott conduct additional development or other activities in relation to such additional indication, Abbott shall in good faith consider either amending this Agreement to include such indication or entering into another similar agreement related to such indication. The Parties agree that any such amendment or other agreement remains subject to the Parties reaching a mutually acceptable agreement on such terms and conditions and the receipt of all necessary management approvals by each of the Parties.

ARTICLE 9 TERM AND TERMINATION

9.1 Term. This Agreement shall become effective as of the Effective Date of this Agreement. Unless earlier terminated pursuant to the provisions of this Article 9, this Agreement shall remain in full force and effect on a country-by-country basis until the date on which Idera ceases to market an Idera Product in such country of the Territory.

9.2 Breach. If either Party (the “Breaching Party”) commits a material breach or default of any of its obligations hereunder, the other Party hereto (the “Non-Breaching Party”) may give the Breaching Party written notice of such material breach or default. If the Breaching Party fails to cure such breach or default within [**] days after the date of the Non-Breaching Party’s notice thereof, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party indicates in writing that it will be unable or is unwilling to cure the breach, this Agreement may be terminated by the Non-Breaching Party with immediate effect.

9.3 Bankruptcy or Insolvency. Each Party shall have the right to terminate this Agreement, immediately by giving written notice of termination to the other Party, if the other Party files a voluntary petition, or if an involuntary petition is granted in respect of the other Party and appeal proceedings are not commenced within ten (10) business days from the date of such petition under the bankruptcy provisions of Applicable Law, or the other Party is declared insolvent, undergoes voluntary or involuntary dissolution, or makes an assignment for the benefit of its creditors, or is unable to pay its debts as they come due, or suffers the appointment of a receiver or trustee over all, or substantially all, of its assets or properties. All rights and licenses granted under or pursuant to this Agreement by Abbott to Idera, and by Idera to Abbott, are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Article 101(52) of the U.S. Bankruptcy Code. The Parties agree that each Party, as a licensee of such intellectual property rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code.

9.4 Injunction. The Non-Responsible Party (as defined below) may terminate this Agreement upon providing the Responsible Party (as defined below) with ninety (90) days prior written notice if: (a) Abbott’s making, having made, importing, exporting, using, distributing, marketing, promoting, offering for sale or selling the Diagnostic Test for the Diagnostic Intended Use, or (b) Idera’s making, having made, importing, exporting, using, distributing, marketing, promoting, offering for sale or selling the Idera Product; in either case is permanently enjoined by a court of competent jurisdiction because such enjoined activity infringes or misappropriates a Third Party’s intellectual property rights; provided that, such termination shall be limited to the countries affected by such injunction. In the event of any such injunction, each Party shall make a reasonable effort to notify the other Party of such injunction and the Party with the obligation to indemnify (the “Responsible Party”) the other Party (the “Non-Responsible Party”) with respect to the applicable Third Party intellectual property rights shall use Commercially Reasonable Efforts to obtain a license to such Third Party intellectual property rights or to otherwise cause the injunction to be lifted. For the avoidance of doubt, neither Party shall have an obligation under this Agreement to violate any injunction issued by a court of competent jurisdiction.

9.5 Unilateral Termination by Idera. Idera may terminate this Agreement upon ninety (90) days written notice to Abbott; provided that in the event that Idera terminates this Agreement pursuant to this Section 9.5 at any time following the Effective Date but prior to FDA approval, Idera shall pay to Abbott a termination fee of [**] U.S. Dollars (\$[**]). The total aggregate amount paid to Abbott by Idera pursuant to this Agreement, including the termination fee costs, shall not exceed [**] U.S. Dollars (\$[**]) or any other larger amount which Abbott and Idera have mutually agreed upon in the event of a scope change prior to termination. During the ninety (90) day termination notice period Abbott shall not be entitled to any further payments under Section 5.1 that had not already become payable prior to Idera’s notice of termination, but Idera shall (in addition to any termination fee described in this Section 9.5) reimburse Abbott for its actual wind-down costs during such ninety (90) day period, such wind-down costs not to exceed \$[**].

9.6 Survival. Termination of the Agreement for whatever reason in accordance with the provisions hereof or expiration of this Agreement shall not affect the accrued rights of the Parties, and shall not limit remedies that may be otherwise available in law or equity. Articles 6, 8, 9, 10 and 11 shall survive expiration or termination of this Agreement for any reason. Survival of the licenses granted in Article 7 shall be governed by Section 9.7.

9.7 Licenses Survive. Upon expiration of this Agreement for any reason, the licenses and rights set forth in Section 2.4 and Article 7 shall continue on a fully paid and perpetual basis.

9.8 Continuing Rights. Notwithstanding anything in this Agreement to the contrary, if this Agreement expires or is terminated for any reason, as a whole or on a country-by-country basis, Abbott shall retain the right to continue manufacturing, marketing, selling and using the Diagnostic Test in the Territory for use in the Field or for any other purposes and Idera shall retain the right to continue manufacturing, marketing, selling and using the Idera Product(s) in the Territory for use in the Field or for any other purposes.

9.9 Return of Confidential Information. Upon expiration or termination of this Agreement for any reason, the Receiving Party shall use reasonable efforts to either return to the Disclosing Party or destroy Confidential Information of the Disclosing Party (including hard and electronic copies thereof) that is not required by the Receiving Party to exercise surviving license rights as set forth in Section 9.7; *provided, however*, that the Receiving Party is not required to destroy electronic copies of the Confidential Information stored in its electronic archive systems, and may retain one (1) copy of such Confidential Information for purpose of complying with its obligations under this Agreement or under Applicable Law, but shall not otherwise use or rely on such Confidential Information. The Receiving Party shall provide written confirmation that the Receiving Party has complied with its obligations under this Section 9.9 of the return or destruction of such Confidential Information reasonably promptly after termination of the Agreement.

9.10 Certain Other Terminations

Either Party may terminate this Agreement upon (30) days prior written notice to the other Party upon the occurrence of any of the following:

(a) if by the seventh (7th) anniversary of the Effective Date, the Parties fail to obtain Regulatory Approval for the Compound in conjunction with the Diagnostic Test in at least one of the Major Market Countries, unless at such time the Parties are actively pursuing such approval and such approval is reasonably likely to be received within the succeeding twelve (12) months (or such other reasonable amount of time as may be mutually agreed to), provided that, the deadlines for achieving Regulatory Approval set forth in this Section 9.10(a) shall be automatically extended by any additional period of time covered by funding provided by Idera pursuant to an amendment to Idera's payment obligations hereunder pursuant to Section 5.2; or

(b) the Compound is permanently withdrawn from the market in all of the Major Market Countries for health or safety reasons.

ARTICLE 10
INDEMNIFICATION, LIABILITY LIMITATION AND INSURANCE

10.1 Indemnification by Idera.

(a) Subject to Sections 10.3 and 10.4, Idera shall indemnify, defend and hold Abbott, its Affiliates, and its and their officers, directors, agents and employees (individually and/or collectively referred to herein as an “Abbott Party”) harmless from and against any and all losses, liabilities, damages, expenses (including reasonable attorney’s fees) paid or payable by Abbott or an Abbott Party to a Third Party (collectively, “Abbott Losses”) to the extent that such Abbott Losses result from or arise in connection with a claim, suit or other proceeding made or brought by a Third Party against Abbott or an Abbott Party (an “Abbott Claim”) based on, resulting from, or arising in connection with:

- (i) the breach of any obligation, covenant, agreement, representation or warranty of Idera or an Idera Party contained in this Agreement; or
 - (ii) any act or omission by Idera, or an Idera Party, which constitutes gross negligence or willful misconduct on the part of Idera, or an Idera Party;
- or
- (iii) any violation of Applicable Law by Idera or an Idera Party in connection with the performance of Idera’s or its Affiliates’ obligations under this Agreement; or
 - (iv) the development, manufacturing, commercialization, sale or use of any Idera Product.

(b) Idera shall not be obligated to indemnify, defend or hold harmless Abbott or an Abbott Party under this Section from any Abbott Claim or for any Abbott Losses incurred by Abbott or an Abbott Party to the extent arising out of or attributable to: (A) a breach by Abbott, or any Abbott Party of any obligation, covenant, agreement, representation or warranty of Abbott, or any Abbott Party contained in this Agreement; (B) any violation of Applicable Law by Abbott or an Abbott Party in connection with its obligations under this Agreement; or (C) any act or omission by Abbott or an Abbott Party, which constitutes negligence or willful misconduct on the part of Abbott or an Abbott Party.

10.2 Indemnification by Abbott.

(a) Subject to Sections 10.3 and 10.4, Abbott shall indemnify, defend and hold Idera, its Affiliates, and its and their officers, directors, agents and employees (individually and/or collectively referred to herein as an “Idera Party”) harmless from and against any and all losses, liabilities, damages, expenses (including reasonable attorney’s fees) paid or payable by Idera or an Idera Party to a Third Party (collectively, “Idera Losses”) to the extent that such Idera Losses result from or arise in connection with a claim, suit or other proceeding made or brought by a Third Party against Idera or an Idera Party (an “Idera Claim”) based on, resulting from, or arising in connection with:

- (i) the breach of any obligation, covenant, agreement, representation or warranty of Abbott or an Abbott Party contained in this Agreement;

(ii) any act or omission by Abbott or an Abbott Party, which constitutes gross negligence or willful misconduct on the part of Abbott or an Abbott Party; or

(iii) any violation of Applicable Law by Abbott, or an Abbott Party in connection with the performance of Abbott's or its Affiliates' obligations under this Agreement; or

(iv) the development, manufacturing, or sale of the Diagnostic Test.

(b) Abbott shall not be obligated to indemnify, defend or hold harmless Idera or an Idera Party from any Idera Claim or for any Idera Loss incurred by Idera or an Idera Party to the extent arising out of, or attributable to: (A) a breach by Idera or any Idera Party of any obligation, covenant, agreement, representation or warranty of Idera or an Idera Party contained in this Agreement; (B) any violation of Applicable Law by Idera, or an Idera Party in connection with its obligations under this Agreement; or (C) any act or omission by Idera, or an Idera Party, which constitutes negligence, or willful misconduct on the part of Idera, or an Idera Party.

10.3 Indemnification Procedures.

(a) Each indemnified Party shall notify the indemnifying Party in writing (and in reasonable detail) of the Claim within [**] business days after receipt by such indemnified Party of notice of the Idera Claim or Abbott Claim, as the case may be, or otherwise becoming aware of the existence or threatened existence thereof (such Idera Claim or Abbott Claim being referred to as a "Claim"). Failure to give such notice shall not constitute a defense, in whole or in part, to any claim by an indemnified Party hereunder except to the extent the rights of the indemnifying Party are materially prejudiced by such failure to give notice. An indemnifying Party shall have no obligation or liability under this Article 10 as to any Claim for which settlement or compromise of such Claim, or an offer of settlement or compromise of such Claim, is made by an indemnified Party without the prior written consent of the indemnifying Party, which consent shall not be unreasonably withheld.

(b) The indemnifying Party shall assume exclusive control of the defense and settlement (including all decisions relating to litigation, defense and appeal) of any such Claim; *provided, however*, that, without the indemnified Party's prior written consent, which shall not be unreasonably withheld, the indemnifying Party may not settle such Claim in any manner that would: (i) require payment (unless fully indemnified hereunder) or admission of liability by the indemnified Party; (ii) materially adversely affect the rights granted to the indemnified Party under this Agreement; (iii) materially conflict with the terms of this Agreement; or (iv) adversely affect other products or services of the indemnified Party or its Affiliates.

(c) The indemnified Party shall reasonably cooperate with the indemnifying Party, at the Indemnifying Party's expense, in its defense of the Claim (including making documents and records available for review and copying and making persons within its control available for pertinent testimony in accordance with the confidentiality provisions of Article 6, and neither Party shall be required to divulge privileged material to the other). The indemnified Party may participate in, but not control, the defense of such Claim using attorneys of its choice and at its sole cost and expense, with such cost and expense not being covered by the indemnifying Party. If an indemnifying Party does not assume the defense of the Claim asserted against the indemnified Party, or if the indemnifying Party assumes the defense of the Claim in accordance with Section 10.3 yet fails to defend or take other reasonable, timely action, in response to such Claim asserted against the indemnified Party, the indemnified Party shall have the right to defend or take other reasonable action to defend its interests in such proceedings, and shall have the right to litigate, settle or otherwise dispose of any such Claim, without in any way limiting the indemnified Party's right to be fully indemnified under this Section 10.1 for all Abbott Losses or Idera Losses, as applicable; *provided, however*, that, without the indemnifying Party's prior written consent, which shall not be unreasonably withheld, the indemnified Party may not settle such Claim in any manner that would: (i) require payment by the indemnifying Party; (ii) materially adversely affect the rights granted to the indemnifying Party under this Agreement; (iii) materially conflict with the terms of this Agreement; or (iv) adversely affect other products or services of the indemnifying Party or its Affiliates.

(d) Neither Party will assert any Claim for indemnification under this Agreement more than two (2) years after the Claim arises.

10.4 Liability Limitation. EXCEPT WITH RESPECT TO A BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 6, OR FOR SUCH DAMAGES THAT MAY BE PAYABLE TO THIRD PARTIES AND SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 10, OR OTHER THAN AS CONTEMPLATED UNDER THIS AGREEMENT, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR CONSEQUENTIAL, INDIRECT, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES FOR ANY CAUSE OF ACTION, WHETHER IN CONTRACT, TORT OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, LOST REVENUES, PROFITS OR BUSINESS OPPORTUNITIES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, WHETHER OR NOT THE OTHER PARTY WAS OR SHOULD HAVE BEEN AWARE OF THE POSSIBILITY OF THESE DAMAGES.

10.5 Insurance.

(a) Abbott hereby represents that it (through its parent company Affiliate, Abbott Laboratories) is self-insured for product liability and general liability, and that it has and will maintain such coverage for the Term and for a period of [**] years after the expiration of this Agreement or the earlier termination thereof. Such self-insurance is in an amount which is reasonable and customary in the global medical device and diagnostics industry for companies of comparable size and activities. Abbott further represents that it has and will maintain additional coverage for the term of this Agreement and for a period of [**] years after the expiration of this Agreement or the earlier termination thereof, in the amounts and types set forth in a certificate of insurance which Abbott has previously provided to Idera.

(b) Idera hereby represents that it is insured for product liability and general liability, and that it has and will maintain such coverage for the term of this Agreement and for a period of [**] years after the expiration of this Agreement or the earlier termination thereof. Such insurance is in an amount which Idera reasonably determines is reasonable and customary in the global pharmaceutical industry for companies of comparable size and activities to those of Idera.

10.6 Intellectual Property Indemnification.

(a) By Idera. Idera shall indemnify, defend and hold Abbott or an Abbott Party harmless Abbott or an Abbott Party under this Section from any Abbott Claim or for any Abbott Losses to the extent the Losses results from or arise in connection with a claim, suit or other proceeding made or brought by a Third Party against Abbott or an Abbott Party alleging infringement of an intellectual property right directed to the importing, exporting, using, distributing, marketing, promoting, offering for sale or selling of the Diagnostic Test, and the Diagnostic Test Components, for the Diagnostic Test Intended Use, provided that the foregoing indemnity shall not apply to the extent such liability is due to the negligence or willful misconduct of Abbott.

(b) By Abbott. Abbott shall indemnify, defend and hold Idera or an Idera Party harmless Idera or an Idera Party under this Section from any Idera Claim or for any Idera Losses to the extent the Losses results from or arise in connection with a claim, suit or other proceeding made or brought by a Third Party against Idera or an Idera Party alleging infringement of an intellectual property right directed to the PCR platform technology needed to make, use, or sell the Diagnostic Test, provided that the foregoing indemnity shall not apply to the extent such liability is due to the negligence or willful misconduct of Idera.

ARTICLE 11 MISCELLANEOUS

11.1 Assignment. Neither Party shall assign, or transfer to any Third Party this Agreement or its rights and obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, except that Idera may assign

this Agreement (i) to an Affiliate, or (ii) to a Third Party that acquires the exclusive worldwide rights to develop, market or sell any Idera Product and Abbott may assign this Agreement (i) to an Affiliate or (ii) to a Third Party that acquires the exclusive worldwide rights to develop, market or sell the Diagnostic Test. This Agreement shall be binding upon the successors and permitted assigns of the Parties.

11.2 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

11.3 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party, other than a failure to make payment, if the failure is occasioned by government action, war, terrorism, fire, explosion, flood, strike, lockout, embargo, shortage of materials or utilities, vendor failure to supply, act of God, or any other cause beyond the control and without the fault or negligence of the defaulting Party, provided that the Party claiming force majeure has exerted all Commercially Reasonable Efforts to avoid or remedy such force majeure; *provided, however*, that in no event shall a Party be required to settle any labor dispute or disturbance. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, the affected Party shall promptly resume performance hereunder. Each Party agrees to give the other Party prompt written notice of the occurrence of any such condition, the nature thereof, and the extent to which the affected Party will be unable to perform its obligations hereunder. Each Party further agrees to use all Commercially Reasonable Efforts to correct the condition as quickly as possible and to give the other Party prompt written notice when it is again fully able to perform its obligations hereunder.

11.4 Further Assurances. Each Party hereto agrees to execute, acknowledge and deliver such further instruments and do all such further acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

11.5 Modification. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized.

11.6 Independent Contractors. The Parties are independent contractors and this Agreement shall not constitute or give rise to an employer-employee, agency, partnership or joint venture relationship among the Parties and each Party's performance hereunder is that of a separate, independent entity.

11.7 Governing Law; Alternative Dispute Resolution. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, United States of America, without regard to its conflicts of laws principles. The Parties hereby disclaim the application to this Agreement of the United Nations Convention on the International Sale of Goods. Any controversy or claim arising from or related to this Agreement or the breach thereof shall be decided pursuant to the Alternative Dispute Resolution set forth in Exhibit I.

11.8 Headings. Article and section headings in this Agreement are included for convenience of reference and shall not affect the construction or interpretation of any of the provisions of this Agreement.

11.9 Notices. Notices required or permitted under this Agreement shall be in writing and sent by prepaid registered or certified air mail or by overnight express courier providing evidence of receipt (*e.g.*, Federal Express), and shall be deemed to have been properly served to the addressee upon receipt of such written communication, to the following addresses of the Parties:

If to Abbott:

Abbott Molecular Inc.
Attn: Senior Director, Business Development and Licensing
Dept. 09JR
1300 East Touhy Avenue
Des Plaines, Illinois 60018

With a copy to:

Abbott Laboratories
Attn: Division Counsel, AMD
1350 E. Touhy Avenue
Des Plaines, Illinois 60018

If to Idera:

Idera Pharmaceuticals, Inc.
Attn: Chief Executive Officer
167 Sidney Street
Cambridge, Massachusetts 02139

With a copy to:

WilmerHale
Attn: Steven D. Barrett, Esq.
60 State Street
Boston, Massachusetts 02109

11.10 Third Parties. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party.

11.11 Waiver. The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

11.12 Severability. If any part of this Agreement is declared invalid by any legally governing authority having jurisdiction over either Party, then such declaration shall not affect the remainder of the Agreement and the invalidated provision shall be revised in a manner that will render such provision valid while preserving the Parties' original intent to the maximum extent possible.

11.13 Entire Agreement. This Agreement (including the exhibits attached hereto) constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings including the CDA (as modified pursuant to Section 6.1) and LOI.

IN WITNESS WHEREOF, the Parties by their respective authorized officers, have executed this Development and Commercialization Agreement on the date first above written.

ABBOTT MOLECULAR INC.

By: /s/ Deepak Nath
Deepak Nath, President

IDERA PHARMACEUTICALS, INC.

By: /s/ Louis J. Arcudi, III
Name: Louis J. Arcudi, III
Title: Chief Financial Officer

EXHIBIT A
SPECIFICATIONS

Technical Specifications of MYD88 L265P Mutation test

- [**].

Test Performance

- [**].

EXHIBIT B
DEVELOPMENT PLAN

1. Objective

- To develop a RealTime PCR assay for the detection of the MyD88 L265P mutation utilizing genomic DNA from FFPE sections of primary lymph node tissue on the Abbott *m2000* System supporting clinical studies and launch for commercial sale.

2. Responsibilities

- [**].

3. Development Timelines

- The development timeline will be developed and agreed to by the Abbott and Idera Project Managers.

4. Interactions with US FDA

- Idera and Abbott will work together to prepare for and participate in regulatory discussions with FDA for the development of the Diagnostic Test. It is likely that several interactions with US FDA during the development of the test will be required.
 - [**].

5. Reagent/Assay development and manufacture

- [**].

6. External validation – Design validation study to examine clinical samples

- [**].
- [**].

EXHIBIT C
REGULATORY PLAN

Idera and Abbott will actively cooperate in the regulatory process for the development and global regulatory registration of the Diagnostic Test. The regulatory process includes the development of regulatory strategy, the sharing of regulatory information and data and the submission and liaison with global Regulatory Authorities. Abbott will serve as the formal sponsor of any submissions to global Regulatory Authorities that pertain to the Diagnostic Test, and therefore will be ultimately responsible for the submission of such required documentation per the jointly agreed timelines; *provided, however*, that the preparation, including strategy, for such submissions will be done in cooperation and consultation with Idera and Idera shall have the right to attend and participate in all meetings between Abbott and Regulatory Authorities relating to the development of the Diagnostic Test. Abbott shall have the option to participate in the preparation for any regulatory meeting concerning the development of the Idera Product in the Field, where the Diagnostic Test is expected to be discussed. Where practicable, Idera will consider accommodating the attendance of an Abbott representative at any regulatory meeting concerning the development of the Idera Product in the Field, where the Diagnostic Test is expected to be discussed. The attendance of an Abbott representative at a regulatory meeting concerning the development of the Idera Product in the Field where the Diagnostic Test is expected to be discussed may be raised for consideration at the level of the Development Leads and the JSC, but Idera shall have the final say as to who may attend regulatory meetings concerning development of the Idera Product. Activities included in the regulatory process that are subject to this regulatory plan include the following:

- Routine interactions of Abbott and Idera regulatory representatives to share regulatory information relevant to the agreed strategy for development and registration of the Diagnostic Test.
- Abbott will inform Idera about any inspections from Regulatory Authorities related to the Diagnostic Test and will provide reports of any findings to Idera.
- [**].
- [**].
- [**].
- Idera and Abbott will jointly develop a timeline and priority list for global regulatory submissions. The timeline will include submission dates and anticipated approval dates for both the Diagnostic Test and the Idera Product.

As a part of the regulatory plan regarding the timelines for regulatory submissions and target timelines for approval, [**].

EXHIBIT D
COMMERCIALIZATION PLAN

- **[**]**.

DETAILED ACTIVITIES

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 6 pages were omitted. **[**]**

EXHIBIT E
GOVERNANCE OF AGREEMENT

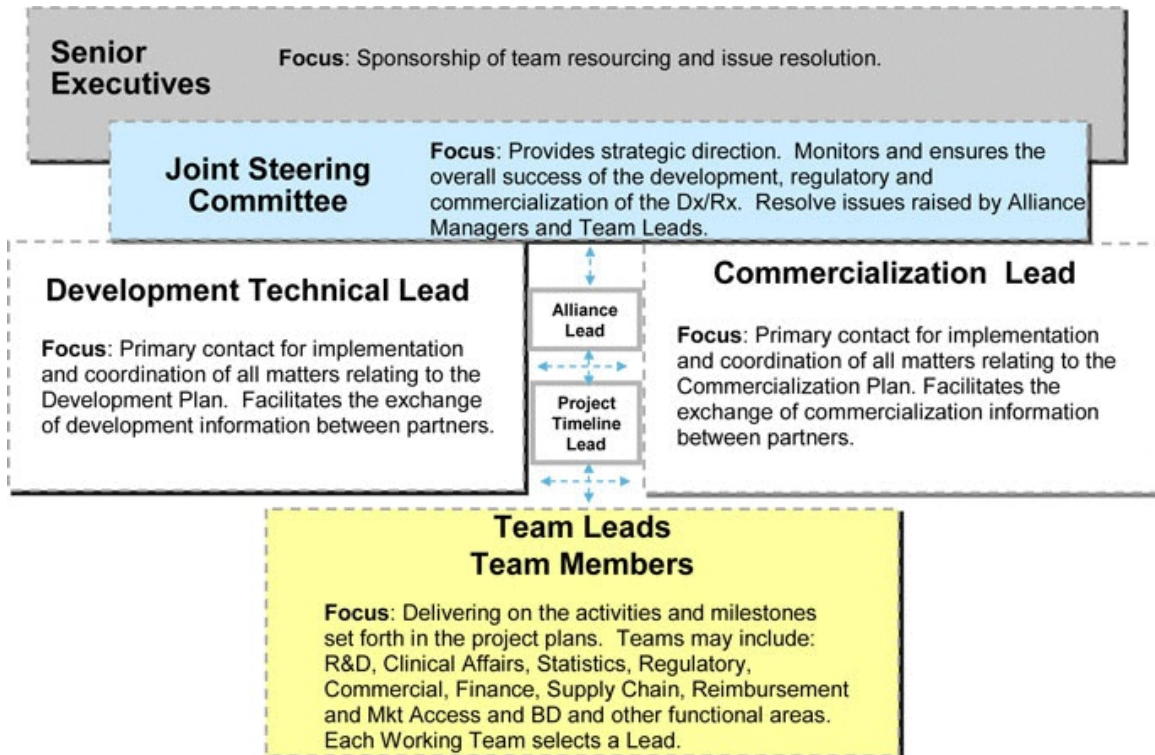


EXHIBIT F
GOVERNANCE ESCALATION PROCESS

ANY REFERENCE TO “PARTNER” IN EXHIBIT F SHALL BE A REFERENCE TO “IDERA”

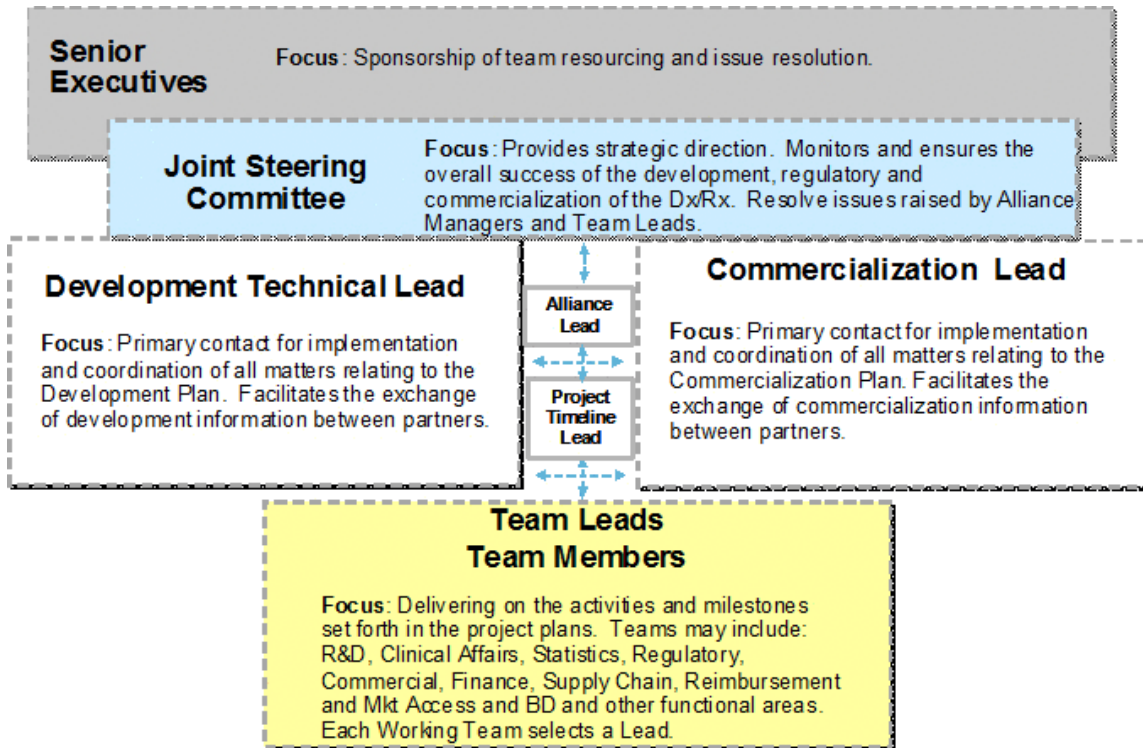


EXHIBIT G
GOVERNANCE ROLES AND RESPONSIBILITIES

ANY REFERENCE TO “PARTNER” IN EXHIBIT G SHALL BE A REFERENCE TO “IDERA”

Role	Team Member	Key Responsibilities Summary	
Senior Executives	- Abbot - Partner	<ul style="list-style-type: none"> • Program sponsorship • Commitment of resources required to maintain effective relationships 	<ul style="list-style-type: none"> • Prioritization of new and existing collaborations • Resolve disputes only if unresolved after consideration by JSC
Joint Steering Committee	Commercial: - Abbott - Partner Regulatory - Abbott - Partner R&D - Abbott - Partner BD - Abbott - Partner	<ul style="list-style-type: none"> • Review, confirm, modify and/or update the Development, Regulatory and Commercialization Plans • Monitor all team activities under the plans • Resolve escalated issues or disagreements raised by the Alliance Leads. Development Technical Leads, Commercial Leads and the functional Working Team Leads 	<ul style="list-style-type: none"> • Exchange of development, regulatory and commercialization information • Alignment of the regulatory submissions and registrations between the therapy and the Dx • Review and management of progress towards and completion of milestones per agreement

EXHIBIT G
GOVERNANCE ROLES AND RESPONSIBILITIES CON'T

Role	Team Member	Key Responsibilities Summary	
Development Technical Lead	<ul style="list-style-type: none"> - Abbot - Partner 	<ul style="list-style-type: none"> • Principal point of contact for all matters related to the Development Plan • Project planning and coordination for all Development activities • Technical leads • Team Meeting leadership, planning and coordination • Manage and recommend updates to the Development Plan including tactics 	<ul style="list-style-type: none"> • Manage risks • Tracking and communication of project status • Consolidates Working Group Team issues • Facilitates issue resolution at Working Group level • Issue escalation (to Alliance and JSC) • Regular reporting to the JSC and Team Leads
Commercial Lead	<ul style="list-style-type: none"> - Abbott - Partner 	<ul style="list-style-type: none"> • Principal point of contact for all matters related to the Commercialization Plan • Develop, coordinate and implement the Commercial Plan • Integrated sales opportunity planning • Market assessment • Planning & Implementation of early access programs 	<ul style="list-style-type: none"> • Facilitates issue resolution at Working Group level • Project planning and coordination for all Commercial activities • Issue escalation (to Alliance and JSC) • Regular reporting to the JSC and Team Leads
Working Team Leads	Representatives from: Development (R&D) Clinical Regulatory Commercial Quality Supply Chain Reimbursement/Market Access Business Development & Licensing	<ul style="list-style-type: none"> • Delivering on the activities and milestones set forth in the project plans • Issue escalation to Project Leads and/or Alliance Leads • Regular reporting to the JSC and the other Team Leads 	

EXHIBIT G
GOVERNANCE ROLES AND RESPONSIBILITIES CON'T

Role	Team Member	Key Responsibilities Summary	
Alliance Leads	- Abbott - Partner	<ul style="list-style-type: none"> • Develops and maintains broad and deep external partner relationships with alliances in all functional areas • Leadership of divisional alliance team collaboration and interactions with alliances • Facilitation of divisional alliance team activities • Ultimate ownership of divisional escalation issues, prioritization of those issues, root cause analysis and resolution • Coordinates and chairs all [**] review meetings • Leadership of team collaboration and interactions with each party • Development and management of communications plan to both internal and external team members 	<ul style="list-style-type: none"> • Ultimate ownership of issue escalation, prioritization, root cause analysis and resolution • Assignment of escalation/resolution responsibilities • Facilitate Joint Steering Committee meetings • Communication of relationship status (e.g. key changes, events, milestones) to stakeholders • Ensure all contract deliverables are met • Facilitation of Executive Contractual Reviews • Champion of collaborative, win-win relationship with alliance • Monitors all KPI's (Key Performance Indicators) post launch
Project Timeline Lead	- Abbott - Partner	<ul style="list-style-type: none"> • Develops the Dx project plan to include all functional tasks required to meet the contract deliverables • Plans for resource allocation and coordination of those resources • Coordinates with Rx Project Timeline Lead and identifies predecessors from the Rx project timeline and incorporates into the Dx project timeline 	<ul style="list-style-type: none"> • Provide the tools and techniques to enable the teams to organize their tasks to meet the timeline constraints • Track and communicate project status to all key stakeholders • Identify risk factors and communicate critical path activities

EXHIBIT H

ESTIMATED CLINICAL TRIAL SITE COSTS

Item	Description	# of events	Cost per event	Total
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
Total				[**]
Cost per sample				[**].
Assumes:				
[**]				
[**]				

Exhibit I
ALTERNATIVE DISPUTE RESOLUTION

The parties recognize that a bona fide dispute as to certain matters may arise from time to time during the term of this Agreement which relates to either party's rights and/or obligations. To have such a dispute resolved by this Alternative Dispute Resolution ("ADR") provision, a party first must send written notice of the dispute to the other party for attempted resolution by good faith negotiations between their respective representatives of the affected subsidiaries, divisions, or business units within [**] days after such notice is received (all references to "days" in this ADR provision are to calendar days).

If the matter has not been resolved within [**] days of the notice of dispute, or if the parties fail to meet within such [**] days, either party may initiate an ADR proceeding as provided herein. The parties shall have the right to be represented by counsel in such a proceeding.

1. To begin an ADR proceeding, a party shall provide written notice to the other party of the issues to be resolved by ADR. Within [**] days after its receipt of such notice, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved within the same ADR.

2. Within [**] days following receipt of the original ADR notice, the parties shall select a mutually acceptable neutral to preside in the resolution of any disputes in this ADR proceeding. If the parties are unable to agree on a mutually acceptable neutral within such period, the parties shall request the President of the Center for Public Resources ("CPR"), 366 Madison Avenue, New York, New York 10017 to select a neutral pursuant to the following procedures:

- (a) The CPR shall submit to the parties a list of not less than five (5) candidates within [**] days after receipt of the request from the parties, along with a *Curriculum Vitae* for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of their subsidiaries or affiliates.
- (b) Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.
- (c) Each party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the CPR within [**] days following receipt of the list of candidates. If a party believes a conflict of interest exists regarding any of the candidates that party shall provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any party failing to return a list of preferences on time shall be deemed to have no order of preference.
- (d) If the parties collectively have identified fewer than three (3) candidates deemed to have conflicts, the CPR immediately shall designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the parties collectively have identified three (3) or more candidates deemed to have conflicts, the

CPR shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the parties collectively have indicated the greatest preference, or (ii) issue a new list of not less than five (5) candidates, in which case the procedures set for in subparagraphs 2(a) - 2(d) above shall be repeated.

3. No earlier than [**] days or later than [**] days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the parties. The ADR proceeding shall take place at a location agreed upon by the parties. If the parties cannot agree, the neutral shall designate a location other than the principal place of business of either party or any of their subsidiaries or affiliates.

4. At least [**] days prior to the hearing, each party shall submit the following to the other party and the neutral:

- (a) a copy of all exhibits on which such party intends to rely in any oral or written presentation to the neutral;
- (b) a list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;
- (c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed [**] per issue.
- (d) a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed [**] pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a) - 4(d) above, no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

5. The hearing shall be conducted on [**] consecutive days and shall be governed by the following rules:

- (a) Each party shall be entitled to [**] hours of hearing time to present its case. The neutral shall determine whether each party has had the [**] hours to which it is entitled.
- (b) Each party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the party conducting the cross-examination.

(c) The party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it has raised but also any issues raised by the responding party. The responding party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.

(d) Witnesses shall be excluded from the hearing until closing arguments.

(e) Neither affidavits nor settlement negotiations shall be admissible under any circumstances. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.

6. Within [**] days following completion of the hearing, each party may submit to the other party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed [**] pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

7. The neutral shall rule on each disputed issue within [**] days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue but may adopt one party's proposed rulings and remedies on some issues and the other party's proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling.

8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

(a) If the neutral rules in favor of one party on all disputed issues in the ADR, the losing party shall pay 100% of such fees and expenses.

(b) If the neutral rules in favor of one party on some issues and the other party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

10. Except as provided in paragraph 9 of this Exhibit or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

11. The neutral may not award punitive damages. The parties hereby waive the right to punitive damages.

12. The hearings shall be conducted in the English language in Boston, Massachusetts.

EXHIBIT J
PRESS RELEASE

Abbott and Idera Collaborate to Develop Companion Diagnostic Test for Investigational Cancer Therapy

ABBOTT PARK, Ill., _____. XX, 2014 — Abbott announced today that it will collaborate with Idera to develop a companion diagnostic test to aid in the development of an Idera investigational cancer therapy.

About PCR

About Abbott Molecular

Abbott Molecular is a leader in molecular diagnostics — the analysis of DNA and RNA at the molecular level. Abbott Molecular's tests can also detect subtle but key changes in patients' genes and chromosomes and have the potential for earlier detection or diagnosis, provide information relevant to the selection of appropriate therapies, and may improve monitoring of disease progression.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries.

About The Idera Product

About Idera

Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

#

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, Sudhir Agrawal, 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: August 12, 2014

/s/ SUDHIR AGRAWAL

Sudhir Agrawal
Chief Executive Officer

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: August 12, 2014

/s/ LOUIS J. ARCUDI, III

Louis J. Arcudi, III
Chief Financial Officer

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 June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sudhir Agrawal, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (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: August 12, 2014

/s/ SUDHIR AGRAWAL

Sudhir Agrawal
Chief Executive Officer

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 June 30, 2014 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:

- (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: August 12, 2014

/s/ LOUIS J. ARCUDI, III

Louis J. Arcudi, III
Chief Financial Officer

